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# Contents

**Federal Register**

Vol. 87, No. 208

Friday, October 28, 2022

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**Separate Parts In This Issue**



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**Reader Aids**
Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.

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## CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

**10 CFR**

**Proposed Rules:**

71 ..... 65177

**11 CFR**

**Proposed Rules:**

110 ..... 65178

**14 CFR**

93 (2 documents) ..... 65159, 65161

**Proposed Rules:**

71 (2 documents) ..... 65178, 65180

**18 CFR**

343 ..... 65163

**34 CFR**

600 ..... 65426
668 ..... 65426
690 ..... 65426

**39 CFR**

**Proposed Rules:**

20 ..... 65181

**48 CFR**

203 ..... 65510
211 ..... 65513
212 (5 documents) ..... 65500, 65510, 65513, 65514, 65515
213 ..... 65515
215 ..... 65502
216 ..... 65512
229 ..... 65515
232 ..... 65515
235 ..... 65512
237 ..... 65500
242 ..... 65502
252 (4 documents) ..... 65500, 65513, 65514, 65515

**Proposed Rules:**

215 ..... 65507
217 ..... 65507
242 ..... 65505
252 ..... 65507

**50 CFR**

679 ..... 65175

**Proposed Rules:**

679 ..... 65183
680 ..... 65183

# Rules and Regulations

Federal Register
Vol. 87, No. 208
Friday, October 28, 2022



## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 93

**[Docket No.: FAA–2006–25755]**

## Operating Limitations at New York Laguardia Airport

**AGENCY:** Federal Aviation Administration (FAA), Department of Transportation.

**ACTION:** Extension to order.

**SUMMARY:** This action extends the Order Limiting Operations at New York LaGuardia Airport (LGA) published on December 27, 2006, as most recently extended September 18, 2020. The Order remains effective until October 26, 2024.

**DATES:** This action is effective on October 28, 2022.

**ADDRESSES:** Requests may be submitted by mail to the Slot Administration Office, System Operations Services, AJR–0, Room 300W, 800 Independence Avenue SW, Washington, DC 20591, or by email to: *7-awa-slotadmin@faa.gov.*

**FOR FURTHER INFORMATION CONTACT:** For questions concerning this Order contact: Al Meilus, Slot Administration and Capacity Analysis, FAA ATO System Operations Services, AJR–G5, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone 202–267–2822; email *al.meilus@faa.gov.*

**SUPPLEMENTARY INFORMATION:**

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(1) Searching the Federal eRulemaking Portal at *www.regulations.gov;*

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(3) Accessing the Government Publishing Office's website at *www.GovInfo.gov.*

You also may obtain a copy by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267–9680. Make sure to identify the docket number.

### Background

The FAA historically limited the number of arrivals and departures at LGA through the implementation of the High Density Rule (HDR).[1] By statute enacted in April 2000, (the Aviation Investment and Reform Act for the 21st Century (AIR–21)), Congress terminated the HDR's applicability to LGA beginning on January 1, 2007.[2] The FAA issued the Order Limiting Operations at New York LaGuardia Airport on December 27, 2006, adopting temporary limits on scheduled and unscheduled operations at LGA pending the completion of rulemaking to address long-term limits and related policies.[3] This Order was amended on November 8, 2007, and August 19, 2008.[4] Under the amended Order, the FAA limited scheduled and unscheduled operations at the airport to prevent congestion-related delays associated with LaGuardia's limited runway capacity. The FAA extended the expiration date of the amended Order on October 7, 2009, April 4, 2011, May 14, 2013, March 27, 2014, May 25, 2016, September 18, 2018, and September 18, 2020.[5]

Under this Order, as amended, the FAA (1) maintains the current hourly limits of 71 for scheduled operations and three for unscheduled operations at LGA during the slot-controlled hours; (2) imposes an 80 percent minimum usage requirement for Operating Authorizations (OAs) [6] with defined exceptions; (3) provides a mechanism for withdrawal of OAs for FAA operational reasons; (4) provides for a lottery to reallocate withdrawn, surrendered, or unallocated OAs; and (5) allows for trades and leases of OAs for consideration for the duration of the Order.

The reasons for retaining the Order have not changed appreciably since its initial issuance. Despite the dynamic demand during the 2020–2022 period due to the COVID–19 pandemic, runway capacity at LGA remains limited, while demand for access to LGA remains high. The FAA has determined that the operational limitations imposed by this Order are appropriate and necessary. During the effective period of this Order, the FAA will continue to monitor demand, performance, and runway capacity at LGA, to determine if changes are warranted.

In 2009, the FAA reduced the scheduling limits under this Order from 75 operations per hour to 71 per hour to provide an opportunity to improve operations.[7] The FAA did not require a reduction of historic slots to reach the new hourly limits. Instead, historic allocations were honored. However, slots voluntarily returned or withdrawn per the terms of the Order are not reallocated if the hourly totals exceed the revised 71 hourly scheduling limit. As a result of this historic practice, between 72 and 75 slots remain authorized in most slot-controlled hours. The FAA, in coordination with the Office of the Secretary of Transportation (OST), will continue to consider potential rulemaking to codify policies for slot-controlled airports.

### Pending Issues

In extending the Orders limiting operations at LGA and John F. Kennedy International Airport (JFK) in 2018, the FAA noted that receipt of specific proposals for policy changes that would necessitate substantive modifications to the Orders.[8] Consideration of these issues is ongoing. Accordingly, the FAA is extending the expiration date of this Order until October 26, 2024. This expiration date coincides with the extended expiration date for the Order limiting scheduled operations at JFK, as

[1] 33 FR 17896 (Dec. 3, 1968). The FAA codified the rules for operating at high density traffic airports in 14 CFR part 93, subpart K. The HDR required carriers to hold a reservation, which came to be known as a ''slot,'' for each takeoff or landing under instrument flight rules at the high density traffic airports.

[2] Aviation Investment and Reform Act for the 21st Century (AIR–21), Public Law 106–181 (Apr. 5, 2000), 49 U.S.C. 41715(a)(2).

[3] 71 FR 77854.

[4] 72 FR 63224; 73 FR 48428

[5] 74 FR 51653; 76 FR 18616, amended by 77 FR 30585 (May 23, 2012); 78 FR 28278; 79 FR 17222; 81 FR 33126; 83 FR 47065; and, 85 FR 58255.

[6] Also referred to herein as ''slots.''

[7] 74 FR 2646 (Jan. 15, 2009).

[8] See discussion of ''Current Issues'' in 2018 JFK Order, 83 FR at 46865, and LGA Order, 83 FR at 47065.

also published elsewhere in the **Federal Register**.

The FAA continues to monitor demand, performance, and runway capacity at LGA in order to determine if changes are warranted during the effective period of this Order. The FAA is working with MITRE's Center for Advanced Aviation System Development on a study analyzing airport runway configurations and capacity. The continuation of this study will investigate the projected delays with alternative demand scenarios, as well as consider a number of the complexities associated with LGA operations, including interaction with other nearby airports and operational growth limitations due to the busy airspace surrounding the New York Area.

The FAA finds that notice and comment procedures under 5 U.S.C. 553(b) are impracticable, unnecessary, and contrary to the public interest, as carriers have planned schedules for the Winter 2022/2023 scheduling season and no substantive amendments are included in this action. For these reasons, the FAA also finds that it is impracticable and contrary to the public interest to delay the effective date of this action under 5 U.S.C. 553(d).

**The Amended Order**

The Order, as amended, is recited below in its entirety:

*A. Scheduled Operations*

With respect to scheduled operations at LaGuardia:

1. The Order governs scheduled arrivals and departures at LaGuardia from 6 a.m. through 9:59 p.m., Eastern Time, Monday through Friday and from 12 noon through 9:59 p.m., Eastern Time, Sunday. Seventy-one (71) Operating Authorizations are available per hour and will be assigned by the FAA on a 30-minute basis. The FAA will permit additional, existing operations above this threshold; however, the FAA will retire Operating Authorizations that are surrendered to the FAA, withdrawn for non-use, or unassigned during each affected hour until the number of Operating Authorizations in that hour reaches seventy-one (71).

2. The Order took effect on January 1, 2007, and will expire on October 26, 2024.

3. The FAA will assign operating authority to conduct an arrival or a departure at LaGuardia during the affected hours to the air carrier that holds equivalent slot or slot exemption authority under the High Density Rule of FAA slot exemption rules as of January 1, 2007; to the primary marketing air carrier in the case of AIR–21 small hub/non-hub airport slot exemptions; or to the air carrier operating the flights as of January 1, 2007, in the case of a slot held by a non carrier. The FAA will not assign operating authority under the Order to any person or entity other than a certificated U.S. or foreign air carrier with appropriate economic authority and with operating authority from FAA under 14 CFR part 121, 129 or 135.

4. For administrative tracking purposes only, the FAA will assign an identification number to each Operating Authorization.

5. An air carrier may lease or trade an Operating Authorization to another carrier for any consideration, not to exceed the duration of the Order. Notice of a trade or lease under this paragraph must be submitted in writing to the FAA Slot Administration Office, facsimile (202) 267–7277 or email *7-AWA-Slotadmin@faa.gov,* and must come from a designated representative of each carrier. The FAA must confirm and approve these transactions in writing prior to the effective date of the transaction. However, the FAA will approve transfers between carriers under the same marketing control up to 5 business days after the actual operation. This post-transfer approval is limited to accommodate operational disruptions that occur on the same day of the scheduled operation.

6. Each air carrier holding an Operating Authorization must forward in writing to the FAA Slot Administration Office a list of all Operating Authorizations held by the carrier along with a listing of the Operating Authorizations actually operated for each day of the two-month reporting period, within 14 days after the last day of the two-month reporting period beginning January 1 and every two months thereafter. Any Operating Authorization not used at least 80 percent of the time over a two-month period will be withdrawn by the FAA except:

A. The FAA will treat as used any Operating Authorization held by an air carrier on Thanksgiving Day, the Friday following Thanksgiving Day, and the period from December 24 through the first Saturday in January.

B. The FAA will treat as used any Operating Authorization obtained by an air carrier through a lottery under paragraph 7 for the first 120 days after allocation in the lottery.

C. The Administrator of the FAA may waive the 80 percent usage requirement in the event of a highly unusual and unpredictable condition which is beyond the control of the air carrier and which affects carrier operations for a period of five consecutive days or more.

7. In the event that Operating Authorizations are withdrawn for nonuse, are surrendered to the FAA, or are unassigned, the FAA will determine whether any of the available Operating Authorizations should be reallocated. If so, the FAA will conduct a lottery using the provisions specified under 14 CFR 93.225. The FAA may retime an Operating Authorization prior to reallocation in order to address operational needs.

8. If the FAA determines that a reduction in the number of allocated Operating Authorizations is required to meet operational needs, such as reduced airport capacity, the FAA will conduct a weighted lottery to withdraw Operating Authorizations to meet a reduced hourly or half-hourly limit for scheduled operations. The FAA will provide at least 45 days' notice unless otherwise required by operational needs. Any Operating Authorization that is withdrawn or temporarily suspended will, if reallocated, be reallocated to the air carrier from which it was taken, provided that the air carrier continues to operate scheduled service at LaGuardia.

9. The Vice President, System Operations Services, in coordination with the Chief Counsel of the FAA, is the final decision maker for determinations under this Order.

10. The FAA may modify or withdraw any provision in this Order on its own or on application by any carrier for good cause shown.

*B. Unscheduled Operations* [9]

With respect to unscheduled flight operations at LaGuardia, the FAA adopts the following:

1. The Order applies to all operators of unscheduled flights, except helicopter operations, at LaGuardia from 6 a.m. through 9:59 p.m., Eastern Time, Monday through Friday and from 12 noon through 9:59 p.m., Eastern Time, Sunday.

2. The Order took effect on January 1, 2007, and will expire on October 26, 2024.

[9] Unscheduled operations are operations other than those regularly conducted by an air carrier between LaGuardia and another service point. Unscheduled operations include general aviation, public aircraft, military, irregular charter, ferry, and positioning flights. Regularly conducted commercial flights require an Operating Authorization and may not use unscheduled operation reservations. Helicopter operations are excluded from the reservation requirement. Unscheduled flights operating under visual flight rules (VFR) may be accommodated by the local air traffic control facilities and are not included in the hourly limits.

3. No person can operate an aircraft other than a helicopter to or from LaGuardia unless the operator has received, for that unscheduled operation, a reservation that is assigned by the David J. Hurley Air Traffic Control System Command Center's Airport Reservation Office (ARO), or for unscheduled visual flight rule operations, received clearance from ATC. Additional information on procedures for obtaining a reservation is available via the internet at *http://www.fly.faa.gov/ecvrs.*

4. Three (3) reservations are available per hour for unscheduled operations at LaGuardia. The ARO will assign reservations on a 30-minute basis.

5. The ARO receives and processes all reservation requests. Reservations are assigned on a ''first-come, first-served'' basis, determined as of the time that the ARO receives the request. A cancellation of any reservation that will not be used as assigned is required.

6. Filing a request for a reservation does not constitute the filing of an instrument flight rules (IFR) flight plan, as separately required by regulation. After the reservation is obtained, an IFR flight plan can be filed. The IFR flight plan must include the reservation number in the ''remarks'' section.

7. Air Traffic Control will accommodate declared emergencies without regard to reservations. Nonemergency flights in direct support of national security, law enforcement, military aircraft operations, or public aircraft operations will be accommodated above the reservation limits with the prior approval of the Vice President, System Operations Services, Air Traffic Organization. Procedures for obtaining the appropriate reservation for such flights are available via the internet at *http://www.fly.faa.gov/ecvrs.*

8. Notwithstanding the limits in paragraph 4, if the Air Traffic Organization determines that air traffic control, weather, and capacity conditions are favorable and significant delay is not likely, the FAA can accommodate additional reservations over a specific period. Unused operating authorizations can also be temporarily made available for unscheduled operations. Reservations for additional operations are obtained through the ARO.

9. Reservations cannot be bought, sold, or leased.

10. The Vice President, System Operations Services, in coordination with the Chief Counsel of the FAA, is the final decision maker for determinations under this Order.

11. The FAA may modify or withdraw any provision in this Order on its own or on application by any carrier for good cause shown.

*C. Enforcement*

The FAA may enforce the Order through an enforcement action seeking a civil penalty under 49 U.S.C. 46301(a). The FAA or Department of Justice also could file a civil action in U.S. District Court, under 49 U.S.C. 46106 or 46107, respectively, seeking to enjoin any carrier from violating the terms of the Order.

Issued in Washington, DC, on October 26, 2022.

**Alyce Hood-Fleming,**

*Acting Vice President, System Operations Services.*

[FR Doc. 2022–23617 Filed 10–26–22; 4:15 pm]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 93

**[Docket No. FAA–2007–29320]**

## Operating Limitations at John F. Kennedy International Airport

**AGENCY:** Federal Aviation Administration (FAA), Department of Transportation (DOT).

**ACTION:** Extension to order.

**SUMMARY:** This action extends the Order Limiting Operations at John F. Kennedy International Airport (JFK) published on January 18, 2008, and most recently extended on September 18, 2020. The Order remains effective until October 26, 2024.

**DATES:** This action is effective on October 28, 2022.

**ADDRESSES:** Requests may be submitted by mail to Slot Administration Office, System Operations Services, AJR–0, Room 300W, 800 Independence Avenue SW, Washington, DC 20591, or by email to: *7-awa-slotadmin@faa.gov.*

**FOR FURTHER INFORMATION CONTACT:** Al Meilus, Slot Administration and Capacity Analysis, FAA ATO System Operations Services, AJR–G5, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone (202) 267–2822; email *al.meilus@faa.gov.*

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You also may obtain a copy by sending a request to the Federal Aviation Administration, Slot Administration and Capacity Analysis Office, AJR–G5, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267–2822. Make sure to identify the docket number.

### Background

The FAA historically limited the number of arrivals and departures at JFK through the implementation of the High Density Rule (HDR).[1] By statute enacted in April 2000 (Aviation Investment and Reform Act for the 21st Century (AIR–21)), operations were added at JFK through provisions permitting exemptions for new entrant carriers and flights to small and non-hub airports.[2]

The HDR's applicability to JFK operations terminated as of January 1, 2007.[3] With the AIR–21 exemptions and the HDR phase-out, some air carriers serving JFK significantly increased their scheduled operations throughout the day and retimed existing flights. This resulted in scheduled demand in peak hours that exceeded the airport's capacity and caused significant congestion and delay.

In January 2008, the FAA placed temporary limits on scheduled operations at JFK to mitigate persistent congestion and delays at the airport.[4] The FAA extended the January 18, 2008, Order placing temporary limits on scheduled operations at JFK on October 7, 2009, April 4, 2011, May 14, 2013, March 26, 2014, May 24, 2016, as corrected June 21, 2016, September 17, 2018, and on September 18, 2020.[5]

Under this Order, as amended, the FAA (1) maintains the current hourly limits of 81 scheduled operations at JFK

[1] 33 FR 17896 (Dec. 3, 1968). The FAA codified the rules for operating at high density traffic airports in 14 CFR part 93, subpart K. The HDR required carriers to hold a reservation, which came to be known as a ''slot,'' for each takeoff or landing under instrument flight rules at the high density traffic airports.

[2] Aviation Investment and Reform Act for the 21st Century (AIR–21), Public Law 106–181 (Apr. 5, 2000), 49 U.S.C. 41715(a)(2).

[3] *Id.*

[4] 73 FR 3510 (Jan. 18, 2008), as amended by 73 FR 8737 (Feb. 14, 2008).

[5] 74 FR 51650; 76 FR 18620; 78 FR 28276; 79 FR 16854; 81 FR 32636; 81 FR 40167; 83 FR 46865; and 85 FR 58258.

during the slot-controlled hours; (2) imposes an 80 percent minimum usage requirement for Operating Authorizations (OAs) [6] with defined exceptions; (3) provides a mechanism for withdrawal of OAs for FAA operational reasons; (4) establishes procedures to allocate withdrawn, surrendered, or unallocated OAs; and (5) allows for trades and leases of OAs for consideration for the duration of the Order.

The reasons for retaining the Order have not changed appreciably since its initial issuance. Despite the dynamic demand during the 2020–2022 period due to the COVID–19 pandemic, demand for access to JFK remains high and multiple new entrant and other incumbent airlines have requested new peak period operations and retiming of existing flights to higher demand hours. The FAA has determined that the operational limitations imposed by this Order remain necessary. In the Summer 2022 scheduling season, the allocated slots in the busiest hours were generally at the limits under this Order. For the Winter 2022/2023 scheduling season, the initial requests for historic slots and retiming of existing slots continue to show demand is higher than the scheduling limits in multiple hours. Notwithstanding the dynamic demand caused by the COVID–19 pandemic, without the operational limitations imposed by the Order, the FAA expects severe congestion-related delays would occur at JFK and at other airports throughout the National Airspace System (NAS) as flights are added or retimed into peak periods at JFK. The FAA will continue to monitor demand, performance, and runway capacity at JFK, to determine if changes are warranted during the effective period of this Order. The FAA, in coordination with the Office of the Secretary of Transportation (OST), will also continue to consider potential rulemaking to codify policies for slot-controlled airports.

**Pending Issues**

In extending the Orders limiting operations at JFK and LaGuardia National Airport (LGA) in 2018, the FAA noted that receipt of specific proposals for policy changes that would necessitate modifications to the Orders.[7] Consideration of these issues is ongoing. In addition, the FAA is reviewing substantive amendments to the International Air Transport Association Worldwide Slot Guidelines (WSG, now known as the Worldwide *Airport* Slot Guidelines or ''WASG'') and considering whether to implement certain changes in the United States.[8] Accordingly, the FAA is extending the expiration date of this Order until October 26, 2024. This expiration date coincides with the extended expiration date for the Order limiting operations at LGA, as also published elsewhere in the **Federal Register**.

The FAA continues to monitor demand, performance, and runway capacity at JFK, to determine if changes are warranted during the effective period of this Order. The FAA is working with MITRE's Center for Advanced Aviation System Development on a study analyzing airport runway configurations and capacity. The continuation of this study will investigate projected delays with alternative demand scenarios, as well as consider a number of the complexities associated with JFK operations, including interaction with other nearby airports and operational growth limitations due to the busy airspace surrounding the New York Area.

The FAA finds that notice and comment procedures under 5 U.S.C. 553(b) are impracticable, unnecessary, and contrary to the public interest, as carriers have planned schedules for the Winter 2022/2023 scheduling season and no significant substantive changes are included in this action. For these reasons, the FAA also finds that it is impracticable and contrary to the public interest to delay the effective date of this Order under 5 U.S.C. 553(d).

This Order is the equivalent of limited local rules as referenced in the WSG and takes precedence over the WSG where there are differences.[9] At JFK, the FAA follows the WSG in many respects such as new entrant priority [10] and consideration of schedule constraints such as terminal, gate, parking, customs and immigration, curfews, and similar operational factors.

**The Amended Order**

The Order, as amended, is recited below in its entirety.

1. This Order continues the process for assigning operating authority to conduct an arrival or a departure at JFK during the affected hours to any certificated U.S. air carrier or foreign air carrier. The FAA will not assign operating authority under this Order to any person or entity other than a certificated U.S. or foreign air carrier with appropriate economic authority and with operating authority from FAA under 14 CFR part 121, 129, or 135. This Order applies to the following:

a. All U.S. air carriers and foreign air carriers conducting scheduled operations at JFK as of the date of this Order, any U.S. air carrier or foreign air carrier that operates under the same designator code as such a carrier, and any air carrier or foreign-flag carrier that has or enters into a codeshare agreement with such a carrier.

b. All U.S. air carriers or foreign air carriers initiating scheduled or regularly conducted commercial service to JFK while this Order is in effect.

c. The Vice President, System Operations Services, in coordination with the Chief Counsel of the FAA, is the final decision maker for determinations under this Order.

2. This Order governs scheduled arrivals and departures at JFK from 6 a.m. through 10:59 p.m., Eastern Time, Sunday through Saturday.

3. This Order took effect on March 30, 2008, and will expire October 26, 2024.

4. Under the authority provided to the Secretary of Transportation and the FAA Administrator by 49 U.S.C. 40101, 40103, and 40113, we hereby order that:

a. No U.S. air carrier or foreign air carrier initiating or conducting scheduled or regularly conducted commercial service at JFK may conduct such operations without an Operating Authorization assigned by the FAA.

b. Except as otherwise authorized by the FAA based on historic precedence, scheduled U.S. air carrier and foreign air carrier arrivals and departures will not exceed 81 per hour from 6 a.m. through 10:59 p.m., Eastern Time.

c. The Administrator may change the limits if the Administrator determines that capacity exists to accommodate additional operations without a significant increase in delays.

5. For administrative tracking purposes only, the FAA will assign an identification number to each Operating Authorization.

[6] Also referred to herein as ''slots.''

[7] *See* discussion of ''Current Issues'' in 2018 JFK Order, 83 FR at 46865, and 2018 LGA Order, 83 FR at 47065.

[8] *https://www.iata.org/en/policy/slots/slot-guidelines/.*

[9] As previously indicated, the FAA is reviewing substantive amendments to the WSG adopted in version 10 (Aug. 1, 2019) and included in the current WASG, and considering whether to implement certain changes in the United States. The FAA continues to generally apply edition 9 of the WSG (Jan. 1, 2019) to inform its slot administration decisions at JFK, available at: *www.regulations.gov/document/FAA-2007-29320-0058.*

[10] Under current policy and procedures, the FAA applies the definitions for ''new entrant'' as set forth in the WSG edition 9 (Jan. 1, 2019), which is ''an airline requesting a series of slots at an airport on any day where, if the airline's request were accepted, it would hold fewer than 5 slots at that airport on that day.''

6. A carrier holding an Operating Authorization may request the Administrator's approval to move any arrival or departure scheduled from 6:00 a.m. through 10:59 p.m. to another half hour within that period. Except as provided in paragraph 7, the carrier must receive the written approval of the Administrator, or his delegate, prior to conducting any adjusted arrival or departure. All requests to move an allocated Operating Authorization must be submitted to the FAA Slot Administration Office, facsimile (202) 267–7277 or email *7-AWA-Slotadmin@faa.gov,* and must come from a designated representative of the carrier. If the FAA cannot approve a carrier's request to move a scheduled arrival or departure, the carrier may then apply for a trade in accordance with paragraph 7.

7. For the duration of this Order, a carrier may enter into a lease or trade of an Operating Authorization to another carrier for any consideration. Notice of a trade or lease under this paragraph must be submitted in writing to the FAA Slot Administration Office, facsimile (202) 267–7277 or email *7-AWA-Slotadmin@faa.gov,* and must come from a designated representative of each carrier. The FAA must confirm and approve these transactions in writing prior to the effective date of the transaction. The FAA will approve transfers between carriers under the same marketing control up to five business days after the actual operation, but only to accommodate operational disruptions that occur on the same day of the scheduled operation. The FAA's approval of a trade or lease does not constitute a commitment by the FAA to grant the associated historical rights to any operator in the event that slot controls continue at JFK after this Order expires.

8. A carrier may not buy, sell, trade, or transfer an Operating Authorization, except as described in paragraph 7.

9. Historical rights to Operating Authorizations and withdrawal of those rights due to insufficient usage will be determined on a seasonal basis and in accordance with the schedule approved by the FAA prior to the commencement of the applicable season.

a. For each day of the week that the FAA has approved an operating schedule, any Operating Authorization not used at least 80% of the time over the time-frame authorized by the FAA under this paragraph will be withdrawn by the FAA for the next applicable season except:

i. The FAA will treat as used any Operating Authorization held by a carrier on Thanksgiving Day, the Friday following Thanksgiving Day, and the period from December 24 through the first Saturday in January.

ii. The Administrator of the FAA may waive the 80% usage requirement in the event of a highly unusual and unpredictable condition which is beyond the control of the carrier and which affects carrier operations for a period of five consecutive days or more.

b. Each carrier holding an Operating Authorization must forward in writing to the FAA Slot Administration Office a list of all Operating Authorizations held by the carrier along with a listing of the Operating Authorizations and:

i. The dates within each applicable season it intends to commence and complete operations.

A. For each winter scheduling season, the report must be received by the FAA no later than August 15 during the preceding summer.

B. For each summer scheduling season, the report must be received by the FAA no later than January 15 during the preceding winter.

ii. The completed operations for each day of the applicable scheduling season:

A. No later than September 1 for the summer scheduling season.

B. No later than January 15 for the winter scheduling season.

iii. The completed operations for each day of the scheduling season within 30 days after the last day of the applicable scheduling season.

10. In the event that a carrier surrenders to the FAA any Operating Authorization assigned to it under this Order or if there are unallocated Operating Authorizations, the FAA will determine whether the Operating Authorizations should be reallocated. The FAA may temporarily allocate an Operating Authorization at its discretion. Such temporary allocations will not be entitled to historical status for the next applicable scheduling season under paragraph 9.

11. The FAA considers the following factors and priorities in allocating Operating Authorizations, which the FAA has determined are available for reallocation—

a. Historical requests for allocation of an Operating Authorization in the same time;

b. New entrant status;

c. Retiming of historic Operating Authorizations;

d. Extension of a seasonal Operating Authorization to year-round service;

e. The effective period of operation;

f. The extent and regularity of intended use with priority given to year-round services;

g. The operational impacts of scheduled demand, including the hourly and half-hour demand and the mix of arrival and departure flights; and,

h. Airport facility constraints.

Any carrier that is not approved for allocation of an Operating Authorization by the FAA may request it be placed on a waiting list for consideration should an Operating Authorization in the requested time become available during that scheduling season.

12. If the FAA determines that an involuntary reduction in the number of allocated Operating Authorizations is required to meet operational needs, such as reduced airport capacity, the FAA will conduct a weighted lottery to withdraw Operating Authorizations to meet a reduced hourly or half-hourly limit for scheduled operations. The FAA will provide at least 45 days' notice unless otherwise required by operational needs. Any Operating Authorization that is withdrawn or temporarily suspended will, if reallocated, be reallocated to the carrier from which it was taken, provided that the carrier continues to operate scheduled service at JFK.

13. The FAA may enforce this Order through an enforcement action seeking a civil penalty under 49 U.S.C. 46301(a). The FAA or Department of Justice also could file a civil action in U.S. District Court, under 49 U.S.C. 46106 or 46107, respectively, seeking to enjoin any carrier from violating the terms of this Order.

14. The FAA may modify or withdraw any provision in this Order on its own or on application by any carrier for good cause shown.

Issued in Washington, DC, on October 26, 2022.

**Alyce Hood-Fleming,**

*Acting Vice President, System Operations Services.*

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## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

## 18 CFR Part 343

**[Docket No. AD20–10–000]**

## Standard Applied to Complaints Against Oil Pipeline Index Rate Changes

**AGENCY:** Federal Energy Regulatory Commission.

**ACTION:** Policy statement.

**SUMMARY:** In this Policy Statement, the Federal Energy Regulatory Commission

(Commission) provides guidance regarding how it will evaluate complaints against oil pipeline index rate increases. Specifically, the Commission replaces the Substantially Exacerbate Test with the Percentage Comparison Test as the preliminary screen for determining whether to investigate complaints against index rate increases.

**DATES:** October 28, 2022.

**FOR FURTHER INFORMATION CONTACT:**
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**SUPPLEMENTARY INFORMATION:**

1. On March 25, 2020, the Commission issued a Notice of Inquiry [1] seeking comments regarding its proposal to replace the Substantially Exacerbate Test as the preliminary screen for determining whether to investigate complaints against index rate increases for oil pipelines and to instead evaluate such complaints using the Percentage Comparison Test, which historically has applied to protests of index rate increases. The Commission also sought comment on whether it should apply the Percentage Comparison Test's existing 10% threshold to complaints.[2]

2. As discussed below, we provide guidance regarding how the Commission will evaluate complaints against index rate increases.[3] Specifically, we adopt the proposal to apply the Percentage Comparison Test with its existing 10% threshold as the preliminary screen in both protest and complaint challenges to index rate increases.

## I. Background

### *A. The Indexing Methodology*

3. The Commission regulates oil pipeline rates pursuant to the Interstate Commerce Act's (ICA) just and reasonable standard.[4] In accordance with the Energy Policy Act of 1992 (EPAct 1992),[5] the Commission adopted indexing to provide a simplified and generally applicable ratemaking methodology for oil pipelines and create streamlined procedures related to oil pipeline rates.[6] Indexing allows oil pipelines to change their tariff rates so long as those rates remain at or below applicable ceiling levels, which change every July 1 based upon an index that tracks industry-wide cost changes. When the Commission adopted indexing, it also added page 700 to FERC Form No. 6 to provide cost, revenue, and throughput information so that the Commission and the industry can monitor pipelines' indexed rates.[7]

4. In adopting indexing, the Commission established a procedure to allow shippers to challenge rate increases that, while in compliance with the applicable ceiling, are substantially in excess of the actual cost changes that the pipeline incurred. Section 343.2(c)(1) of the Commission's regulations provides that a protest or complaint against an index rate increase must allege ''reasonable grounds'' that the index rate increase is ''so substantially in excess of the actual cost increases incurred by the carrier that the rate is unjust and unreasonable.'' [8] The Commission reviews protests and complaints against annual index rate increases by (1) applying a preliminary screen based on data from the pipeline's page 700 and (2) if the preliminary screen is satisfied, investigating the rate increase at a hearing.[9]

5. Under the Commission's current policy, the preliminary screen differs for protests and complaints. When a proposed index rate increase is protested, the Commission applies the Percentage Comparison Test and will investigate the protested increase if there is a more than 10 percentage-point differential between (1) the index rate increase and (2) the change in the prior two years' total cost-of-service data reported on page 700, line 9.[10] By contrast, when a complaint against an index rate increase is filed, the Commission considers ''a wider range of factors beyond the Percentage Comparison Test,'' including the Substantially Exacerbate Test.[11] Under the Substantially Exacerbate Test, the Commission will investigate a complaint against an index rate increase if the complaint shows that (1) the pipeline is substantially over-recovering its cost of service (first prong) and (2) the index rate increase so exceeds the actual increase in the pipeline's costs that the resulting rate increase would substantially exacerbate the pipeline's over-recovery (second prong).[12]

### *B. Procedural History*

6. In *Southwest Airlines Co.* v. *FERC,* the U.S. Court of Appeals for the District of Columbia Circuit vacated and remanded Commission orders applying the Substantially Exacerbate Test to complaints against index rate increases by SFPP, L.P. (SFPP).[13] The court held

[1] *Standard Applied to Complaints Against Oil Pipeline Index Rate Changes,* 85 FR 21420 (Apr. 17, 2020), 170 FERC ¶ 61,252 (2020) (NOI).

[2] *Id.* P 14.

[3] This policy statement does not establish a binding rule or precedent but instead provides guidance by notifying entities of the course of action the Commission intends to follow in future adjudications. *See Pac. Gas & Elec. Co.* v. *FPC,* 506 F.2d 33, 38 (D.C. Cir. 1974).

[4] 49 U.S.C. app. 1(5).

[5] Public Law 102–486 1801(b), 106 Stat. 3010 (Oct. 24, 1992).

[6] *See Revisions to Oil Pipeline Reguls. Pursuant to Energy Pol'y Act of 1992,* Order No. 561, 58 FR 58753 (Nov. 4, 1993), FERC Stats. & Regs. ¶ 30,985 (1993) (cross-referenced at 65 FERC ¶ 61,109), *order on reh'g,* Order No. 561–A, 59 FR 40243 (Aug. 8, 1994), FERC Stats. & Regs. ¶ 31,000 (1994) (cross-referenced at 68 FERC ¶ 61,138), *aff'd sub nom. Ass'n of Oil Pipe Lines* v. *FERC,* 83 F.3d 1424 (D.C. Cir. 1996) (*AOPL* v. *FERC*).

[7] *Cost-of-Service Reporting & Filing Requirements for Oil Pipelines,* Order No. 571, 59 FR 59137 (Nov. 16, 1994), FERC Stats. & Regs. ¶ 31,006 (cross-referenced at 69 FERC ¶ 61,102), *order on reh'g and clarification,* Order No. 571–A, 60 FR 356 (Jan. 4, 1995), FERC Stats. & Regs. ¶ 31,012 (1994) (cross-referenced at 69 FERC ¶ 61,411), *aff'd sub nom. AOPL* v. *FERC,* 83 F.3d 1424 (D.C. Cir. 1996); *see also Revisions to & Elec. Filing of the FERC Form No. 6 & Related Unif. Sys. of Accts.,* Order No. 620, 65 FR 81335 (Dec. 26, 2000), FERC Stats. & Regs. ¶ 31,115 (2000) (cross-referenced at 93 FERC ¶ 61,262), *reh'g denied,* Order No. 620–A, 94 FERC ¶ 61,130 (2001); *Revisions to Page 700 of FERC Form No. 6,* Order No. 783, 78 FR 44424 (July 24, 2013), 144 FERC ¶ 61,049, at PP 29–40 (2013), *reh'g denied,* Order No. 783–A, 148 FERC ¶ 61,235 (2014). All jurisdictional oil pipelines are required to file page 700, including pipelines exempt from filing the full Form No. 6. 18 CFR 357.2(a)(2)–(3) (2021).

[8] 18 CFR 343.2(c)(1).

[9] Such challenges to annual index rate increases are distinct from complaints on a cost-of-service basis against a pipeline's total rate. *See BP W. Coast Prods. LLC* v. *SFPP, L.P.,* 121 FERC ¶ 61,243, at PP 8–10 (2007) (distinguishing complaints against annual index rate increases from complaints against the pipeline's base rate).

[10] *E.g., SFPP, L.P.,* 168 FERC ¶ 61,043, at P 4 (2019) (citing *Calnev Pipe Line, L.L.C.,* 130 FERC ¶ 61,082, at PP 10–11 (2010)); *see also* Appendix (depicting Percentage Comparison Test formula). The Commission has explained that there is an exception to the Percentage Comparison Test whereby the Commission will not investigate a protest if the pipeline's costs exceed its revenues. *SFPP, L.P.,* Opinion No. 527–A, 162 FERC ¶ 61,230, at P 20 (2018) (citing *Shell Pipe Line Co.,* 102 FERC ¶ 61,350, *order on reh'g,* 104 FERC ¶ 61,021 (2003)) (''[W]hen a pipeline is under-recovering its costs, the Commission permits a pipeline to receive the index increase. In these circumstances, the index increase (even if it exceeds the pipeline's cost changes) is not likely to lead to a rate that is 'unjust and unreasonable.' '').

[11] *E.g., Calnev,* 130 FERC ¶ 61,082 at P 11 (citing *BP W. Coast Prods. LLC* v. *SFPP, L.P.,* 121 FERC ¶ 61,243 at PP 8–9; *BP W. Coast Prods., LLC* v. *SFPP, L.P.,* 121 FERC ¶ 61,141, at P 7 (2007) (*BP West Coast II*)).

[12] *BP West Coast II,* 121 FERC ¶ 61,141 at P 10; *see also* Appendix (depicting Substantially Exacerbate Test formulas).

[13] *Sw. Airlines Co.* v. *FERC,* 926 F.3d 851, 856 (D.C. Cir. 2019) (*Southwest Airlines*). In the vacated

that the Commission had departed from its prior policy by considering post-rate-increase data in evaluating the complaints.[14] The court vacated and remanded the Commission's orders dismissing the complaints. The court emphasized the general principle that the Commission must ''explain its action in a way that coheres with the rest of its indexing scheme'' and ''provide a reasoned explanation that treats like cases alike.'' [15] These complaint proceedings subsequently settled.[16]

7. Following the remand in *Southwest Airlines,* the Commission issued the NOI and sought comment upon its proposal to eliminate the Substantially Exacerbate Test as the preliminary screen applied to complaints against index rate increases and to instead evaluate such complaints by applying the Percentage Comparison Test.[17] The NOI outlined the Commission's concerns regarding the Substantially Exacerbate Test: that the test lacks clear standards, suffers from an inherent mechanical flaw that yields irrational results, and is inconsistent with the purpose of indexing and the Commission's regulations.[18] The Commission sought comment addressing the merits of the proposal, including whether the Commission should apply the Percentage Comparison Test's existing 10% threshold to complaints and whether and how the Commission should consider additional factors beyond the Percentage Comparison Test in evaluating complaints against index rate increases.[19]

orders, the Commission addressed complaints filed in 2014 against SFPP's index rate increases for the 2012 and 2013 index years. The Commission dismissed the complaints for failing the second prong of the Substantially Exacerbate Test. *HollyFrontier Ref. & Mktg. LLC* v. *SFPP, L.P.,* 157 FERC ¶ 61,186, at P 8 (2016) (December 2016 Order), *reh'g denied,* 162 FERC ¶ 61,232, at P 14 (2018). The Commission explained that notwithstanding the challenged rate increases, page 700 data that became available after SFPP implemented the rate increases and before the complaints were filed (post-rate-increase data) showed that the difference between SFPP's costs and revenues declined between 2011 and 2013. December 2016 Order, 157 FERC ¶ 61,186 at P 9.

[14] *Southwest Airlines,* 926 F.3d at 858.

[15] *Id.* at 859.

[16] *SFPP, L.P.,* 178 FERC ¶ 61,019 (2022); *SFPP, L.P.,* 173 FERC ¶ 61,295 (2020).

[17] NOI, 170 FERC ¶ 61,252 at P 14. The Commission first described this proposal in an order on remand following *Southwest Airlines. HollyFrontier,* 170 FERC ¶ 61,133 at P 21; *see also* NOI; 170 FERC ¶ 61,252 at P 14 (soliciting public comment on the Commission's proposal).

[18] NOI, 170 FERC ¶ 61,252 at P 9.

[19] *Id.* P 14.

*C. Comments*

8. Initial and reply comments on the NOI were submitted by Joint Complainants,[20] the Liquids Shippers Group (Liquids Shippers),[21] SFPP, the Canadian Association of Petroleum Producers (CAPP), and the Liquid Energy Pipeline Association (LEPA).[22]

9. SFPP and LEPA generally support the proposal in the NOI, arguing that the Percentage Comparison Test is well-founded in precedent and aligns with the Commission's goals of streamlined and simplified index-based ratemaking.[23] Liquids Shippers, CAPP, and Joint Complainants oppose the proposal and also propose alternatives to the Percentage Comparison Test.

## II. Discussion

10. In this policy statement, we adopt the proposal set forth in the NOI to use the Percentage Comparison Test as the preliminary screen for both protests and complaints against annual index rate increases and to eliminate the Substantially Exacerbate Test. As explained below, we conclude that: (1) the Substantially Exacerbate Test should be eliminated; (2) the Percentage Comparison Test provides a preferable alternative for evaluating complaints against index rate changes; (3) the Percentage Comparison Test's 10% threshold is supported; (4) commenters' alternative proposals are incompatible with the indexing scheme; (5) the Commission intends to generally limit its consideration to the Percentage Comparison Test in evaluating complaints against index rate changes but will address other arguments as they arise in specific cases; and (6) proposals to adopt broader changes to the Commission's oil pipeline ratemaking methodologies are beyond the scope of this proceeding.

*A. The Substantially Exacerbate Test Should Be Eliminated*

11. As discussed below, we are ending our use of the Substantially Exacerbate Test because it (1) lacks clear standards, (2) suffers from an inherent mechanical flaw, and (3) does not effectively implement the Commission's regulations.

1. The Substantially Exacerbate Test Lacks Clear Standards

12. The Substantially Exacerbate Test lacks clear standards for evaluating complaints. Consistent with EPAct 1992's mandate for a simplified and streamlined ratemaking methodology, we conclude that the preliminary screen used to determine whether to investigate a complaint against an annual index rate increase would benefit from clear percentage thresholds to avoid complex case-specific analysis. Also, clear percentage thresholds facilitate ''treat[ing] like cases alike,'' as the D.C. Circuit emphasized in *Southwest Airlines.*[24]

13. However, in establishing the Substantially Exacerbate Test, the Commission did not set clear percentage thresholds of over-recovery and exacerbation for using the test to determine whether to set a complaint for hearing.[25] Since 2007, only a small number of shipper complaints have invoked the Substantially Exacerbate Test. Among the six sets of proceedings in which complainants sought relief pursuant to the Substantially Exacerbate Test,[26] the Commission applied the Substantially Exacerbate Test to establish a hearing on only one occasion. However, in that case, the Commission did not establish a minimum percentage threshold that could be applied going forward in other cases.[27] The five other complaint

[20] Joint Complainants are the complainants from the *HollyFrontier* proceedings: American Airlines, Inc.; Chevron Products Company; HollyFrontier Refining & Marketing LLC; Southwest Airlines Co.; and Valero Marketing and Supply Company.

[21] Liquids Shippers are Apache Corporation, Cenovus Energy Marketing Services Ltd., ConocoPhillips Company, Devon Gas Services, L.P., Equinor Marketing & Trading US Inc., Fieldwood Energy LLC, Marathon Oil Company, Ovinitiv Marketing Inc., and Pioneer Natural Resources USA, Inc.

[22] At the time its comments were filed, LEPA was known as the Association of Oil Pipe Lines.

[23] *E.g.,* LEPA Initial Comments at 4–5; SFPP Initial Comments at 13–19.

[24] *Southwest Airlines,* 926 F.3d at 859. Although the court made this statement while specifically addressing the Commission's use of post-rate-increase data in evaluating the complaints in *HollyFrontier,* we find the general principle instructive that like cases must be treated similarly and that the Commission's indexing policies must be internally coherent. *See id.*

[25] *HollyFrontier,* 170 FERC ¶ 61,133 at PP 22–23; *see also supra* P 5 (explaining that the Substantially Exacerbate Test considers whether (1) the pipeline is substantially over-recovering its cost of service and (2) the index rate increase so exceeds the actual increase in the pipeline's costs that the resulting rate increase would substantially exacerbate the pipeline's over-recovery).

[26] These six proceedings include (1) Docket Nos. OR07–08 and OR07–11, (2) Docket No. OR07–16, (3) Docket No. OR07–20, (4) Docket No. OR09–18, (5) Docket Nos. OR14–35 and OR14–36, and (6) Docket Nos. OR19–21, OR19–33, and OR19–37. Moreover, although the Commission has received index filings from over 200 pipelines annually in recent years, these complaints were all against either SFPP or its affiliate Calnev Pipe Line, L.L.C.

[27] In Docket Nos. OR07–08 and OR07–11, the Commission established a hearing to investigate complaints alleging that SFPP was over-recovering its cost of service by $16 million and that the challenged index rate increase would have ''represented an increase in SFPP's return of some 25%.'' *BP West Coast II,* 121 FERC ¶ 61,141 at P 8.

Continued

proceedings likewise did not specify the thresholds for establishing a substantial over-recovery or substantial exacerbation.[28] As a result, the Substantially Exacerbate Test lacks clear standards on which parties may rely in bringing or defending against index increase complaints or which the Commission may apply in deciding whether to investigate such complaints at a hearing. Comments in response to the NOI, addressed below, do not persuade us to reach a different conclusion. Rather, as discussed in the following section, clear standards are difficult to develop due to the Substantially Exacerbate Test's mechanical flaws, and we are unpersuaded by Joint Complainants' argument that such thresholds are unnecessary.[29]

2. The Substantially Exacerbate Test Is Mechanically Flawed

14. The Substantially Exacerbate Test suffers from an inherent mechanical flaw that makes developing analytically sound percentage thresholds unworkable. For example, as a pipeline's over-recovery increases, an index rate increase will exacerbate the over-recovery by a lower percentage; thus, if a pipeline has a relatively high over-recovery, even a relatively large index increase will lead to a minimal exacerbation.[30] Conversely, applying the same index rate increase to a lower level of over-recovery will result in a higher degree of exacerbation.[31] This relationship between the Substantially Exacerbate Test's two prongs causes the Substantially Exacerbate Test to yield results whereby complaints against pipelines with higher over-recoveries are less likely to be investigated because a large index increase will lead to minimal exacerbation.[32]

15. Moreover, there appears to be no combination of threshold levels for these two prongs of the test that would consistently yield reasonable results, such that the test fails to provide a workable standard for evaluating complaints against index rate increases.[33] This phenomenon is demonstrated in the table below, which presents results of the Substantially Exacerbate Test over a relevant range of over-recovery and index levels.[34] The table shows that the Substantially Exacerbate Test is driven by (1) the extent of the pipeline's over-recovery and (2) the level of the index rate increase.

**Table—Exacerbation Percentages at Various Over-Recovery-Index Combinations**

| | | Index Level | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | 1% | 2% | 3% | 4% | 5% | 6% | 7% | 8% | 9% |
| Revenues Exceeding Costs (%) | 5% | 21 | 42 | 63 | 84 | 105 | 126 | 147 | 168 | 189 |
| | 10% | 11 | 22 | 33 | 44 | 55 | 66 | 77 | 88 | 99 |
| | 15% | 8 | 15 | 23 | 31 | 38 | 46 | 54 | 61 | 69 |
| | 20% | 6 | 12 | 18 | 24 | 30 | 36 | 42 | 48 | 54 |
| | 25% | 5 | 10 | 15 | 20 | 25 | 30 | 35 | 40 | 45 |
| | 30% | 4 | 9 | 13 | 17 | 22 | 26 | 30 | 35 | 39 |
| | 35% | 4 | 8 | 12 | 15 | 19 | 23 | 27 | 31 | 35 |
| | 40% | 3 | 7 | 11 | 14 | 18 | 21 | 25 | 28 | 32 |
| | 45% | 3 | 6 | 10 | 13 | 16 | 19 | 23 | 26 | 29 |
| | 50% | 3 | 6 | 9 | 12 | 15 | 18 | 21 | 24 | 27 |

16. The table shows that at low levels of over-recovery, a modest index rate increase exacerbates the over-recovery by a large percentage. For example, the second line of the table indicates that applying a 4% index rate increase to an over-recovery of 10% will exacerbate the over-recovery by 44%. In comparison, the same increase would only exacerbate a 50% over-recovery by 12%. This leads to a result whereby a complaint against the pipeline with the 50% over-recovery is less likely to be set for hearing under the Substantially Exacerbate Test than a complaint against the pipeline with the 10% over-recovery due to the lower degree of exacerbation. Due to this mechanical flaw, there is no combination of threshold levels that would consistently yield reasonable results. Accordingly, the Substantially Exacerbate Test fails to provide a workable standard for the Commission to evaluate complaints under § 343.2(c)(1).

17. We disagree with Joint Complainants' argument that the

The complaints resulted in settlement. *See ExxonMobil Oil Corp.* v. *SFPP, L.P.,* 122 FERC ¶ 61,129, at P 1 (2008) (setting complaints for hearing); *BP W. Coast Prods., LLC* v. *SFPP, L.P.,* 125 FERC ¶ 61,138, at P 2 (2008) (approving uncontested settlement resolving complaints).

[28] The Commission found in three of these proceedings that the complaint failed the Substantially Exacerbate Test because the challenged index rate increases were smaller than the actual changes in the pipelines' costs. *See Tesoro Ref. & Mktg. Co.* v. *Calnev Pipe Line, L.L.C.,* 121 FERC ¶ 61,142, at P 7 (2007) (OR07–16); *BP W. Coast Prods. LLC* v. *SFPP, L.P.,* 121 FERC ¶ 61,243 at P 4 (OR07–20); *SFPP, L.P.,* 129 FERC ¶ 61,228, at P 41 (2009) (OR09–18). The fourth set of proceedings involved the complaints at issue in *Southwest Airlines.* As discussed above, the Commission held that these complaints failed the Substantially Exacerbate Test's second prong because post-rate-increase page 700 data showed that SFPP's cost-revenue divergence decreased after SFPP implemented the challenged increases. *Supra* note 13. Finally, the fifth set of proceedings involved complaints addressed in the Commission's order on remand following *Southwest Airlines, HollyFrontier,* 170 FERC ¶ 61,133 (OR19–21, OR19–33, OR19–37), and these complaints ultimately settled. *SFPP,* 178 FERC ¶ 61,019; *SFPP,* 173 FERC ¶ 61,295.

[29] *See infra* PP 14–19.

[30] *HollyFrontier,* 170 FERC ¶ 61,133 at P 24.

[31] *Id.* This flaw was illustrated in *HollyFrontier* with a table presenting results of the Substantially Exacerbate Test over a range of over-recovery and index levels. *Id.* P 25. For example, if a pipeline's revenues exceed its costs by 50%, a 3% index increase leads to an exacerbation of 9%. *Id.* In contrast, if a pipeline's revenues exceed its costs by only 5%, that same 3% index increase leads to an exacerbation of 63%. *Id.*

[32] *Id.* P 24; *see also supra* P 5 (explaining that the Substantially Exacerbate Test considers whether (1) the pipeline is substantially over-recovering its cost of service and (2) the index rate increase so exceeds the actual increase in the pipeline's costs that the resulting rate increase would substantially exacerbate the pipeline's over-recovery).

[33] *Id.* PP 24, 26.

[34] Since its inception in 1995, the oil pipeline index has ranged from approximately −2.0% to 8.7%. Because the Substantially Exacerbate Test would not apply to an index that is less than zero (a negative index), the range of index levels presented in the columns of the table encompasses only the positive historical levels of the oil pipeline index.

Substantially Exacerbate Test does not produce irrational results because it is not meant to provide an absolute mathematical threshold, but rather provides information to help the Commission determine, in its judgment, whether a substantial over-recovery would be substantially exacerbated.[35] As discussed above, we find that, to further the goals of streamlining and simplifying the ratemaking process, the preliminary screen used to determine whether to investigate a complaint against an index rate increase benefits from clear thresholds. Furthermore, a clearly established threshold also facilitates ''treat[ing] like cases alike'' consistent with *Southwest Airlines*.[36]

18. Similarly, we disagree with Joint Complainants' argument that the Commission could apply the Substantially Exacerbate Test on a case-by-case basis using a ''pragmatic quantitative and qualitative analysis'' similar to the analysis used in full cost-of-service rate cases.[37] The purpose of indexing is to avoid the complexity of cost-of-service litigation,[38] and therefore we view clear thresholds as a means to effectuate the streamlining and simplification required by EPAct 1992.[39] Finally, Joint Complainants do not explain how their ''pragmatic quantitative and qualitative analysis'' would function as a workable standard for evaluating complaints in the indexing regime.

19. We are also not persuaded by Joint Complainants' reliance upon the Commission's prior statement in Order No. 561–A that precise thresholds are not feasible for reviewing challenges to index rate changes.[40] Our experience since Order No. 561–A, including applying the Percentage Comparison Test's 10% threshold,[41] has demonstrated that precise thresholds are feasible, and in fact preferable, in this setting.

3. The Substantially Exacerbate Test Does Not Effectively Implement the Commission's Regulations

20. The Substantially Exacerbate Test does not effectively implement § 343.2(c)(1)'s ''substantially in excess'' requirement. Section 343.2(c)(1) provides that complaints ''must allege reasonable grounds for asserting . . . that the rate increase is *so substantially in excess of the actual cost increases* incurred by the carrier that the rate is unjust and unreasonable.'' [42] When the Commission first established the Substantially Exacerbate Test, it concluded that complaints applying that test did not need to satisfy the regulation's ''substantially in excess'' requirement.[43] On rehearing, recognizing the Commission could not wholly disregard this part of its regulation, the Commission sought to rectify the error by explaining that the complainant applying the Substantially Exacerbate Test needed to show that the rate change substantially exceeded the cost change (''in dollar amounts'' or percentages) as part of its demonstration that the rate change substantially exacerbated the prior over-recovery.[44]

21. Upon further consideration, we now conclude that the Substantially Exacerbate Test does not effectively implement the regulation. As discussed above, this is because the Substantially Exacerbate Test primarily considers pre-existing over-recoveries and the exacerbation of those over-recoveries. As discussed below, the Substantially Exacerbate Test provides inadequate consideration to whether the annual rate increase is ''substantially in excess'' to the annual cost increase, which is the standard provided in the regulation.

22. First, in applying the Substantially Exacerbate Test, the Commission stated that ''dollar amounts'' could be used to satisfy the regulation's ''substantially in excess'' requirement. However, we find that defining ''substantially in excess'' in dollar terms hinders the development of consistent and transparent standards for implementing a simplified and streamlined ratemaking regime. This is because the relative significance of a certain dollar value varies greatly between large and small pipelines. For example, an over-recovery of $1 million would likely be insignificant for a large pipeline with substantial costs and revenues, but it could be significant for a smaller pipeline with lower costs and revenues. Thus, this approach is in tension with the goals of the Commission's indexing regime.[45]

23. Second, conversely, using percentages instead of dollar amounts would be redundant of the Percentage Comparison Test. To the extent the Substantially Exacerbate Test simply compares the pipeline's percentage cost change with the percentage index rate change, this duplicates the calculation already used in the Percentage Comparison Test.[46] Thus, the Substantially Exacerbate Test's application of the regulation's ''substantially in excess'' requirement either (a) undercuts the goals of simplified and streamlined ratemaking (relying upon dollar terms) or (b) is redundant (relying upon percentages, which uses the same standard as the Percentage Comparison Test). We disagree with Joint Complainants' arguments that the Substantially Exacerbate Test is consistent with the Commission's indexing regulations because (1) § 343.2(c)(1) requires that index rate changes must produce rates that are just and reasonable under the ICA and (2) the Commission can only determine whether an index rate change will produce an unjust and unreasonable rate by considering whether the pipeline's revenues exceed its costs.[47] Joint Complainants'

[35] *E.g.,* Joint Complainants Reply Comments at 13.

[36] 926 F.3d at 859; *see also supra* note 24.

[37] Joint Complainants Initial Comments at 26 (arguing that clear thresholds are unnecessary and that the Commission could use a ''pragmatic quantitative and qualitative analysis'' similar to the analysis used in full cost-of-service rate cases).

[38] *See, e.g.,* Order No. 561, FERC Stats. & Regs. ¶ 30,985 at 30,948 (explaining that indexing avoids ''the need of strict regulatory review of the pipeline's individual cost of service, thus saving regulatory manpower, time and expense'').

[39] We also find that using, as a screen for complaints against index rate increases, the same analytical approach that the Commission uses in base-rate proceedings could exacerbate the protracted length of complaint proceedings, about which Joint Complainants also express concern. Joint Complainants Initial Comments at 19–20.

[40] *Id.* at 22 (citing Order No. 561–A, FERC Stats. & Regs. ¶ 31,000 at 31,103).

[41] *E.g., SFPP, L.P.,* 168 FERC ¶ 61,043, at P 21 (2019) (declining to investigate protested index rate increase where differential under Percentage Comparison Test was less than 10%); *N.D. Pipeline Co.,* 163 FERC ¶ 61,235, at P 11 (2018) (setting protested index rate increase for hearing where Percentage Comparison Test differential exceeded 10%).

[42] 18 CFR 343.2(c)(1) (emphasis added).

[43] *BP West Coast I,* 119 FERC ¶ 61,241 at PP 10–11.

[44] *BP West Coast II,* 121 FERC ¶ 61,141 at P 9. However, the Commission has provided limited guidance regarding how this would be applied. First, in establishing the Substantially Exacerbate Test, the Commission concluded that a $4 million additional return resulting from the index rate increase satisfied the ''substantially in excess'' standard. Second, in other cases, the Commission stated that it would reject index rate increases where the dollar increase in costs exceeded the projected dollar increase in revenues. *SFPP, L.P.,* 129 FERC ¶ 61,228 at P 41 & n.74. Moreover, along the same lines, the Commission also rejected complaints where the pipeline's percentage cost change exceeded the percentage index rate increase. *See BP W. Coast Prods. LLC* v. *SFPP, L.P.,* 121 FERC ¶ 61,243 at P 4; *Tesoro Ref. & Mktg. Co.* v. *Calnev Pipe Line, L.L.C.,* 121 FERC ¶ 61,142 at PP 4, 7.

[45] 926 F.3d at 859.

[46] As discussed above, under the Percentage Comparison Test, a rate change is ''substantially in excess'' of the cost change when the cost change exceeds the percentage index rate by 10 percentage points. *See supra* P 5. No commenter has advanced a viable proposal for differentiating this aspect of the Substantially Exacerbate Test from the Percentage Comparison Test. Thus, the Substantially Exacerbate Test is redundant of the Percentage Comparison Test and, to the extent it differs, simply imposes a burden on shippers to show a *preexisting* over-recovery, a requirement that is not supported by the regulation.

[47] Joint Complainants Initial Comments at 28–29, 32–33, 35; *see also* 18 CFR 343.2(c)(1) (requiring that protests or complaints against index rate

Continued

arguments do not explain how the Substantially Exacerbate Test effectively implements § 343.2(c)(1), which requires comparing the proposed rate increase to the amount of cost increases the pipeline has incurred.

24. For the same reason, Joint Complainants' reliance on the Commission's statement in Opinion No. 527–A that ''a comparison between revenues and costs can be relevant'' under § 343.2(c)(1) is inapposite.[48] The fact that consideration of revenues can be relevant under the regulation does not demonstrate that the Substantially Exacerbate Test effectively implements the regulation requiring a comparison between the ''rate increase'' and the ''cost increases.'' [49]

25. We find unpersuasive Joint Complainants' contention that the Substantially Exacerbate Test should be retained because indexing is designed to allow recovery of historical costs and not prospective costs. In particular, they argue that indexing is designed to allow recovery of historical costs and not prospective costs based on (1) the Commission's statement in Order No. 561 that indexing ''merely preserves the value of just and reasonable rates in real economic terms'' and (2) the Commission's practice of solely considering data preceding the index increase in cases challenging index rate changes.[50] The quoted language in Order No. 561 does not support Joint Complainants' contention. Rather, annual index rate increases preserve the economic value of pipeline rates by allowing them to keep pace with industry-wide cost changes so that rates will be sufficient to recover future years' costs.[51] Although the Commission considers page 700 data from the preceding two years in evaluating a challenged index rate increase, index rate changes simply adjust a pipeline's existing rate so that it does not lose ground relative to industry-wide cost changes going forward.[52] Indexing is not a true-up to account for prior-period over- or under-recoveries; rather, it is a permanent change in the pipeline's rate to recover future costs.

26. Therefore, the concerns outlined above support eliminating the Substantially Exacerbate Test as the preliminary screen applied to index increase complaints.

*B. The Percentage Comparison Test Offers a Preferable Alternative for Evaluating Complaints Against Index Rate Increases*

27. We find that the Percentage Comparison Test provides a more consistent way to evaluate complaints against index rate changes than the Substantially Exacerbate Test.[53] As discussed below, (1) the Percentage Comparison Test lacks the same analytical flaws as the Substantially Exacerbate Test, (2) the Percentage Comparison Test conforms to the Commission's regulations, and (3) it is preferable to evaluate challenges to index rate changes, whether via protest or a complaint, using a single test. As discussed below, the comments do not dissuade us from adopting this alternative approach.

1. The Percentage Comparison Test Lacks the Analytical Flaws of the Substantially Exacerbate Test

28. We find that the Percentage Comparison Test is preferable to the Substantially Exacerbate Test.

29. We disagree with the Joint Complainants' and Liquids Shippers' objections that the Percentage Comparison Test must be rejected because it is also mechanically flawed. They argue that the Percentage Comparison Test improperly compares percentages with different bases.[54] We recognize that in other situations the Commission may seek to avoid comparisons of percentages with two different bases, but that concern is not persuasive here. Joint Complainants and Liquids Shippers neither cite evidence that the difference in bases leads to a distortion nor have they provided a workable alternative for comparing the pipeline's cost change to the index rate change that does not involve different bases. In fact, the Percentage Comparison Test has been workably applied to protests of index rate increases.[55] Applying this simplified and streamlined formula is appropriate within the simplified and streamlined indexing regime, and Joint Complainants and Liquids Shippers do not propose any adjustment to the Percentage Comparison Test or viable alternative method for performing the rate-change to cost-change comparison that § 343.2(c)(1) requires.

30. We also reject Joint Complainants' and Liquids Shippers' argument that the Percentage Comparison Test does not ensure just and reasonable rates because it permits pipelines with over-recoveries and declining costs to implement index rate increases.[56] As an initial matter, we emphasize that index rate increases are limited to the industry-wide index level and do not recover a pipeline's cost changes in excess of that amount. At the same time, the Commission implemented the indexing methodology with the understanding that some individual pipelines' revenues could potentially exceed their costs under the scheme and that some individual pipelines' annual rate changes could also exceed their annual cost changes.[57] By permitting revenues to exceed costs to some degree, indexing encourages pipelines to operate efficiently by allowing them to benefit from their cost

changes ''allege reasonable grounds for asserting that the rate is so substantially in excess of the actual cost increase incurred by the carrier *that the rate is unjust and unreasonable*'') (emphasis added). Joint Complainants further argue that the Commission's proposal ignores the fact that § 343.2(c)(1) resulted from Order Nos. 561 and 561–A, which expressly envisioned an evaluation of over-recovery of costs and the proposed rate increase's impact on that over-recovery. Joint Complainants Initial Comments at 33 (citing Order No. 561–A, FERC Stats. & Regs. ¶ 31,000 at 31,103; *BP West Coast,* 121 FERC ¶ 61,141 at P 10).

[48] Joint Complainants Initial Comments at 35 (quoting *SFPP, L.P.,* Opinion No. 527–A, 162 FERC ¶ 61,230, at P 20 (2018)).

[49] 18 CFR 343.2(c)(1). Further, in Opinion No. 527–A, the Commission allowed for the consideration of revenue as ''tied to the language of the regulation'' in the context of the Percentage Comparison Test at the hearing stage. Opinion No. 527–A, 162 FERC ¶ 61,230 at P 20. Thus, the Percentage Comparison Test responds to both parts of the regulation by comparing the index rate change with the pipeline's cost changes and considering whether the divergence renders the pipeline's rate ''unjust and unreasonable.'' 18 CFR 343.2(c)(1).

[50] Joint Complainants Initial Comments at 29–31, 33–34 (quoting Order No. 561, FERC Stats. & Regs. ¶ 30,985 at 30,950).

[51] *HollyFrontier,* 170 FERC ¶ 61,133 at P 27. Each prior year's inflation sets a new industry-wide cost level and inflationary changes compound in future years. Thus, if inflation is 10% each year and the cost level is $100 in Year 1, then in Year 2 the cost level will be $110 and in Year 3 will be $121. Indexing allows pipeline rates to increase accordingly.

[52] Order No. 561, FERC Stats. & Regs. ¶ 30,985 at 30,950; *Ass'n of Oil Pipe Lines* v. *FERC,* 83 F.3d at 1430.

[53] NOI, 170 FERC ¶ 61,252 at PP 10–12 (citing *HollyFrontier,* 170 FERC ¶ 61,133 at PP 32–35, 39, 42–45).

[54] Joint Complainants Initial Comments at 20, 40–41 (citing *Am. W. Airlines, Inc.* v. *Calnev Pipe Line, L.L.C.,* 121 FERC ¶ 61,241, at P 8 (2007) (''[I]t is incorrect to use the sum of the changes in two percentages as a measure of absolute change when the percentages have different bases.'')); Liquids Shippers Initial Comments at 34–35. For example, when considering an index increase filed on July 1, 2022, the Percentage Comparison Test compares the rate change (new rate/prior rate) to the cost change ((2021 costs—2020 costs)/(2020 costs)). Because one denominator is the ''prior rate'' and the other denominator is the ''2020 costs,'' Joint Complainants and Liquids Shippers assert that the Percentage Comparison Test compares percentages with ''different bases.''

[55] *See, e.g., SFPP,* 163 FERC ¶ 61,232 at PP 13, 20; *SFPP, L.P.,* 135 FERC ¶ 61,274, at P 11 (2011); *Calnev Pipe Line,* 130 FERC ¶ 61,082 at P 10; *Calnev Pipe Line L.L.C.,* 115 FERC ¶ 61,387, at PP 10–11 (2006).

[56] Joint Complainants Initial Comments at 46; Liquids Shippers Initial Comments at 34–35; *see also* CAPP Initial Comments at 14.

[57] *See* Order No. 561, FERC Stats. & Regs. ¶ 30,985 at 30,949.

savings.[58] Likewise, denying index rate increases whenever a pipeline's costs decline could discourage pipelines from operating efficiently.[59] Thus, while indexing allows some pipelines to increase their rates above their individual cost changes, indexed rate changes are below other pipelines' cost changes. Accordingly, denying an index rate increase whenever a pipeline's revenues exceed its costs, even slightly, and/or the pipeline's costs decline would make indexing a lopsided methodology in which pipelines are presented with a significant risk of under-recovery without commensurate potential for benefits for operating efficiently.

31. We are unpersuaded by Liquids Shippers' argument that the Commission should expand the scope of indexing proceedings to include a review of the pipeline's underlying base rate.[60] Shippers can challenge a pipeline's base rate at any time. The choice of whether to challenge a pipeline's index rate increase or its base rate belongs to the complaining shipper.[61] Since indexing's inception, the Commission has limited its review of index rate increase challenges to the proposed incremental rate change and rejected arguments to expand these proceedings to encompass challenges to the pipeline's base rate.[62] Although Liquids Shippers contend that the rationale for this policy no longer applies,[63] they do not explain how enlarging indexing proceedings to include a full cost-of-service review of the pipeline's base rate would cohere with streamlined and simplified ratemaking or conform to the limited scope of § 343.2(c)(1).

2. The Percentage Comparison Test Conforms to Commission Regulations

32. We find that the Percentage Comparison Test effectively implements the Commission's regulations. As discussed above, § 343.2(c)(1) requires protests and complaints against index rate increases to show that the rate increase is ''substantially in excess'' of the pipeline's actual cost changes.[64] Unlike the Substantially Exacerbate Test, the Percentage Comparison Test more closely conforms to this language by comparing the challenged index rate change to the pipeline's already incurred cost changes and relying upon this comparison to determine whether the rate increase was, in fact, ''substantially in excess'' of the cost changes.

33. Joint Complainants and Liquids Shippers contend that the Percentage Comparison Test is inconsistent with the Commission's regulations because § 343.2(c)(1) inquires whether a challenged index rate increase substantially exceeds the pipeline's ''*actual cost increases,*'' thereby limiting index rate increases to pipelines that experienced cost increases and excluding pipelines that experienced cost decreases.[65] We disagree with these arguments. First, the regulatory language that Joint Complainants and Liquids Shippers cite describes when shippers can *challenge* an index rate change, not whether a pipeline can *implement* such a change. To the extent that this language could be construed as only allowing challenges to rate increases where a pipeline's costs have increased, this would not prohibit a pipeline from implementing a rate increase when its costs have decreased.

34. Second, Joint Complainants' and Liquids Shippers' interpretation of the regulation is inconsistent with the Commission's indexing precedent. Although the regulation discusses comparing rate increases to ''actual cost increases'' and rate decreases to ''actual cost decreases,'' [66] the Commission has consistently interpreted this regulation as requiring a comparison of the challenged rate change to the pipeline's cost change, whether positive or negative.[67]

35. Third, as discussed above, interpreting the regulation as Joint Complainants and Liquids Shippers propose would undermine indexing's cost-efficiency incentives. Indexing aims to provide pipelines ''with the incentive to cut costs aggressively,'' [68] but denying index rate increases to pipelines that succeed in reducing costs would undermine that goal.[69] In contrast, adopting the Percentage Comparison Test appropriately triggers investigations where an index rate change diverges markedly from the pipeline's recent reported cost changes.

3. It Is Preferable To Evaluate Challenges to Index Rate Changes Using a Single Test

36. Based on the record in this proceeding, we conclude that it is preferable to evaluate protests and complaints against index rate changes using the same preliminary screen.[70] The court in *Southwest Airlines* instructed the Commission to evaluate complaints against index rate increases in a manner that coheres with the rest of its indexing scheme and ''treats like cases alike.'' [71] Section 343.2(c)(1) requires protests and complaints to make the same showing: that the challenged rate increase ''is so substantially in excess of the actual cost increases incurred by the carrier that the rate is unjust and unreasonable.'' [72] Given that the same standard applies to all challenges to index rate changes regardless of form, we conclude that evaluating protests and complaints using a single test conforms to the structure of the regulation and will better ensure that similar cases are not treated differently.

37. We acknowledge that the Commission has previously found in *BP*

[58] *See HollyFrontier,* 170 FERC ¶ 61,133 at P 42. Moreover, tying indexed rates to pipeline-specific costs would reduce the efficacy of the indexing scheme as a streamlined, simplified ratemaking methodology, counter to the Commission's goals in Order No. 561. *See* Order No. 561, FERC Stats. & Regs. ¶ 30,985 at 30,949.

[59] This also leads to irrational results. For instance, if the index increase in any given year is 3%, it would be illogical to deny a pipeline whose costs declined by 0.01% (or less) an index rate increase whereas a pipeline whose costs increased by 0.01% would receive the full 3% index increase.

[60] Liquids Shippers argue that the Percentage Comparison Test improperly focuses on the incremental change (both in costs and separately in rates) rather than the entirety of the pipeline's underlying base rate. Liquids Shippers Initial Comments at 2–3, 27–33; Liquids Shippers Reply Comments at 15–16.

[61] If a shipper is concerned that an index rate increase substantially exceeds the pipeline's cost changes, it can file a complaint against the index rate increase. If successful, such a complaint would eliminate or reduce the index rate increase. On the other hand, if a shipper is concerned that a pipeline's base rates may be substantially over-recovering the pipeline's costs, it can file a cost-of-service complaint against the base rates. If successful, such a complaint against the base rates would eliminate the pipeline's over-recovery.

[62] *E.g., SFPP, L.P.,* 107 FERC ¶ 61,334, at P 10 (2004); *Calnev Pipe Line, L.L.C.,* 96 FERC ¶ 61,350, at 62,304 (2001) (explaining that the Commission ''is not subject to a statutory duty to examine the whole rate when an indexed change is proposed''); Order No. 561–A, FERC Stats. & Regs. ¶ 31,000 at 31,104; *see also SFPP, L.P.,* 140 FERC ¶ 61,016, at P 34 (2012) (''Indexing cases are intended to be streamlined proceedings that do not delve into cost-of-service issues.''); Order No. 561, FERC Stats. & Regs. ¶ 30,985, at 30,952–53 (finding that requiring protests under § 343.2(c)(1) to compare the proposed incremental rate change to the pipeline's cost changes, while permitting complaints against the pipeline's base rates, achieves an adequate balance between competing interests).

[63] Liquids Shippers Initial Comments at 28–29.

[64] 18 CFR 343.2(c)(1); *see also supra* P 20.

[65] Joint Complainants Initial Comments at 47–48 (quoting 18 CFR 343.2(c)(1) (emphasis in original)); Liquids Shippers Initial Comments at 34 (same); Liquids Shippers Reply Comments at 15.

[66] 18 CFR 343.2(c)(1).

[67] *See, e.g., SFPP, L.P.,* 139 FERC ¶ 61,267, at PP 9–10 (2012), *reh'g denied,* 143 FERC ¶ 61,140 (2013).

[68] Order No. 561, FERC Stats. & Regs. ¶ 30,985 at 30,949 n.37.

[69] For example, if reducing costs by 1% precludes a pipeline from implementing a 5% index rate increase it could obtain if its costs instead increased by 1%, the pipeline's incentives to reduce costs would diminish.

[70] *HollyFrontier,* 170 FERC ¶ 61,133 at P 37.

[71] *Southwest Airlines,* 926 F.3d at 859.

[72] 18 CFR 343.2(c)(1).

*West Coast II* that it is not arbitrary to interpret § 343.2(c)(1) differently depending upon whether the challenge to the index rate change takes the form of a protest or a complaint.[73] In making this finding, the Commission reasoned that the different procedural frameworks for protest and complaint proceedings warranted applying different interpretations of § 343.2(c)(1) to these pleadings and that applying the same standard in both types of proceedings ''would effectively deprive shippers of any opportunity to question the rate levels and the returns resulting from the pipeline's annual index-based rate filings based on changes in the dollar yield from the rate index.'' [74]

38. Upon review of the record in this proceeding, we now conclude that it is preferable to evaluate protests and complaints under § 343.2(c)(1) using a single test. The considerations identified in *BP West Coast II* do not compel evaluating complaints against index rate increases differently than protests. While different procedural frameworks may justify different kinds of evidence that the Commission would consider in evaluating complaints as compared to accelerated protest proceedings, the different procedural frameworks here—where our regulations set forth the requirement for filing protests and complaints against index rate adjustments in the same sentence under a single standard—do not warrant applying different tests. Here, as discussed above, we find the Percentage Comparison Test to be superior to the Substantially Exacerbate Test and, given the flaws in the Substantially Exacerbate Test, we conclude that it is preferable to apply the Percentage Comparison Test to both protests and complaints.

39. In addition, shippers will be able to challenge index rate increases by demonstrating that such increases are disallowed under the Percentage Comparison Test. Thus, contrary to commenters' arguments,[75] we disagree that shippers are effectively precluded from challenging proposed index rate increases. The Percentage Comparison Test provides an effective preliminary screen that enables shippers to challenge index rate increases that substantially diverge from the pipeline's cost changes.[76]

40. Furthermore, although the Percentage Comparison Test does not permit shippers to raise existing over-recoveries to challenge index rate increases,[77] this is consistent with the plain language of the Commission's regulations and with the purpose of annual index rate increases. As discussed above, § 343.2(c)(1) requires a complainant to show that the pipeline's cost change substantially exceeds its rate change, not to evaluate pre-existing over-recoveries.[78] In addition, indexing allows annual pipeline rate increases to reflect industry-wide cost changes during the prior year to ensure that the pipeline's rate is sufficient to recover future years' costs. Consistent with this purpose, the Commission has previously held that the only relevant information in reviewing index rate increases is the change in the pipeline's costs over the two years preceding the increase.[79] Applying the Percentage Comparison Test to both protests and complaints would bring the standard applied to complaints in line with this precedent by limiting the inquiry in index increase complaint proceedings to the relationship between the rate increase and the pipeline's prior changes in cost.

41. Moreover, even a successful complaint challenging an index rate increase based upon the Substantially Exacerbate Test would merely prevent the index increase at issue; it would not address any pre-existing over-recoveries. Regardless of the standard applied to complaints against individual index rate increases, shippers concerned that a pipeline may be substantially over-recovering may file a cost-of-service complaint challenging the pipeline's rates that have historically been indexed. If successful, such a complaint would eliminate the pipeline's over-recovery.

### *C. The Percentage Comparison Test's 10% Threshold Is Reasonable*

42. We reaffirm our continued use of a 10% threshold in the application of the Percentage Comparison Test.[80] This record does not support a different threshold, and we find the 10% threshold continues to be reasonable. As an initial matter, the 10% threshold fulfills the Commission's regulations by denying index rate increases where the rate increase significantly exceeds the pipeline's cost changes.[81] In contrast, imposing a lower threshold (such as a 5% threshold) could prevent a majority or near-majority of the industry from taking full index rate increases.[82] This would undercut the purpose of indexing by precluding large portions of the industry from adjusting their rates to reflect industry-wide cost changes.

43. Moreover, the 10% threshold preserves indexing's cost-efficiency incentives and encourages pipelines to control costs. Indexing allows for some gap between an individual pipeline's rates and its costs, and allowing rates to exceed costs by a modest degree encourages pipelines to operate efficiently by permitting them to retain a portion of their cost savings while also placing downward pressure on the industry-wide index level through the five-year review process.[83] Setting the threshold at 10% provides a reasonable gap between rate increases and cost changes above a *de minimis* level so that pipelines have the incentive to control costs and reap the benefits of efficiency gains.

44. Conversely, setting the threshold below 10% could undermine these efficiency incentives. Industry-wide cost data illustrate this point. The average of the annual index levels from 2004 to 2019 is approximately 4.10%. In 10 of those 16 years, the index level exceeded

[73] *BP West Coast II,* 121 FERC ¶ 61,141 at P 7.

[74] *Id.; see also supra* P 22 (discussing why the use of the dollar yield is not appropriate).

[75] Joint Complainants Initial Comments at 19, 39; Liquids Shippers Initial Comments at 20–23; *see also* CAPP Initial Comments at 14; CAPP Reply Comments at 2–3.

[76] Dr. Webb's analysis demonstrates that for each year between 2001–2018, a significant segment of oil pipelines filing cost-of-service information would have failed the Percentage Comparison Test's 10% threshold had they attempted to take a full index rate increase. SFPP Reply Comments, Ex. B at 7–8 (Affidavit of Michael J. Webb). In most years, the 10% threshold would have screened all pipelines in the upper quartile of all pipelines from implementing a full index rate increase. *Id.*

[77] Liquids Shippers Initial Comments at 20–23; *see also* CAPP Initial Comments at 14; CAPP Reply Comments at 2–3.

[78] 18 CFR 343.2(c)(1).

[79] *E.g., SFPP, L.P.,* 140 FERC ¶ 61,016 at P 34 (finding that ''[t]he only relevant evidence in indexing cases'' is the change in the pipeline's cost of service in the two years preceding the index rate increase).

[80] The Percentage Comparison Test's 10% threshold developed gradually through the adjudication of protests to index rate increases. *HollyFrontier,* 170 FERC ¶ 61,133 at P 41. The Commission made this threshold explicit a decade ago in 2012. *SFPP, L.P.,* 139 FERC ¶ 61,267 at P 10.

[81] An analysis of page 700 data indicates that the 10% threshold generally excludes pipelines in the top 30% of industry-wide cost changes from implementing index rate increases. Moreover, between 2017–2020, an average of 32 pipelines per year (or approximately 12% of pipelines filing page 700) experienced a divergence of 10% or more between their annual percentage change in cost of service and the full index rate increase. *See also* SFPP Reply Comments, Ex. B at 8, Figure 2 (Affidavit of Dr. Michael J. Webb) (illustrating that in most years between 2001–2018, the 10% threshold would have excluded pipelines in the top 30% of industry-wide cost changes reported on page 700 from implementing full index rate increases).

[82] *Id.* at 8–9.

[83] *HollyFrontier,* 170 FERC ¶ 61,133 at P 42 (citing Order No. 561, FERC Stats. & Regs. ¶ 30,985 at 30,949). The Commission recalculates the index based upon industry-wide cost changes over the prior five-year period; therefore, any cost savings over that prior period will tend to reduce the index level.

4.10%. Moreover, in five of those years, the index level exceeded 5%, reaching as high as 8.6%. If the threshold is only slightly higher than the index level for a given year, pipelines would have little incentive to reduce costs because a slight cost reduction could render the pipeline unable to implement a full index rate increase.[84] Moreover, a threshold equal to [85] or lower than [86] the index level for a given year would create incentives for pipelines to maintain or increase costs in order to implement an index rate increase. As a result, a threshold at or slightly above the index level could weaken pipelines' incentive to reduce costs which, in turn, could inflate the index adder for future years.[87] Accordingly, we find that the existing 10% threshold balances indexing's efficiency incentives without shielding unreasonable rate increases from scrutiny.

45. Further, the potential that a threshold below 10% could yield distorted outcomes is amplified by the high annual volatility in oil pipeline cost and volume data.[88] Because a pipeline's cost changes may vary significantly from year to year, the pipeline's ability to implement an annual index rate increase in a given year may likewise vary. Depending upon the magnitude of the pipeline's cost increases or decreases, the level of divergence between cost changes and index rate increases permitted under the Percentage Comparison Test can impact pipelines' ability to recover costs over time. For example, a 5% cost decline in one year, which could lead to the denial of an index rate increase, may be followed by a 15% cost increase in the next year, which would likely significantly exceed the permitted index rate increase. In this way, a low threshold that does not account for annual shifts in pipeline costs could cause pipelines to under-recover their costs over time.[89] Along similar lines, a low threshold could also unfairly differentiate between a pipeline with sizable one-year cost declines and a pipeline whose costs decline at a more consistent pace: the former may be barred from implementing an index rate increase while the latter is not, even where the former's cost changes deviate less from the index level than the latter's.[90]

46. Joint Complainants have not persuaded us to lower the 10% threshold.[91] Joint Complainants observe that the Commission previously stated that the index should not be set so ''sufficiently high and generous to encompass even the most extraordinary costs.'' [92] As discussed above, however, the 10% threshold would not encompass extraordinary costs and imposing a 5% threshold could prevent a majority or near-majority of the industry from taking full index rate increases.[93] This result would fail to account for pipeline cost- and throughput-volatility and risk, creating a lopsided ratemaking methodology that deprives pipelines an appropriate opportunity for sufficient cost recovery.[94]

47. We find misplaced Joint Complainants' argument that pipelines have cost-efficiency incentives even without the possibility of an index rate increase. If a pipeline risks losing a future index increase because it reduces costs, then the pipeline's incentive to reduce those costs will erode.[95] As noted above, we remain concerned setting the threshold for the Percentage Comparison Test too low would undermine pipelines' incentives to control costs. The 10% threshold reasonably balances that concern with the need to constrain index rate increases that are substantially in excess of pipelines' cost changes.[96]

48. We are similarly unpersuaded by Joint Complainants' argument regarding how a threshold slightly above or below the index level in a given year could impact pipelines' incentives to reduce costs. Specifically, Joint Complainants claim that even if pipelines could forecast the next year's index level, it is highly unlikely that they could precisely calibrate their cost changes to take the index level into account.[97] Although Joint Complainants are correct that pipelines likely cannot precisely calibrate their costs to account for an index level to be published the following year, this misses the point. Even if pipelines cannot calibrate their costs with such exactitude or anticipate future index levels, losing all or part of an index rate increase due to an overly stringent Percentage Comparison Test threshold could erode pipelines' incentives to control costs going forward. This erosion can become pronounced at thresholds less than 10%. For example, if the threshold is set at 5% and the index level is 4.1%, a pipeline whose costs declined by more than 1% could lose at least a portion of any index rate increase for that year.[98] Because this slight cost reduction caused the pipeline to lose an index rate increase in a year with an average index level, a 5% threshold could weaken the pipeline's incentive to reduce costs going forward.

49. Joint Complainants' remaining contentions are also without merit. Their argument that the 10% threshold can produce large disparities between pipeline revenues and costs lacks support because the examples that Joint Complainants provide assume without basis that pipelines' revenues will increase in future periods while their costs and throughput will remain unchanged.[99] Joint Complainants also provide no evidence that the application of the Percentage Comparison Test and the 10% threshold to protested index

[84] For example, if the threshold is set at 5%, pipelines that reduce costs by 1% over the prior two years may be unable to implement a full index rate increase at the 4.10% average. An index level exceeding 4.10% would further diminish a pipeline's incentive to reduce costs.

[85] If, for instance, the index level for a given year is 6%, and the Percentage Comparison Test threshold is set at 6%, pipelines would have little incentive to reduce their costs because even a 1% cost reduction would result in the pipeline's cost change diverging from the 6% index level by more than the 6% threshold.

[86] If the index level is 7% and the Percentage Comparison Test threshold is 6%, pipelines could be incentivized to increase their costs to bring the gap between their cost change and the index level within 7%, thereby undermining indexing's cost efficiency incentives.

[87] *HollyFrontier,* 170 FERC ¶ 61,133 at P 43.

[88] Because oil pipelines are common carriers, throughput can change significantly from year to year. For example, using page 700 data, the median annual change in throughput was 14% from 2017–2018. Significant changes in throughput can produce significant changes in pipeline costs and revenues.

[89] This potential distortion would be magnified by the sheer number of pipelines that would lose index increases under a threshold lower than 10% as discussed above.

[90] *HollyFrontier,* 170 FERC ¶ 61,133 at P 44. For example, if the threshold is set at 8%, Pipeline A with 3% cost decreases in year one and year two would be permitted to implement index rate increases at the 4.10% average for both years. However, Pipeline B with no cost changes in year one and a 5% cost decrease in year two would be unable to implement a full 4.10% index rate increase for year two, despite the fact that Pipeline B's costs deviated less from the index level over two years than the costs of Pipeline A (by 5% instead of 6%).

[91] Joint Complainants Initial Comments at 42–44.

[92] *Id.* at 49–50 (quoting Order No. 561–A, FERC Stats. & Regs. ¶ 31,000 at 31,097).

[93] *Id.* at 8–9.

[94] *HollyFrontier,* 170 FERC ¶ 61,133 at P 44.

[95] For example, if a pipeline is considering steps that could reduce its costs by 5% but this would cause the pipeline to lose a 5% index increase in the next year, then the pipeline will not have an incentive to implement the cost reduction.

[96] *HollyFrontier,* 170 FERC ¶ 61,133 at P 43. Furthermore, reducing costs often requires pipelines to invest in cost-saving measures, such as more efficient pumps. A stringent Percentage Comparison Test threshold that places pipelines at risk of losing all or part of an index rate increase when the pipeline modestly controls its costs could discourage pipelines from making such investments.

[97] Joint Complainants Initial Comments at 51 (citing *HollyFrontier,* 170 FERC ¶ 61,133 at P 43, nn.77, 78, & 79; Brattle Report at PP 21–24).

[98] *HollyFrontier,* 170 FERC ¶ 61,133 at P 43 n.77.

[99] Joint Complainants Initial Comments at 52.

rate increases has in fact lead to significant over-recoveries.

50. Similarly, we disagree with Joint Complainants' claim that indexing only weakly reflects industry-wide cost changes because it lacks a recurring requirement to reset industry-wide oil pipeline rates on a cost-of-service basis (''rebasing'' mechanism).[100] As an initial matter, it is not clear whether a rebasing mechanism would increase pipeline incentives to operate efficiently.[101] Moreover, this proposal is beyond the scope of this proceeding. As discussed above, the Commission established indexing as a simplified, streamlined ratemaking methodology in response to EPAct 1992's mandate to develop an alternative to complex, costly, and lengthy cost-of-service rate proceedings. Periodically resetting oil pipeline rates to cost-of-service levels as Joint Complainants propose could be contrary to that mandate,[102] requiring the Commission to resolve a large number of cost-of-service rate cases on a recurring basis and imposing substantial burdens on shipper, pipeline, and Commission resources.[103] Joint Complainants do not explain how a recurring rebasing mechanism would be consistent with simplified and streamlined ratemaking.

51. Liquids Shippers likewise fail to adequately challenge the Percentage Comparison Test's 10% threshold. While Liquids Shippers claim that the threshold is arbitrary and unsupported,[104] it has in fact been developed over time through several proceedings.[105] Although Liquids Shippers argue that the Commission has not justified setting the threshold at 10% as opposed to a slightly lower level,[106] we find, based on our experience with its application and the record before us, that the 10% threshold strikes an appropriate balance between upholding the indexing methodology's cost-efficiency incentives and ensuring just and reasonable rates.[107] Moreover, the Commission has considerable discretion in setting numerical thresholds,[108] and Liquids Shippers have not demonstrated that the 10% threshold is so objectionable as to be ''patently unreasonable.'' [109]

52. Accordingly, we will apply the 10% threshold when using the Percentage Comparison Test to evaluate complaints. Although Joint Complainants and Liquids Shippers criticize the 10% threshold, they do not persuade us that an alternative Percentage Comparison Test threshold better satisfies our statutory obligations. As discussed above, the Commission possesses significant discretion in setting numerical thresholds. We find no reason based upon the record here to depart from our proposal in the NOI and our prior precedent.[110]

*D. The Alternative Proposals Presented Are Inconsistent With the Indexing Scheme*

53. Several commenters suggest alternatives to the Percentage Comparison Test they assert would provide superior means for evaluating complaints against index rate increases. As discussed below, these proposals are the ''cost-decrease test'' and the ''revenues test.'' We disagree that these alternatives are superior to the Percentage Comparison Test. Moreover, both proposals are inconsistent with the Commission's regulations requiring that a challenge to an index increase be assessed based on whether the increase is substantially in excess of the pipeline's cost increases.[111] Accordingly, we decline to adopt these proposals here.

1. Cost-Decrease Test

a. Proposal

54. Joint Complainants propose that the Commission deny index rate increases where (i) the pipeline's revenues exceed its costs and (ii) the pipeline's costs have decreased for the relevant index period (cost-decrease test).[112] Joint Complainants argue that granting an index rate increase in such circumstances would negate the cost basis of the index rate increase by allowing the pipeline to double-recover the industry-wide cost changes that the rate increase seeks to address. Joint Complainants further assert that Opinion No. 511–A supports this proposal.[113]

b. Commission Determination

55. We decline to adopt Joint Complainants' proposed cost-decrease test. The proposal is fundamentally flawed. First, the cost-decrease test is inconsistent with the Commission's regulations because it may permit challenges to index rate increases even though the rate change is not substantially in excess of the pipeline's costs changes as required by § 343.2(c)(1). For instance, if a pipeline's total costs decrease by 0.01% and the index increase is only 0.1%, it is not the case that the rate increase is substantially in excess of the cost change.

56. Second, the cost-decrease test is also conceptually flawed. As discussed above, some gap between revenues and costs must be permitted to preserve indexing's efficiency incentives.[114]

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[100] *Id.* at 52–53.

[101] Regularly reducing the pipeline's rates to the cost-of-service level would reduce pipeline incentives to operate efficiently. Moreover, even pipelines that are already earning revenues above their costs have an incentive to control costs in order to further increase the return to investors.

[102] *See Ass'n of Oil Pipe Lines* v. *FERC,* 281 F.3d 239, 244 (D.C. Cir. 2002) (*AOPL II*) (quoting EPAct 1992, Pub. L. 102–486 1801(a)) (finding that ''a regime based in large part on [cost-of-service proceedings] would be inconsistent with Congress's mandate under the EPAct for FERC to establish 'a simplified and generally applicable ratemaking methodology' '').

[103] In establishing indexing, the Commission explicitly declined to undertake a periodic review of individual pipeline costs and the D.C. Circuit affirmed this decision. Order No. 561–A, FERC Stats. & Regs. ¶ 31,000 at 31,104–05, *aff'd, AOPL* v. *FERC,* 83 F.3d at 1437.

[104] Liquids Shippers Initial Comments at 35.

[105] The 10% threshold evolved through orders in which the Commission initiated investigations when the divergence between a pipeline's cost increases and the proposed rate increase was more than 10% and declined to initiate investigations where such divergence was less than 10%. *Compare SFPP,* 139 FERC ¶ 61,267 at P 10 (rejecting protests where divergence was 9.88%), *with Calnev Pipeline L.L.C.,* 115 FERC ¶ 61,387 at PP 10–11 (setting protest for hearing based upon 10.95% divergence), *and SFPP, L.P.,* 139 FERC ¶ 61,266, at P 7 (2012) (setting protest for hearing where divergence was 13.1%).

[106] Liquids Shippers Reply Comments at 18 (arguing that the Commission has not justified setting the threshold at 10% rather than 9.88%).

[107] *See HollyFrontier,* 170 FERC ¶ 61,133 at PP 41–44. In addition, Liquids Shippers' argument that the 10% threshold allows for improper gamesmanship is unconvincing. Liquids Shippers support this claim by citing an example where a pipeline, faced with a shipper protest, withdrew a proposed index rate increase that exceeded the 10% threshold and refiled a lower rate increase that fell below the threshold. Liquids Shippers Initial Comments at 36 (citing Buckeye Pipe Line Transportation LLC, Tariff Filing, Docket No. IS15–352–000 (filed May 28, 2015)). However, rather than undermine the Percentage Comparison Test, this example illustrates how the 10% threshold can constrain pipelines from implementing rate increases that diverge considerably from their cost changes.

[108] *E.g., ExxonMobil Gas Mktg. Co.* v. *FERC,* 297 F.3d 1017, 1085 (D.C. Cir. 2002) (quoting *AT&T Corp.* v. *FCC,* 220 F.3d 607, 627 (D.C. Cir. 2000)) (''FERC 'has wide discretion to determine where to draw administrative lines.' ''); *Mo. Pub. Serv. Comm'n* v. *FERC,* 215 F.3d 1, 4 (D.C. Cir. 2000). Courts will generally uphold an agency's threshold if ''the figure selected by the agency reflects its informed discretion, and is neither patently unreasonable nor 'a dictate of unbridled whim.' '' *Vonage Holdings Corp.* v. *FCC,* 489 F.3d 1232, 1242 (D.C. Cir. 2007) (quoting *WJG Tel. Co.* v. *FCC,* 675 F.2d 386, 388–89 (D.C. Cir. 1982)).

[109] *Vonage Holdings Corp.* v. *FCC,* 489 F.3d at 1242.

[110] *See, e.g., SFPP, L.P.,* 140 FERC ¶ 61,106 (2012), *order on reh'g,* 143 FERC ¶ 61,141 (2013); *SFPP, L.P.,* 143 FERC ¶ 61,297, at P 11 (2013), *order on reh'g,* 147 FERC ¶ 61,012 (2014); *SFPP,* 163 FERC ¶ 61,232 at PP 13, 20.

[111] 18 CFR 343.2(c).

[112] Joint Complainants Initial Comments at 56.

[113] *Id.* at 57 (citing *SFPP, L.P.,* Opinion No. 511–A, 137 FERC ¶ 61,220, at P 407 (2011)).

[114] *See supra* P 43.

Likewise, Joint Complainants' proposal would make indexing a lopsided methodology in which pipelines face significant risk of under-recovery without commensurate potential for benefits for operating efficiently.[115] Finally, Joint Complainants' proposal includes no flexibility for the annual fluctuations in a pipeline's costs and revenues.[116]

57. Third, we are not persuaded by Joint Complaints' arguments in support of the cost-decrease test. In seeking to justify this proposal, Joint Complainants mischaracterize the purpose of indexing. Joint Complainants argue that index rate increases are designed to recover a pipeline's past costs, and therefore to avoid a double-recovery index rate increases should not be extended to pipelines whose rates already recover these costs.[117] Contrary to Joint Complainants' assertions, and as noted above, an index rate change is not a true-up to account for prior period over- or under-recoveries. Rather, indexing allows pipeline rates to increase (or decrease) to keep pace with annual industry-wide cost changes so that the pipeline can recover its costs in *future* years.[118] Likewise, indexing does not address a pipeline's base costs as in a cost-of-service rate case.[119] Thus, to the extent that a pipeline's rates generate revenues sufficient to recover the pipeline's base costs as reported on its page 700, this does not necessarily indicate that those rates also recovered the annual industry-wide cost changes that indexing is designed to recover. As a result, adjusting a pipeline's rate to account for industry-wide cost changes, even where the pipeline's cost of service has declined, does not negate the cost basis for the rate increase.[120]

58. Moreover, we disagree with Joint Complainants' assertion that Opinion No. 511–A supports the cost-decrease test. Opinion No. 511–A involved different circumstances than those under consideration here. As explained in Opinion No. 511–A, the Commission has rejected index rate increases following a new cost-of-service rate filing where the increase addressed prior-period inflationary cost changes that were already incorporated into the test period data used to determine the pipeline's cost-of-service rate.129F [121] Opinion No. 511–A involved situations where the test period for setting cost-of-service rates and the time period for measuring industry-wide cost changes reflected in the index rate increase overlapped, in total or in part. In that cost-of-service rate case, the Commission correctly found that the pipeline's new cost-of-service rates already reflected the prior-period cost changes (*i.e.,* the costs in the test period) that would have been reflected in the proposed index rate increase. Because that proceeding involved new base rates set at the pipeline's cost-of-service level, there was no need to adjust those rates to account for inflationary industry-wide costs that took place during the cost-of-service test period. By contrast, under the indexing regime, it is appropriate as a general matter for pipelines to adjust their rates to account for industry-wide cost changes where the Commission did not set the rate using cost data from the period covered by the index rate change.[122]

2. Revenues Test

a. Proposal

59. Joint Complainants, Liquids Shippers, and CAPP propose versions of a revenues test, wherein the Commission would grant challenges to an index rate increase where the pipeline's page 700 revenues exceeded its page 700 cost of service by a certain percentage for two consecutive years. Joint Complainants propose a 7.5% threshold,[123] Liquids Shippers propose a 5% threshold,[124] and CAPP proposes a 10% threshold.[125] Joint Complainants explain that over-recovering by 7.5% would contribute a 25% impact on the pipeline's return on equity (ROE), which Joint Complainants argue is a reasonable threshold and is consistent with the Commission's existing framework for rate evaluation, including the evaluation of grandfathered rates.[126] Liquids Shippers submit that a 5% threshold is appropriate because it translates to a real ROE of 12.3%, which they claim approximates the top of the zone of reasonableness as determined by the discounted cash flow (DCF) analysis in recent pipeline cost-of-service rate cases.[127] CAPP argues that there are numerous reporting pipelines whose revenues exceed its proposed 10% threshold, which in turn represents an unwarranted over-recovery that cannot be reconciled with the just and reasonable rate standard.[128]

b. Commission Determination

60. We are not persuaded to adopt the proposed revenues tests. As an initial matter, a revenues test is inconsistent with the regulations because it evaluates existing over-recovery, while the regulations require a comparison of cost changes to rate changes.[129] While commenters are correct that the Commission proposed a similar revenues test in the 2016 ANOPR, the Commission ultimately declined to adopt such a test.[130]

61. Moreover, this record does not provide support for a workable application of a revenues test. For example, we conclude that the proposed revenues test thresholds lack support. Joint Complainants criticize the 2016 ANOPR's 15% threshold as arbitrary

[115] *See supra* P 30.

[116] Because oil pipelines are common carriers, throughput can change significantly from year to year and this significantly affects oil pipeline revenues.

[117] Joint Complainants Initial Comments at 57.

[118] *See* discussion *supra* P 25.

[119] *SFPP, L.P.,* Opinion No. 522–B, 162 FERC ¶ 61,229, at P 16 n.25 (2018).

[120] Applying the Percentage Comparison Test as the preliminary screen for both protests and complaints under § 343.2(c)(1) provides an additional safeguard by triggering investigations where an index rate change diverges markedly from the pipeline's recent reported cost changes.

[121] Opinion No. 511–A, 137 FERC ¶ 61,220 at P 407 (citing *SFPP, L.P.,* 117 FERC ¶ 61,271 (2006), *reh'g denied,* 120 FERC ¶ 61,245 (2007). For instance, in Opinion No. 511–A, the Commission allowed SFPP to implement one-quarter of an index rate increase for 2008 where cost data from the first nine months were reflected in a Commission order approving new cost-of-service rates for SFPP. Opinion No. 511–A, 137 FERC ¶ 61,220 at PP 405, 409–411.

[122] In these circumstances, the industry-wide cost changes that the index rate change is designed to recover are not already incorporated into the pipeline's underlying rate. Thus, the mere fact that the pipeline's revenues exceed its cost of service does not establish that its rates have already recovered the cost changes that indexing seeks to recover.

[123] Joint Complainants Initial Comments at 59.

[124] Liquids Shippers Initial Comments at 36–37.

[125] CAPP Initial Comments at 14–16.

[126] Joint Complainants Initial Comments at 61 (citing Order No. 783, 144 FERC ¶ 61,049 at P 5). EPAct 1992 ''grandfathered,'' or deemed just and reasonable, rates that were in effect for the 365-day period ending on the date of enactment of EPAct 1992, or that were in effect on the 365th day preceding enactment, and which were not subject to a protest, complaint, or an investigation during this 365-day period. These grandfathered rates can be challenged under certain limited conditions, including where the complainant establishes that ''a substantial change has occurred after the date of the enactment of'' EPAct 1992 in ''the economic circumstances . . . which were the basis for the rate.'' EPAct 1992 1803(b)(1). The Commission has interpreted that test to require a complainant to demonstrate that the ROE earned on the rate at issue has increased by at least 25% over the ROE embedded in the grandfathered rate and that the increase has occurred since the passage of EPAct in 1992. *See, e.g., Tesoro Ref. & Mktg. Co.* v. *Calnev Pipe Line LLC,* 134 FERC ¶ 61,214, at PP 17–18, 60 (2011).

[127] Liquids Shippers Initial Comments at 38 (citing *Revisions to Indexing Policies & Page 700 of FERC Form No. 6,* 157 FERC ¶ 61,047, at n.25 (2016) (2016 ANOPR), *withdrawn,* 170 FERC ¶ 61,134 (2020); *El Paso Nat. Gas Co.,* Opinion No. 528–A, 154 FERC ¶ 61,120, at P 215 (2016); *Seaway Crude Pipeline Co.,* Opinion No. 546, 154 FERC ¶ 61,070, at P 194 (2016)).

[128] CAPP Initial Comments at 14.

[129] *See* 18 CFR 343.2(c)(1).

[130] *See Revisions to Indexing Policies & Page 700 of FERC Form No. 6,* 170 FERC ¶ 61,134 at P 11.

and capricious,[131] but they fail to provide substantive support for their proposed 7.5% threshold.[132] Liquids Shippers similarly fail to justify their proposed 5% threshold.[133] In addition, we are concerned that the proposed 5% and 7.5% thresholds are inconsistent with a streamlined, generally applicable ratemaking methodology, because they could necessitate the use of cost-of-service rate filings for many pipelines where the pipeline's revenues slightly exceed costs over a short period but not necessarily in the long term.[134] Moreover, such narrow thresholds risk making indexing a one-sided methodology in which pipelines face significant risk of under-recovery without commensurate potential for benefits for operating efficiently.[135]

*E. Consideration of Additional Factors in Complaint Proceedings*

1. Comments

62. The NOI invited comment on how and whether the Commission should consider additional factors in evaluating complaints against index rate increases.[136] SFPP objects to the Commission's proposal, arguing that introducing undefined ''additional factors'' would create ambiguity and regulatory uncertainty, which would impede the gains achieved by eliminating the Substantially Exacerbate Test as well as undermine the goal of creating streamlined procedures that reduce litigation.[137] Therefore, SFPP requests that the Commission clarify that it will not consider additional factors beyond the Percentage Comparison Test.

2. Commission Determination

63. We decline to clarify that the Commission will not consider additional factors beyond the Percentage Comparison Test when evaluating complaints to an index rate increase. While our intention, based upon this record in this proceeding, is to generally limit our consideration of challenges to index rate increases to the Percentage Comparison Test, we recognize that the Commission must address specific arguments as they arise in specific cases.

*F. Whether To Adopt Broader Changes to the Commission's Oil Pipeline Ratemaking Methodologies*

1. Comments

64. Liquids Shippers claim that the indexing methodology allows for significant over-recovery and should be reexamined, referring to arguments they made in support of the 2016 ANOPR.[138]

65. CAPP contends that the Commission should perform a comprehensive review of the indexing regime to ensure that shipper and pipeline interests are appropriately balanced and to determine whether the regime can be improved.[139] CAPP further argues that because the current cost-of-service ratemaking process is cumbersome, costly, and time-consuming, the Commission should consider overhauling the cost-of-service ratemaking process rather than using its flaws as justification for increased reliance on the indexing system.[140]

2. Commission Determination

66. We reject Liquids Shippers' and CAPP's arguments that the Commission should reexamine the indexing methodology and cost-of-service ratemaking process as outside the scope of this proceeding. The NOI requested comment on the Commission's proposal for evaluating complaints against index rate increases under § 343.2(c)(1).[141] Because Liquids Shippers' and CAPP's arguments exceed the scope of this inquiry, we decline to address their proposals.

## III. Document Availability

67. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*).

68. From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

69. User assistance is available for eLibrary and the Commission's website during normal business hours from the Commission's Online Support at (202) 502–6652 (toll free at 1–866–208–3676), via email at *ferconlinesupport@ferc.gov,* or from the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov*.

By the Commission. Commissioner Danly is not participating.

[131] Joint Complainants Initial Comments at 60.

[132] Joint Complainants justify this threshold on the basis that a 1992 oil pipeline rate is ''de-grandfathered'' if the pipeline's ROE has increased by 25% over the grandfathered level. Joint Complainants Initial Comments at 60–61 (citing *Tesoro,* 134 FERC ¶ 61,214 at PP 53, 60–62). Joint Complainants assert that a gap between revenues and costs of 7.5% equates to a 25% increase in ROE over the industry-wide average reported on page 700. Joint Complainants Initial Comments at 61–62 (citing Brattle Report at PP 41–47 & Figures 7–9). However, the threshold for de-grandfathering rates serves the different purpose of measuring a ''substantial change in economic circumstances'' since a specific point in time. *E.g.,* Order No. 561, FERC Stats. & Regs. ¶ 30,985 at 30,944. The issue when evaluating an index rate increase is not a change in economic circumstances, but, rather, whether the annual index increase ''is so substantially in excess of the actual cost increases'' that the resulting rate is unjust and unreasonable. 18 CFR 343.2(c)(1).

[133] We are not persuaded by Liquids Shippers' claim that the Commission should investigate index increases when revenues are 105% of costs, arguing that this approximates the top of the zone of reasonableness (an ROE of 12.3%) as determined by the discounted cash flow (DCF) analysis in recent oil pipeline cost-of-service cases. This argument fails because the just and reasonable return permitted by a rate case is not equivalent to the return permitted by indexing. Indexing permits efficient pipelines to recover more (earn a higher return) than they would under a cost-of-service model. Likewise, inefficient pipelines recover less than they would under a cost-of-service model (earning a lower return). By capping the return at a cost-of-service level, Liquids Shippers' proposal would deny the benefit that indexing is meant to provide to efficient pipelines while continuing to subject less efficient pipelines to the downsides of indexing.

[134] *See AOPL II,* 281 F.3d at 244 (quoting EPAct 1992, Pub. L. 102–486 1801(a)) (''[A] regime based in large part on [cost-of-service proceedings] would be inconsistent with Congress's mandate under the EPAct for FERC to establish 'a simplified and generally applicable ratemaking methodology.' ''). Such narrow thresholds fail to account for variability of costs and revenues from year to year. Over- and under-recovery can vary widely from year to year. For example, in 2020 and considering the data set of all pipelines, the median variation from the prior year's recoveries was by 37.03 percentage points. Although a pipeline's revenues resulting from indexed rates may track its costs, this is not necessarily true over the short term. If such a pipeline's recoveries fluctuate around zero but with significant annual variations, denying the pipeline index rate increases in those years when revenues modestly exceed costs would, over time, cause the pipeline to under-recover its costs in the long term. To avoid such under-recoveries, the pipeline would need to file a cost-of-service rate increase.

[135] *See supra* P 30. For instance, if a pipeline's revenues exceed its costs by 5%, the pipeline would be denied an index rate increase under Liquids Shippers' 5% revenues-test threshold. On the other hand, if a pipeline's costs exceeded its revenues by 5%, then the pipeline would only receive that year's index rate increase, which may be insufficient for the pipeline to eliminate the under-recovery.

[136] NOI, 170 FERC ¶ 61,252 at P 14.

[137] SFPP Initial Comments at 21.

[138] *See* Liquids Shippers Initial Comments at 21–22.

[139] CAPP Initial Comments at 9–13.

[140] *Id.* at 9, 17–18; CAPP Reply Comments at 1–3.

[141] NOI, 170 FERC ¶ 61,252 at P 14.

Issued: October 20, 2022.

**Kimberly D. Bose,**

*Secretary.*

**Appendix: Percentage Comparison Test and Substantially Exacerbate Test Formulas**

**BILLING CODE 6717–01–P**

Percentage Comparison Test

$$[Index\ Adjustment]_t - \left(\frac{[Costs]_{t-1} - [Costs]_{t-2}}{[Costs]_{t-2}}\right)$$

Where [Index Adjustment] is expressed in percentage terms and
$t$ = index adjustment year

Substantially Exacerbate Test

$$\text{Exacerbation} = \frac{[Post\text{-}Index\ Over\text{-}Recovery] - [Existing\ Over\text{-}Recovery]}{[Existing\ Over\text{-}Recovery]}$$

$$\text{Post-Index Over-Recovery} = \frac{[Index\ Adjustment]_t * [Revenues]_{t-1} - [Costs]_{t-1}}{[Costs]_{t-1}}$$

$$\text{Existing Over-Recovery} = \frac{[Revenues]_{t-1} - [Costs]_{t-1}}{[Costs]_{t-1}}$$

Where [Index Adjustment] is expressed in percentage terms and
$t$ = index adjustment year

[FR Doc. 2022–23343 Filed 10–27–22; 8:45 am]

**BILLING CODE 6717–01–C**

**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

**50 CFR Part 679**

**[Docket No. 220216–0049]**

**RTID 0648–XC499**

## Fisheries of the Exclusive Economic Zone Off Alaska; Shortraker Rockfish in the Central Regulatory Areas of the Gulf of Alaska

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Temporary rule; closure.

**SUMMARY:** NMFS is prohibiting retention of shortraker rockfish in the Central Regulatory Areas of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the 2022 total allowable catch of shortraker rockfish in the Central Regulatory Areas of the GOA.

**DATES:** Effective 12 p.m., Alaska local time (A.l.t.), October 25, 2022, through 12 a.m., A.l.t., December 31, 2022.

**FOR FURTHER INFORMATION CONTACT:** Obren Davis, 907–586–7228.

**SUPPLEMENTARY INFORMATION:** NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR parts 600 and 679.

The 2022 total allowable catch (TAC) of shortraker rockfish in the Central Regulatory Areas of the GOA is 280 metric tons (mt) as established by the final 2022 and 2023 harvest specifications for groundfish of the GOA (87 FR 11599, March 2, 2022).

In accordance with § 679.20(d)(2), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2022 shortraker rockfish TAC in the Central Regulatory

Areas of the GOA will soon be reached. Therefore, NMFS is requiring that shortraker rockfish in the Central Regulatory Areas of the GOA be treated as prohibited species in accordance with § 679.21(b), as described under § 679.21(a), for the remainder of the year, except shortraker rockfish in the Central Regulatory Areas of the GOA caught by catcher vessels using hook-and-line, pot, or jig gear as described in § 679.20(j). This action does not apply to fishing by trawl catcher/processors in the cooperative fishery in the Rockfish Program for the Central GOA.

**Classification**

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 679, which was issued pursuant to section 304(b), and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion, and would delay prohibiting retention of shortraker rockfish in the Central Regulatory Areas of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of October 24, 2022.

The Assistant Administrator for Fisheries, NOAA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

**Authority:** 16 U.S.C. 1801 *et seq.*

Dated: October 25, 2022.

**Jennifer M. Wallace,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 2022–23526 Filed 10–25–22; 4:15 pm]

**BILLING CODE 3510–22–P**

# Proposed Rules

Federal Register
Vol. 87, No. 208
Friday, October 28, 2022

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## NUCLEAR REGULATORY COMMISSION

### 10 CFR Part 71

**[NRC–2016–0179]**

**RIN 3150–AJ85**

## Harmonization of Transportation Safety Requirements With IAEA Standards; Correction

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Proposed rule and guidance; extension of comment period and correcting supplement.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is correcting a document that was published in the **Federal Register** on September 12, 2022, regarding changes to maintain a consistent regulatory framework with the U.S. Department of Transportation for the domestic packaging and transportation of radioactive material and to ensure general accord with International Atomic Energy Agency standards. This action is necessary to make corrections in the estimated burden for the information collection and to make other corrections. The public comment period on the amended information collection was originally scheduled to close on November 14, 2022. The NRC has decided to extend the public comment period for the information collection to allow more time for members of the public to develop and submit their comments; the extended comment period for the information collection now aligns with the end of the general period for public comment.

**DATES:** The due date of comments on the amended information collection requested in the document published on September 12, 2022 (87 FR 55708) is extended. Comments on the amended information collection should be filed no later than November 28, 2022, at the end of the general comment period. Comments received after this date will be considered, if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

**ADDRESSES:** Please refer to Docket ID NRC–2016–0179 when contacting the NRC about the availability of information for this action. Comment on the proposed information collection using any of the following methods:

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.*
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. eastern time (ET), Monday through Friday, except Federal holidays.
- *Mail Comments to:* FOIA, Library, and Information Collections Branch T6–A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or by email to *Infocollects.Resource@nrc.gov.*
- *Submit to OMB Directly:* Written comments and recommendations for the proposed information collection should be sent within 60 days of publication of this document to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently Under Review—Open for Public Comments'' or by using the search function.
- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2016–0179. Address questions about NRC dockets to Dawn Forder; telephone: 301–415–3407; email: *Dawn.Forder@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

**FOR FURTHER INFORMATION CONTACT:** James Firth, 301–415–6628, email: *James.Firth@nrc.gov;* or Bernard White, 301–415–6577, email: *Bernard.White@nrc.gov.* Both are staff of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

**SUPPLEMENTARY INFORMATION:** The NRC may post materials related to this document, including public comments, on the Federal rulemaking website at *https://www.regulations.gov* under Docket ID NRC–2016–0179. In addition, the Federal rulemaking website allows members of the public to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) navigate to the docket folder (NRC–2016–0179); (2) click the ''Subscribe'' link; and (3) enter an email address and click on the ''Subscribe'' link.

The public comment period on the amended information collection was originally scheduled to close on November 14, 2022. The NRC has decided to extend the public comment period on the amended information collection until November 28, 2022, to allow more time for members of the public to submit their comments.

The NRC is announcing the following corrected language to the proposed rule published at 87 FR 55708. On page 87 FR 55721, in the first full paragraph in the first column, ''mass limit of 140 g'' should read ''mass limit of 140 grams''. On page 87 FR 55725, in the first column, the number of respondents and the number of responses for the information collection are provided, ''An estimate of the number of annual responses: 7.5. The estimated number of annual respondents: 6.5.'' should read ''An estimate of the number of annual responses: 100. The estimated number of annual respondents: 99.'' On page 87 FR 55725, in the first column, an estimate of the total hourly burden is provided: ''An estimate of the total number of hours needed annually to complete the requirement or request: 1,376.7 hours'' should read ''An estimate of the total number of hours needed annually to complete the requirement or request: 1,377 hours''.

Additionally, on page 87 FR 55728, in the table in section XIX, ''Document Availability,'' the document ''Regulatory Analysis for this proposed rule'' (ML22209A039) included several errors. The ''Regulatory analysis for this proposed rule'' (ML22209A039) document has been reposted to the

Federal rulemaking website to correct a publication error, restoring pages 48–55 and pages A–1–A–15 and an unnumbered last page.

Dated: October 17, 2022.

For the Nuclear Regulatory Commission.

**Cindy K. Bladey,**

*Chief, Regulatory Analysis and Rulemaking Support Branch, Division of Rulemaking, Environmental, and Financial Support, Office of Nuclear Material Safety and Safeguards.*

[FR Doc. 2022–22866 Filed 10–27–22; 8:45 am]

**BILLING CODE 7590–01–P**

## FEDERAL ELECTION COMMISSION

### 11 CFR Part 110

**[Notice 2022–19]**

### Rulemaking Petition: Conduit Reporting Threshold

**AGENCY:** Federal Election Commission.

**ACTION:** Rulemaking petition: notification of availability.

**SUMMARY:** On August 22, 2022, the Federal Election Commission received a Petition for Rulemaking asking the Commission to amend its existing regulations regarding the threshold amount at which conduits forwarding contributions to political committees must identify the contributors to the recipient political committees and the Commission. The petitioner requests that the Commission establish an itemization threshold equal to the contribution amount at which political committees must report the identification of contributors.

**DATES:** Comments must be submitted on or before December 27, 2022.

**ADDRESSES:** All comments must be in writing. Commenters may submit comments electronically via the Commission's website at *http://sers.fec.gov/fosers/,* reference REG 2022–05.

Each commenter must provide, at a minimum, his or her first name, last name, city, and state. All properly submitted comments, including attachments, will become part of the public record, and the Commission will make comments available for public viewing on the Commission's website and in the Commission's Public Records Office. Accordingly, commenters should not provide in their comments any information that they do not wish to make public, such as a home street address, personal email address, date of birth, phone number, social security number, or driver's license number, or any information that is restricted from disclosure, such as trade secrets or commercial or financial information that is privileged or confidential.

**FOR FURTHER INFORMATION CONTACT:** Ms. Amy Rothstein, Assistant General Counsel, or Mr. Tony Buckley, Attorney, Office of the General Counsel, at *threshold@fec.gov,* or at (202) 694–1650 or (800) 424–9530.

**SUPPLEMENTARY INFORMATION:** On August 22, 2022, the Commission received a Petition for Rulemaking (''Petition'') from WinRed, ''a non-connected political action committee (''PAC'') registered with the FEC that largely operates as an intermediary through which donors may make earmarked contributions to the political committees of the donors' choosing.'' Petition at 1. The Petition asks the Commission to amend its regulations at 11 CFR 110.6 to include an itemization threshold consistent with 11 CFR 104.3(a)(4) for reports of earmarked contributions filed by conduit political committees.

The Petition notes that the Federal Election Campaign Act and Commission regulations require each treasurer of a political committee to file reports of receipts and disbursements which disclose, *inter alia,* ''the identification of each person (other than a political committee) who makes a contribution to the reporting committee during the reporting period, whose contribution or contributions have an aggregate amount or value in excess of $200 . . . together with the date and amount of any such contribution . . . .'' Petition at 2 (citing 52 U.S.C. 30104(b)(3)). The Petition further notes that Congress set the reporting threshold ''in excess of $200'' to ''simplify reporting requirements for candidates and committees'' and to ''reduce the marginal intrusion on personal privacy resulting from disclosure of individual contributions.'' Petition at 2–3.

Commission regulations require a conduit to report to the Commission and to the recipient candidate or authorized committee, the name and mailing address of each contributor. *See* 11 CFR 110.6(c)(1)(i), (iv)(A). Commission regulations do not specify a threshold below which a conduit need not report the source information.

The Petition asserts that most of the contributions made through WinRed are for less than $25, with many as low as one dollar, and that current Commission regulations require that every single receipt must be itemized, since the $200 itemization threshold applicable to reports filed by the recipients of earmarked contributions is not similarly in effect for conduit PAC reports. Petition at 5. According to the Petition, ''this leads to the incongruous result whereby the name and address information of small-dollar donors who make earmarked contributions is disclosed on conduit PAC reports but that information is not subsequently included on the reports of the recipients of those same earmarked contributions.'' *Id.* The Petition argues that this ''lack of consistency in how the itemization threshold applies to conduit PAC reports and reports of recipient committees defeats the threshold's underlying purposes—namely, easing administrative burdens related to reporting and protecting the privacy interests of small-dollar donors.'' *Id.*

The Commission seeks comment on the Petition. The public may inspect the Petition on the Commission's website at *http://sers.fec.gov/fosers/.*

The Commission will not consider the Petition's merits until after the comment period closes. If the Commission decides that the Petition has merit, it may begin a rulemaking proceeding. The Commission will announce any action that it takes in the **Federal Register**.

Dated: October 21, 2022.

On behalf of the Commission.

**Allen Dickerson,**

*Chairman, Federal Election Commission.*

[FR Doc. 2022–23362 Filed 10–27–22; 8:45 am]

**BILLING CODE 6715–01–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### 14 CFR Part 71

**[Docket No. FAA–2022–1232; Airspace Docket No. 22–ASO–19]**

**RIN 2120–AA66**

### Proposed Amendment of Class D and E Airspace; Hickory and Morganton, NC

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** This action proposes to amend Class D airspace and Class E surface airspace for Hickory Regional Airport, Hickory, NC, as runways one and nineteen have been permanently closed. This action would also amend Class E airspace extending upward from 700 feet above the surface for Foothills Regional Airport, Morganton, NC, by updating the airport's name and geographic coordinates and removing Grace Hospital from the description.

Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

**DATES:** Comments must be received on or before December 12, 2022.

**ADDRESSES:** Send comments on this proposal to: the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001; Telephone: (800) 647–5527, or (202) 366–9826. You must identify Docket No. FAA–2022–1232; Airspace Docket No. 22–ASO–19 at the beginning of your comments. You may also submit comments through the internet at *www.regulations.gov.*

FAA Order JO 7400.11G Airspace Designations and Reporting Points and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* For further information, contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; Telephone: (202) 267–8783.

**FOR FURTHER INFORMATION CONTACT:** John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; Telephone: (404) 305–6364.

**SUPPLEMENTARY INFORMATION:**

## Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it would amend airspace in Hickory and Morganton, NC, to support IFR operations in the area.

## Comments Invited

Interested persons are invited to comment on this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide a factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (Docket No. FAA–2021–1232 and Airspace Docket No. 22–ASO–19) and be submitted in triplicate to DOT Docket Operations (see **ADDRESSES** section for the address and phone number). You may also submit comments through the internet at *www.regulations.gov.*

Persons wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2021–1232; Airspace Docket No. 22–ASO–19.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this document may be changed in light of the comments received. All comments submitted will be available for examination in the public docket before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

## Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except on federal holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except for federal holidays at the office of the Eastern Service Center, Federal Aviation Administration, Room 350, 1701 Columbia Avenue, College Park, GA 30337.

## Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022. FAA Order JO 7400.11G is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

## The Proposal

The FAA proposes an amendment to 14 CFR part 71 to amend Class D airspace and Class E surface airspace for Hickory Regional Airport, Hickory, NC, as runways one and nineteen have been permanently closed. In addition, this action would replace the outdated terms Airport/Facility Directory with the term Chart Supplement and Notice to Airmen with the term Notice to Air Missions in the appropriate airspace descriptions.

This action would also amend Class E airspace extending upward from 700 feet above the surface for Foothills Regional Airport (formerly Morganton-Lenoir Airport), Morganton, NC, by updating the airport's name and geographic coordinates, as well as removing Grace Hospital Heliport from the description, as the heliport no longer has instrument approaches. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

Class D and E airspace designations are published in Paragraphs 5000, 6002, and 6005, respectively, of FAA Order JO 7400.11G, dated August 19, 2022, and effective September 15, 2022, which is incorporated by reference in 14 CFR 71.1. The Class D and E airspace designations listed in this document will subsequently be published in FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points is published yearly and effective on September 15.

## Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact

on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

**Environmental Review**

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' prior to any FAA final regulatory action.

**Lists of Subjects in 14 CFR Part 71**

Airspace, Incorporation by reference, Navigation (air).

**The Proposed Amendment**

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

## PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

**Authority:** 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

**§ 71.1 [Amended]**

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

*Paragraph 5000 Class D Airspace.*

* * * * *

**ASO NC D Hickory, NC [Amended]**

Hickory Regional Airport, NC
(Lat. 35°44′28″ N, long. 81°23′22″ W)

That airspace extending upward from the surface to and including 3,700 feet MSL within a 4.1-mile radius of Hickory Regional Airport. This Class D airspace is effective during the specific days and times established in advance by a Notice to Air Missions. The effective days and times will thereafter be continuously published in the Chart Supplement.

*Paragraph 6002 Class E Surface Airspace.*

* * * * *

**ASO NC E2 Hickory, NC [Amended]**

Hickory Regional Airport, NC
(Lat. 35°44′28″ N, long. 81°23′22″ W)

That airspace extending upward from the surface within a 4.1-mile radius of Hickory Regional Airport. This Class E airspace is effective during the specific days and times established in advance by a Notice to Air Missions. The effective days and times will thereafter be continuously published in the Chart Supplement.

*Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.*

* * * * *

**ASO NC E5 Morganton, NC [Amended]**

Foothills Regional Airport, NC
(Lat. 35°49′13″ N, long. 81°36′41″ W)
Fiddlers NDB
(Lat. 35°42′37″ N, long. 81°40′17″ W)

That airspace extending upward from 700 feet above the surface within a 9.5-mile radius of the Foothills Regional Airport and within 2.5 miles each side of the 205° bearing from Fiddlers NDB, extending from the 9.5-mile radius to 7 miles southwest of the NDB.

Issued in College Park, Georgia, on October 18, 2022.

**Andreese C. Davis,**

*Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.*

[FR Doc. 2022–22901 Filed 10–27–22; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 71

**[Docket No. FAA–2022–1262; Airspace Docket No. 22–ASO–21]**

**RIN 2120–AA66**

## Proposed Establishment of Class E Airspace; Union Springs, AL

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** This action proposes to establish Class E airspace extending upward from 700 feet above the surface at Franklin Field Airport, Union Springs, AL, to accommodate area navigation (RNAV) global positioning system (GPS) standard instrument approach procedures (SIAPs) serving this airport. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

**DATES:** Comments must be received on or before December 12, 2022.

**ADDRESSES:** Send comments on this proposal to: the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001; Telephone: (800) 647–5527, or (202) 366–9826. You must identify Docket No. FAA–2022–1262; Airspace Docket No. 22–ASO–21 at the beginning of your comments. You may also submit comments through the internet at *www.regulations.gov.*

FAA Order JO 7400.11G Airspace Designations and Reporting Points and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* For further information, contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; Telephone: (202) 267–8783.

**FOR FURTHER INFORMATION CONTACT:** John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; Telephone (404) 305–6364.

**SUPPLEMENTARY INFORMATION:**

**Authority for This Rulemaking**

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it would establish airspace in Union Springs, AL, to support IFR operations in the area.

**Comments Invited**

Interested persons are invited to comment on this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (Docket No. FAA–2021–1262 and Airspace Docket No. 22–ASO–21) and be submitted in triplicate to DOT Docket Operations (see **ADDRESSES** section for the address and phone number). You may also submit comments through the internet at *www.regulations.gov.*

Persons wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: Comments to FAA Docket No. FAA–2021–1262; Airspace

Docket No. 22–ASO–21. The postcard will be dated/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal in this document may be changed in light of the comments received. All comments submitted will be available for examination in the public docket before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

**Availability of NPRMs**

An electronic copy of this document may be downloaded through the internet at *www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except on federal holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except for federal holidays at the office of the Eastern Service Center, Federal Aviation Administration, Room 350,1701 Columbia Avenue, College Park, GA 30337.

**Availability and Summary of Documents for Incorporation by Reference**

This document proposes to amend FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022. FAA Order JO 7400.11G is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

**The Proposal**

The FAA proposes an amendment to 14 CFR part 71 to establish Class E airspace extending upward from 700 feet above the surface at Franklin Field Airport, Union Springs, AL, to accommodate RNAV GPS standard instrument approach procedures (SIAPs) serving this airport.

Class E airspace designations are published in Paragraph 6005 of FAA Order JO 7400.11G, dated August 19, 2022, and effective September 15, 2022, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

**Regulatory Notices and Analyses**

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a significant regulatory action'' under Executive Order 12866; (2) is not a significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

**Environmental Review**

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures,,''''''', prior to any FAA final regulatory action.

**Lists of Subjects in 14 CFR Part 71**

Airspace, Incorporation by reference, Navigation (air).

**The Proposed Amendment**

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

## PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

**Authority:** 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

**§ 71.1 [Amended]**

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

*Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.*

* * * * *

**ASO AL E5 Union Springs, AL [Established]**

Franklin Field Airport, AL
(Lat. 32°10′03″ N, long. 85°48′40″ W)

That airspace extending upward from 700 feet above the surface within an 8.1-mile radius of Franklin Field Airport.

Issued in College Park, Georgia, on October 18, 2022.

**Andreese C. Davis,**

*Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.*

[FR Doc. 2022–22990 Filed 10–27–22; 8:45 am]

**BILLING CODE 4910–13–P**

## POSTAL SERVICE

## 39 CFR Part 20

## International Mailing Services: Proposed Price Changes

**AGENCY:** Postal Service™.

**ACTION:** Proposed rule; request for comments.

**SUMMARY:** The Postal Service proposes to revise *Mailing Standards of the United States Postal Service,* International Mail Manual (IMM®), to reflect changes coincident with the recently announced mailing services price adjustments.

**DATES:** We must receive your comments on or before November 28, 2022.

**ADDRESSES:** Mail or deliver comments to the manager, Product Classification, U.S. Postal Service®, 475 L'Enfant Plaza SW, RM 4446, Washington, DC 20260–5015. You may inspect and photocopy all written comments at USPS® Headquarters Library, 475 L'Enfant Plaza SW, 11th Floor N, Washington, DC by appointment only between the hours of 9 a.m. and 4 p.m., Monday through Friday by calling 1–202–268–2906 in advance. Email comments, containing the name and address of the commenter, to: *PCFederalRegister@usps.gov,* with a subject line of ''January 2023 International Mailing Services Proposed Price Changes.'' Faxed comments are not accepted. All submitted comments and attachments are part of the public record and subject to disclosure. Do not enclose any material in your comments that you consider to be confidential or inappropriate for public disclosure.

**FOR FURTHER INFORMATION CONTACT:** Dale Kennedy at 202–268–6592 or Kathy Frigo at 202–268–4178.

**SUPPLEMENTARY INFORMATION:**

## International Price and Service Adjustments

On October 7, 2022, the Postal Service filed a notice of mailing services price adjustments with the Postal Regulatory Commission (PRC), effective on January 22, 2023. The Postal Service proposes to revise Notice 123, *Price List,* available on Postal Explorer® at *https://pe.usps.com,* to reflect these new price changes. The new prices are or will be available under Docket Number R2023–1 on the Postal Regulatory Commission's website at *www.prc.gov.*

In addition, in PRC Docket No. R2023–1, the Postal Service proposed to update country names throughout mailing standards, changing ''Turkey'' to ''Turkiye,'' which is the official short name for ''Republic of Turkiye.''

This proposed rule describes the price changes for the following market dominant international services:

- First-Class Mail International (FCMI) service.
- International extra services and fees.

*First-Class Mail International*

The Postal Service plans to increase prices for single-piece FCMI postcards, letters, and flats by approximately 3.7%. The proposed price for a single-piece postcard will be $1.45 worldwide. The First-Class Mail International letter nonmachinable surcharge will increase to $0.40. The proposed FCMI single-piece letter and flat prices will be as follows:

LETTERS

| Weight not over (oz.) | Price groups | | | |
|---|---|---|---|---|
| | 1 | 2 | 3–5 | 6–9 |
| 1 | $1.45 | $1.45 | $1.45 | $1.45 |
| 2 | 1.45 | 2.19 | 2.71 | 2.51 |
| 3 | 2.05 | 2.90 | 3.96 | 3.57 |
| 3.5 | 2.65 | 3.63 | 5.22 | 4.62 |

FLATS

| Weight not over (oz.) | Price groups | | | |
|---|---|---|---|---|
| | 1 | 2 | 3–5 | 6–9 |
| 1 | $2.90 | $2.90 | $2.90 | $2.90 |
| 2 | 3.15 | 3.74 | 4.06 | 4.00 |
| 3 | 3.42 | 4.58 | 5.23 | 5.11 |
| 4 | 3.66 | 5.44 | 6.43 | 6.22 |
| 5 | 3.93 | 6.29 | 7.60 | 7.33 |
| 6 | 4.19 | 7.13 | 8.78 | 8.46 |
| 7 | 4.46 | 8.00 | 9.96 | 9.56 |
| 8 | 4.72 | 8.84 | 11.13 | 10.67 |
| 12 | 6.03 | 10.67 | 13.50 | 12.98 |
| 15.994 | 7.33 | 12.51 | 15.86 | 15.27 |

*International Extra Services and Fees*

The Postal Service plans to increase prices by approximately 4.4% for certain market dominant international extra services including:

- Certificate of Mailing
- Registered Mail™
- Return Receipt
- Customs Clearance and Delivery Fee
- International Business Reply™ Mail Service

| Certificate of mailing | Fee |
|---|---|
| Individual pieces: | |
| Individual article (PS Form 3817) | $1.85 |
| Duplicate copy of PS Form 3817 or PS Form 3665 (per page) | 1.85 |
| Firm mailing sheet (PS Form 3665), per piece (minimum 3) | |
| First-Class Mail International only | 0.54 |
| Bulk quantities: | |
| For first 1,000 pieces (or fraction thereof) | 10.40 |
| Each additional 1,000 pieces (or fraction thereof) | 1.35 |
| Duplicate copy of PS Form 3606 | 1.85 |

Registered Mail

*Fee:* $19.05.

Return Receipt

*Fee:* $5.30.

Customs Clearance and Delivery

*Fee:* per piece $7.85.

International Business Reply Service

*Fee:* Cards $2.00; Envelopes up to 2 ounces $2.50.

Following the completion of Docket No. R2023–1, the Postal Service will adjust the prices for products and services covered by the International Mail Manual. These prices will be on Postal Explorer at *pe.usps.com.*

Accordingly, although exempt from the notice and comment requirements of the Administrative Procedure Act (5 U.S.C. 553(b), (c)) regarding proposed rulemaking by 39 U.S.C. 410(a), the Postal Service invites public comment on the proposed changes to *Mailing Standards of the United States Postal Service,* International Mail Manual (IMM®), set out in this **SUPPLEMENTARY INFORMATION** section, which is incorporated by reference in the *Code of Federal Regulations* in accordance with 39 CFR 20.1, and to associated changes to Notice 123, *Price List.*

The Postal Service will publish an appropriate update to Notice 123, *Price List* of the IMM, to reflect these changes following the completion of the notice and comment period for this proposed rule. The Postal Service annually

publishes an amendment to 39 CFR part 20 to finalize updates to the IMM.

**Sarah E. Sullivan,**

*Attorney, Ethics and Legal Compliance.*

[FR Doc. 2022–23525 Filed 10–27–22; 8:45 am]

**BILLING CODE 7710–12–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 50 CFR Parts 679 and 680

**[RTID 0648–XC495]**

## Fisheries of the Exclusive Economic Zone off Alaska; Petition for Emergency Action To Close the Red King Crab Savings Area and Subarea to All Fishing Gear With Bottom Contact

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Announcement of receipt of petition for rulemaking; request for comments.

**SUMMARY:** NMFS announces the receipt of a petition for emergency rulemaking under the Magnuson-Stevens Fishery Conservation and Management Act (MSA) from the Alaska Bering Sea Crabbers (ABSC). This petition requests NMFS take action to close the Red King Crab Savings Area (RKCSA) and Red King Crab Savings Subarea (RKCSS) to all fishing gear to protect Bristol Bay red king crab (BBRKC) and their habitat at a time of historically low crab abundance for a period of 6 months from January 1, 2023 to June 30, 2023.

**DATES:** Submit comments on or before December 5, 2022.

**ADDRESSES:** You may send comments, identified by Docket ID NOAA–NMFS–2022–0111 by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *https://www.regulations.gov* and enter NOAA–NMFS–2022–0111 in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS. Mail comments to P.O. Box 21668, Juneau, AK 99802–1668.

*Instructions:* Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

**FOR FURTHER INFORMATION CONTACT:** Kelly Cates, 907–586–7228.

**SUPPLEMENTARY INFORMATION:**

### Background

This petition requests that NMFS take emergency action to close the RKCSA and RKCSS to all fishing gear with bottom contact (*i.e.,* bottom trawl, pelagic trawl, pot gear and longline gear). Section 305(c)(1) of the MSA states: ''If the Secretary finds that an emergency exists or that interim measures are needed to reduce overfishing for any fishery, he may promulgate emergency regulations or interim measures necessary to address the emergency or overfishing, without regard to whether a fishery management plan exists for such fishery.'' NMFS's Policy Guidelines for the Use of Emergency Rules require that an emergency must exist and that NMFS have an administrative record justifying emergency regulatory action and demonstrating compliance with the MSA and the National Standards (see NMFS Procedure 01–101–07; 62 FR 44421, August 21, 1997). Emergency rulemaking is intended for circumstances that are ''extremely urgent,'' where ''substantial harm to or disruption of the . . . fishery . . . would be caused in the time it would take to follow standard rulemaking procedures (62 FR 44421, August 21, 1997).''

Under NMFS's Policy Guidelines for the Use of Emergency Rules, the phrase ''an emergency exists involving any fishery'' is defined as a situation that meets the following three criteria:

1. Results from recent, unforeseen events or recently discovered circumstances;

2. Presents serious conservation or management problems in the fishery; and

3. Can be addressed through emergency regulations for which the immediate benefits outweigh the value of advance notice, public comment, and deliberative consideration of the impacts on participants to the same extent as would be expected under the normal rulemaking process.

The RKCSA and RKCSS are areas of the Bering Sea that have been identified by the North Pacific Fishery Management Council (Council) and NMFS as important for BBRKC conservation and subject to multiple management actions over time to reduce non-directed fishery impacts to the BBRKC stock. The petitioner's requested action would affect fisheries in the exclusive economic zone off Alaska managed under the fishery management plan (FMP) for the Bering Sea and Aleutian Islands Management Area (BSAI) King and Tanner Crab Fisheries (Crab FMP) and the FMP for Groundfish of the BSAI. The Council prepared these FMPs under the authority of the Magnuson-Stevens Act (16 U.S.C. 1801 *et seq.*). Regulations implementing the FMPs appear at 50 CFR parts 679 and 680.

The Crab FMP was approved by the Secretary of Commerce on June 2, 1989. The Crab FMP establishes a State/Federal cooperative management regime that delegates crab management to the State of Alaska with Federal oversight. State regulations are subject to the provisions of the Crab FMP, including its goals and objectives, the MSA, and other applicable Federal laws.

The abundance estimate calculated for mature female BBRKC using the eastern Bering Sea bottom trawl survey (Trawl Survey) data in 2021 and 2022 were the lowest two abundances on record since 1995. Using the data from the Trawl Survey, the State provided an abundance estimation that was below the State of Alaska regulatory harvest strategy threshold of 8.4 million mature female crab to open a directed fishery in 2021 and in 2022. As a result, the directed fishery was closed for the 2021–2022 and 2022–2023 seasons. While BBRKC are closed to directed fishing, the stock is not currently overfished or subject to overfishing.

### Information in the Petition

NMFS received the petition on September 29, 2022. The ABSC requests that the Secretary undertake emergency rulemaking to close the RKCSA and RKCSS to all fishing gears with bottom contact from January 1, 2023 to June 30, 2023 in order to protect BBRKC and their habitat at a time of historically low crab abundance. According to the petition filed by the ABSC, the reasons such action is needed through emergency rulemaking are:

1. The RKCSA is already closed year-round to bottom trawl gear to protect BBRKC and crab habitat from fishing impacts. In addition, in years when the directed fishery is closed, the RKCSS, the additional area to the south of the

RKCSA, is also closed year-round to bottom trawl to protect crab and crab habitat.

2. BBRKC molting and mating occurs from January through June/July, and during this period their shells are soft, providing less protection from interaction with fishing gear and being handled. Therefore, impacts to the stock may be more intensive during this time period.

3. Closing these areas to all fishing gears known to contact the bottom (which would effectively add pelagic trawl, pot gear, and longline gear to the existing closure to bottom trawl gear) would provide additional protections for BBRKC and reduce impacts on their habitat from fishing during a critical period of the crab life cycle. This would help the stock rebuild to produce optimum yield over the long-term.

NMFS solicits comments on whether the request for rulemaking meets the requirements of section 305(c)(1) of the MSA and the likely benefits and impacts of NMFS taking the requested action. Comments received will be considered by NMFS in determining whether to proceed with the development of the emergency action suggested by ABSC. The Council will also consider the petition at its December Council Meeting and accept public comments at that time. NMFS will consider all comments submitted in response to this announcement and at the December Council Meeting. If NMFS approves the petition and undertakes an emergency rulemaking, the Assistant Administrator Fisheries, NOAA, will publish a notice of the agency's decision or action in the **Federal Register**.

**Authority:** 16 U.S.C. 1801 *et seq.*

Dated: October 25, 2022.

**Samuel D. Rauch, III,**

*Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.*

[FR Doc. 2022–23549 Filed 10–27–22; 8:45 am]

**BILLING CODE 3510–22–P**

# Notices

Federal Register
Vol. 87, No. 208
Friday, October 28, 2022

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

**[Doc No. AMS–CP–22–0014]**

### Barriers Facing Small Firms and Businesses Providing Halal, Kosher and Organic Products in Commodity Contracting With the Agricultural Marketing Service

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Notice of request for public comments.

**SUMMARY:** In keeping with ongoing efforts to increase the number of small and underserved businesses participating in the USDA food procurement program, as well as increasing access to culturally appropriate foods, the Agricultural Marketing Service (AMS) is seeking public input on perceived barriers that small businesses, those owned by underserved businesses, and providers of organic, kosher, and halal agricultural products face in working with AMS' Commodity Procurement Program (CPP). This input will be used to update CPP's Small Business and New Vendor Strategy as appropriate.

**DATES:** Comments must be received on or before December 27, 2022.

**ADDRESSES:** Interested persons are invited to submit written comments concerning this notice. All comments must be submitted through the Federal e-rulemaking portal at *https://www.regulations.gov* and should reference the document number and the date and page number of this issue of the **Federal Register**. Instructions for submitting and reading comments are detailed on the site. All comments submitted in response to this notice will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting comments will be made public on the internet at the address provided above.

**FOR FURTHER INFORMATION CONTACT:** Andrea Lang, or Diana Dau David, New Vendor Coordinators, USDA, AMS, Commodity Procurement Program, at *NewVendor@usda.gov.*

**SUPPLEMENTARY INFORMATION:** Each year the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS) collaborates with the Food and Nutrition Service, Foreign Agricultural Service and the U.S. Agency for International Development to purchase and distribute over $4 billion of U.S. agricultural products for distribution to schools, food banks, Tribal organizations, and international food aid operations, among others. AMS solicits for a large variety of products from vendors qualified to do business with the Agency. It is AMS's ongoing goal to increase the number of small and underserved businesses participating in the USDA food procurement program, as well as to increase the availability of culturally appropriate foods.

President Biden issued Executive Order (E.O.) E.O. 14017, ''America's Supply Chains''; E.O. 13985, ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government''; and E.O. 14036, ''Promoting Competition in the American Economy.'' E.O. 14017 focuses on the need for resilient, diverse, and secure supply chains to ensure U.S. economic prosperity and national security. E.O. 13985 focuses on identifying potential barriers that underserved communities and individuals may face in taking advantage of agency contracting opportunities. E.O. 14036 focuses on reviewing the state of competition within the agricultural market, including areas where a lack of competition may be of concern. In support of these executive orders, AMS is focusing on identifying and reducing barriers to becoming an approved vendor in order to increase competition and the availability of vital agricultural commodities for use in the USDA's nutrition assistance programs.

Commodity food products are purchased and delivered to schools, food banks, and households in communities on a domestic and global scale. Small and underserved companies play a crucial role in supplying food to the USDA. Last year, AMS awarded a record $1.4 billion dollars to small businesses through prime contracts, of which 13.73% of the contracts were awarded to small, underserved businesses; yet there is a need for more participation in the commodity procurement program. In addition to increasing the participation of small and underserved businesses, AMS is interested in purchasing larger volumes of halal, kosher, organic, and other culturally appropriate products.

This notice requests comments and information from the public to assist AMS in updating CPP's Small Business and New Vendor Strategy as appropriate.

AMS is particularly interested in comments and information directed to the policy objectives listed in E.O. 14017, E.O. 14036, and E.O. 13985 as they affect the U.S. and global supply chains. AMS is seeking input on the following topics:

i. Government business practices that might inhibit or deter small or underserved businesses, as well as halal, kosher, and organic providers, from participating in the USDA commodity procurement program, *i.e.,* by producing and/or providing goods, services, and materials for CPP contracts;

ii. Regulations and business practices which may strain rather than strengthen the relationship between CPP and these providers;

iii. The use of past performance information during the vendor qualification process, source selection, contract performance, and the collection of such information;

iv. Increasing the CPP's utilization of small and underserved businesses, as well as halal, kosher, and organic providers;

v. CPP's efforts to assist businesses that seek to do business with the government, including experiences in working with CPP's contracting workforce;

vi. Contracting timelines (*e.g.,* annual procurement schedule, length of advertising of opportunities, time between bid opening and contract award, delivery lead times, etc.) and the impact of those timelines;

vii. The availability of skilled labor and other personnel to sustain a competitive ecosystem;

viii. Policy recommendations or suggested executive, legislative,

regulatory action to foster more resilient supply chains, greater competition in the agricultural market, and/or more small or underserved business participation in the procurement process;

ix. Any additional comments concerning small or underserved businesses and halal, kosher, organic, or others relevant to the assessment of supply chain resilience.

AMS plans to hold a listening session open to the public so that interested parties can provide verbal as well as written input. A date and time will be provided.

AMS encourages respondents to structure their comments using the same text above as identifiers for the areas of inquiry to which they are responding. This will assist the AMS in more easily reviewing and summarizing the comments received in response to these specific areas. For example, a commenter submitting comments responsive to (i), ''Government business practices that might inhibit or deter small or underserved businesses, as well as halal, kosher, and organic providers, from participating in the USDA commodity procurement program, *i.e.,* by producing and/or providing goods, services, and materials for CPP contracts'' would use that same text as a heading in the public comment followed by the commenter's specific comments in this area. AMS encourages the use of an executive summary at the beginning of all comments and information to assist AMS in a more efficient review of the submitted documents.

**Erin Morris,**

*Associate Administrator, Agricultural Marketing Service.*

[FR Doc. 2022–23513 Filed 10–27–22; 8:45 am]

**BILLING CODE 3410–02–P**

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

**[Docket No. APHIS–2022–0054]**

### Notice of Request for Extension of Approval of an Information Collection; Case-Control Study on Highly Pathogenic Avian Influenza in Poultry

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Extension of approval of an information collection; comment request.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request an extension of approval of an information collection associated with the case-control study on highly pathogenic avian influenza in U.S. commercial poultry flocks.

**DATES:** We will consider all comments that we receive on or before December 27, 2022.

**ADDRESSES:** You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov.* Enter APHIS–2022–0054 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2022–0054, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *regulations.gov* or in our reading room, which is located in Room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

**FOR FURTHER INFORMATION CONTACT:** For information on this HPAI in poultry study, contact Dr. Alice Green, Veterinary Medical Officer, Center for Epidemiology and Animal Health, VS, APHIS, 2150 Centre Avenue, Building B, Fort Collins, CO 80526; (970) 494–7528. For more detailed information on the information collection, contact Mr. Joseph Moxey, APHIS' Paperwork Reduction Act Coordinator, at (301) 851–2483.

**SUPPLEMENTARY INFORMATION:**

*Title:* Case-Control Study on Highly Pathogenic Avian Influenza in Poultry.

*OMB Control Number:* 0579–0483.

*Type of Request:* Extension of approval of an information collection.

*Abstract:* Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Secretary of Agriculture is authorized to protect the health of livestock, poultry, and aquaculture populations in the United States by preventing the introduction and interstate spread of serious diseases and pests of livestock, poultry, and aquaculture, and for eradicating such diseases within the United States when feasible. This authority has been delegated to the Animal and Plant Health Inspection Service (APHIS).

Highly pathogenic avian influenza (HPAI) is an infectious and fatal disease of poultry. Between February and June 2022, APHIS mobilized over 1,125 employees to respond to outbreaks of HPAI within the United States. As of the end of May 2022, nearly $800 million in Federal expenditures has been authorized to support emergency response work in relation to HPAI, which affected over 40 million birds.

Avian influenza viruses vary in transmissibility and ability to cause disease symptoms. Evidence suggests that the predominance of infections in 2022 have been due to independent wild bird introductions. As the risk of a resurgence of new infections increases, it is critical to identify current risk factors to mitigate future outbreaks.

APHIS initiated an HPAI study in 2022 and will continue the study as needed to generate up-to-date information for determining current risk factors for infection with this environmentally hardy foreign animal disease pathogen. Current information on risk factors is critical for science-based updates to prevention and control recommendations.

The information collection activity associated with this study consists of a multi-question survey administered to commercial poultry producers.

APHIS requested and was granted emergency approval to use this information collection activity for 6 months. We are asking the Office of Management and Budget (OMB) to approve our use of this information collection activity for an additional 3 years in the event the study needs to be extended because of unanticipated outbreaks.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

*Estimate of burden:* The public burden for this collection of information is estimated to average 0.45 hours per response.

*Respondents:* State agricultural officials and poultry producers.

*Estimated annual number of respondents:* 270.

*Estimated annual number of responses per respondent:* 1.289.

*Estimated annual number of responses:* 348.

*Estimated total annual burden on respondents:* 155 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 25th day of October 2022.

**Anthony Shea,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 2022–23537 Filed 10–27–22; 8:45 am]

**BILLING CODE 3410–34–P**

## DEPARTMENT OF AGRICULTURE

### Foreign Agricultural Service

### Notice of Request for a Revision of a Currently Approved Information Collection

**AGENCY:** Foreign Agricultural Service, USDA.

**ACTION:** Notice and request for comments.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, this notice announces that the Foreign Agricultural Service (FAS) intends to request a revision of a currently approved information collection for the Refined Sugar Re-Export Program, the Sugar-Containing Products Re-Export Program, and the Polyhydric Alcohol Program.

**DATES:** Comments should be received on or before December 27, 2022 to be assured of consideration.

**ADDRESSES:** FAS invites interested persons to submit comments on this notice by any of the following methods:

☐ *Federal eRulemaking Portal:* This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments. Go to *https://www.regulations.gov.* Follow the on–line instructions at the site for submitting comments.

☐ *Email: William.Janis@usda.gov.* Include OMB Number 0551–0015 in the subject line of the message.

☐ *Mail, Hand Delivery, or Courier:* William Janis, International Economist, Multilateral Affairs Division, Trade Policy and Geographic Affairs, Foreign Agricultural Service, U.S. Department of Agriculture, Room 5550, Stop 1070, 1400 Independence Ave. SW, Washington, DC 20250–1070.

*Instructions:* All submissions received must include the agency names and OMB Control Number for this notice. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

**FOR FURTHER INFORMATION CONTACT:** William Janis at the address stated above, by telephone at (202) 720–2194 or by email at: *FAS.Sugars@usda.gov.*

**SUPPLEMENTARY INFORMATION:**

*Title:* Sugar Imported for Export as Refined Sugar or as Sugar-Containing Products or used in the Production of Certain Polyhydric Alcohols.

*OMB Number:* 0551–0015.

*Expiration Date of Approval:* September 30, 2025.

*Type of Request:* Revision of a currently approved information collection.

*Abstract:* As provided in 7 CFR part 1530, the Refined Sugar Re-Export Program, the Sugar-Containing Products Re-Export Program, and the Polyhydric Alcohol Program Sugar Re-Export Program, collectively referred to as the ''Sugar Re-Export Program,'' permit entry of raw cane sugar, unrestricted by the quantitative limit established by the sugar tariff-rate quota, for re-export in refined form or in sugar containing products or for production of certain polyhydric alcohols. As many as 200 licensees are currently eligible to participate in these programs. In early 2023, the Foreign Agricultural Service (FAS) intends to launch a new data reporting system called Sugar Unified Certification Review, Oversight, Statistics, and Evaluation (SUCROSE) for the Sugar Re-Export Program, which will lead to a slight increase in reporting burden for licensees compared to the current Sugars Users Group Accounting and Reporting System (SUGARS).

*Estimate of Burden:* The public reporting burden for each respondent resulting from information collection under the Sugar Re-Export Program varies in direct relation to the number and type of agreements entered into by such respondent. The estimated average reporting burden for the Sugar Re-Export Program is 0.50 hours per response. Under 7 CFR part 1530, the information collected is used by the licensing authority to manage, plan, evaluate, and account for program activities. The reports and records are required to ensure the proper operations of these programs.

*Respondents:* Sugar refiners, manufacturers of sugar containing products, and producers of polyhydric alcohol.

*Estimated Number of Respondents:* 325.

*Estimated Number of Responses per Respondent:* 8.

*Estimated Total Annual Burden on Respondents:* 720 hours.

Copies of this information collection can be obtained from Dacia Rogers, the Agency Information Collection Coordinator, at *Dacia.Rogers@usda.gov.*

*Request for Comments:* Send comments regarding (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information including validity of the methodology and assumption used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be available without change, including any personal information provided, for inspection online at *http://www.regulations.gov* and at the mail address listed above between 8:00 a.m. and 4:30 p.m., Monday through Friday, except holidays.

Comments will be summarized and included in the submission for Office of Management and Budget approval.

Persons with disabilities who require an alternative means for communication of information (Braille, large print, audiotape, etc.) should contact *FAS-ReasonableAccommodation@usda.gov* or Felice Robinson (Senior Reasonable Accommodations Specialist), *Felice.Robinson@usda.gov.*

**Brooke Jamison,**

*Acting Administrator, Foreign Agricultural Service.*

[FR Doc. 2022–23470 Filed 10–27–22; 8:45 am]

**BILLING CODE 3410–10–P**

## DEPARTMENT OF AGRICULTURE

### Forest Service

### Alpine County Resource Advisory Committee

**AGENCY:** Forest Service, Agriculture (USDA).

**ACTION:** Notice of meeting.

**SUMMARY:** The Alpine County Resource Advisory Committee (RAC) will hold a public meeting according to the details shown below. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act (FACA). The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act, as well as make recommendations on recreation fee proposals for sites on the Humboldt-Toiyabe National Forest within Alpine County, California, consistent with the Federal Lands Recreation Enhancement Act.

**DATES:** The meeting will be held on November 9, 2022, from 1 p.m.–3 p.m., Pacific Daylight Time. All RAC meetings are subject to cancellation. For status of the meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

**ADDRESSES:** This meeting is open to the public and will be held at the Turtle Rock Park Community Center, located at 17300 State Route 89/4, Markleeville, CA 96120. The public may also join virtually via telephone and/or video conference. Virtual meeting participation details can be found by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received upon request.

**FOR FURTHER INFORMATION CONTACT:** Matt Zumstein, Designated Federal Officer (DFO), by phone at 775–884–8100 or email at *matthew.zumstein@usda.gov* or Matt Dickinson, RAC Coordinator at 775–884–8154 or email at *Matthew.Dickinson@usda.gov.*

Individuals who use telecommunication devices for the deaf and hard of hearing (TDD) may call the Federal Relay Service (FRS) at 800–877–8339, 24 hours a day, every day of the year, including holidays.

**SUPPLEMENTARY INFORMATION:** The meeting agenda will include:

1. Introductions of the committee members;
2. Elect a Chairperson;
3. Discuss available funding;
4. Discuss a process for soliciting and reviewing project proposals;
5. Approve meeting minutes;
6. Schedule the next meeting.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should make a request in writing at least three days prior to the meeting date to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time for oral comments must be sent to Matt Zumstein, DFO, Carson Ranger District, 1536 South Carson Street, Carson City, Nevada, 89701; or by email to *matthew.zumstein@usda.gov.*

USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (*e.g.,* Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at 202–720–2600 (voice and TTY) or contact USDA through the Federal Relay Service at 800–877–8339. Additionally, program information may be made available in languages other than English.

Equal opportunity practices in accordance with USDA's policies will be followed in all appointments to the Committee. To ensure that the recommendations of the Committee have taken in account the needs of the diverse groups served by USDA, membership shall include to the extent possible, individuals with demonstrated ability to represent minorities, women, and person with disabilities. USDA is an equal opportunity provider, employer, and lender.

Dated: October 24, 2022.

**Cikena Reid,**

*USDA Committee Management Officer.*

[FR Doc. 2022–23454 Filed 10–27–22; 8:45 am]

**BILLING CODE 3411–15–P**

## DEPARTMENT OF AGRICULTURE

### Rural Business-Cooperative Service

### Rural Utilities Service

**[Docket Number: RBS–22–NONE–0025]**

### Inflation Reduction Act Listening Session

**AGENCY:** Rural Business—Cooperative Service and Rural Utilities Service, USDA.

**ACTION:** Request for information and notice of public listening sessions.

**SUMMARY:** The Rural Business-Cooperative Service (RBCS) and the Rural Utilities Service (RUS), agencies of the Rural Development (RD) mission areas of the United State Department of Agriculture, announce that they are hosting listening sessions for public input regarding implementation of the Inflation Reduction Act (IRA) of 2022. Specifically, these listening sessions will provide an opportunity for stakeholders and other interested parties to offer their comments and input.

**DATES:** *Written Comments:* Interested parties must submit written comments on or before November 28, 2022. All written comments received will be publicly available on *www.regulations.gov.*

*Listening Sessions:* Two virtual listening session will be held from 2–4 p.m. ET on Thursday November 3, 2022, and 2–4 p.m. ET Friday, November 4, 2022.

*November 3, 2022*—This listening session will focus on Sections 22001, 22002, and 22003. The session is aimed at rural communities, rural small businesses, and agricultural producers including renewable energy generation providers, distribution utilities, transportation fueling facilities, fuel distribution facilities, environmental, community and consumer groups, industry associations, and Federal, state, and local government and agencies. To participate interested parties must register at *https://www.zoomgov.com/webinar/register/WN_l_ptMftKRU2zlJPMdiXF9A.*

*November 4, 2022*—This listening session will focus on Sections 22004. This listening session will be targeted at rural electric cooperatives and related stakeholders as described above. To participate interested parties must

register at *https://www.zoomgov.com/webinar/register/WN_HeGqpB7YTYOG6tmBjDyx7g.*

Listening Sessions will be recorded and made publicly available. If you require special accommodations, such as a sign language interpreter, use the contact information above. The listening session locations are accessible to persons with disabilities.

**ADDRESSES:** Comments may be submitted electronically by the Federal eRulemaking Portal: Go to *http://www.regulations.gov* and in the ''Search for Rules, Proposed Rules, Notices or Supporting Documents'' box, enter the following docket number: (RBS–22–NONE–0025). To submit or view public comments, click ''Search'' button, select the ''Documents'' tab, then select the following document title: (Inflation Reduction Act Listening Session) from the ''Search Results'' and select the ''Comment'' button. Before submitting your comments, you may also review the ''Commenter's Checklist'' (optional). Insert your comments under the ''Comment'' title, click ''Browse'' to attach files (if available). Input your email address and select ''Submit Comment.'' Information on using *Regulations.gov*, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's ''FAQ'' link. Other Information: Additional information about Rural Development and its programs is available on the internet at *https://www.rd.usda.gov.* All comments will be available for public inspection online at the Federal eRulemaking Portal (*https://www.regulations.gov*).

**FOR FURTHER INFORMATION CONTACT:** Jacki Lazaruk-Ponti, Rural Development Chief Innovation Officer at 202–692–0036. Persons with disabilities who require alternative means for communication (Braille, large print, audio tape, etc.) should contact the USDA Target Center at (202) 720–2600 (voice and TDD).

**SUPPLEMENTARY INFORMATION:**

*Background:* Rural Development is an advocate for rural America, administering a multitude of programs, ranging from housing and community facilities to infrastructure and business development. The Agency's mission is to increase economic opportunity and improve the quality of life in rural communities by providing the leadership, infrastructure, capital, and technical support that enables rural communities to prosper. To achieve its mission, the Agency provides financial support, including loan guarantees, direct loans and grants, and technical assistance to enhance the quality of life and provide the foundation for economic development in rural areas.

The RBCS and RUS received significant funding through the Inflation Reduction Act (IRA) of 2022, Public Law Number 117–169. It is anticipated that this funding will support the long-term resilience, reliability, and affordability of rural electric systems by providing financial assistance to purchase renewable energy, other zero-emission systems, and energy efficiency improvements that will achieve the greatest reduction in greenhouse gas emissions associated with the rural electric system. Additionally, with funding received in the IRA, Rural Development will support renewable energy and energy efficiency projects for farms and small businesses through the Rural Energy for America Program and invest in fueling and distribution infrastructure to increase demand for higher blends of biofuels.

Section 22001 of the IRA provides $1 billion in budget authority for loans for renewable energy infrastructure and requires the agency to forgive up to 50 percent of the loan amount if the loan terms and conditions are complied with. In addition, the Secretary may allow forgiveness above 50 percent so long as additional criteria are met. Eligible entities include electric service providers, including municipals, cooperatives, investor-owned and Tribal utilities. Pursuant to IRA all projects must be for build-out of energy conservation systems fueled by solar, hydro, wind, geothermal and biomass, as required by section 317 of the Rural Electrification Act (7 U.S.C. 940g), or for storage of such energy types. Priority will be given to new construction of renewable infrastructure.

Section 22002 of the IRA provides $2.025 Billion for the Rural Energy for America Program (REAP) which includes a $303.8 million set aside for underutilized technologies and technical assistance. Both amounts will be administered under REAP as a single program, as any monies not used for underutilized technologies will revert to the general REAP fund the following fiscal year. The federal share can increase from 25 percent to 50 percent of total project cost.

Section 22003 of the IRA provides $500 million in grants for infrastructure for blending, storing, supplying, or distributing biofuels. The program may provide a federal share at up to 75% of the total project cost.

Section 22004 of the IRA provides $9.7 billion in budget authority for loans, grants, loan modifications and other financial assistance to support purchase of renewable energy, renewable energy systems, zero-emissions, and carbon capture systems to deploy such systems or to make energy efficiency improvements to generation and transmission systems of eligible entities. Eligible entities include electric cooperatives, current and former RUS electric borrowers, or a cooperative that is serving a predominantly rural area (or a wholly or jointly owned subsidiary of such electric cooperative). Pursuant to the statute, no eligible entity may receive an amount equal to or more than 10% ($970 million in budget authority) of the total amount made available by the subsection (cumulative across all three products). RUS may consider establishing lower funding limits under a Funding Opportunity Announcement.

Rural Development is beginning the development of the funding tools that will be used to deliver this important funding and stakeholder feedback is vital in developing financial assistance products that will be integral to ensuring this funding reaches the intended customers. Rural Development will hold the listening sessions as outlined in the **ADDRESSES** section of this notice to receive oral comments from stakeholders and the public. The following questions and discussion items are provided as examples of topics stakeholders may wish to provide comment on. Rural Development welcomes pertinent comments that are beyond the scope of these questions. Rural Development is requesting comment and discussion on the following topics:

**General Questions**

*Question 1:* IRA requires that funds be fully disbursed by 9/30/2031, meaning construction and processing of all reimbursements must occur before then. Do you have a project(s) that could meet the statutory requirements of any of the RD IRA sections that could be completed within this time frame? When would be the soonest you would anticipate filing? When would financing need to be approved so project(s) could be completed within this time frame?

*Question 2:* How do you recommend RUS/RBCS balance the interests of large and small applicants? What measures should be taken and stakeholders or partners should be engaged to ensure active participation in RD IRA funding in socially disadvantaged and distressed communities, particularly with projects that will have an Environmental Justice impact?

*Question 3:* Projects funded under IRA are intended to increase energy

efficiency (decrease consumption of energy) and increase the deployment and use of renewable energy and/or clean energy. Knowing this requirement, what metric is most appropriate to measure progress toward meeting the goal of achieving greenhouse gas reductions and the expansion of renewable/clean energy infrastructure?

**Section Specific**

*Question 4:* In particular, for Section 22004, what is the most effective way to measure comparative reductions in carbon dioxide, methane and nitrous oxide emissions?

*Question 5:* Section 22001 of the IRA authorizes a new financing mechanism for the RUS Electric Program by providing partial loan forgiveness. The maximum amount allowed to be forgiven is 50 percent. Under the statute, the Secretary may authorize forgiveness above 50 percent.

- Should loan forgiveness be a standard amount for all applicants or tiered based on certain criteria?
- What circumstances should justify the Secretary exceeding the 50% limitation under Sec. 22001?

*Question 6:* As consumer owned entities, how can cooperatives ensure that savings resulting from this program contribute to Section 22004's statutory purpose of ''affordability?''

*Question 7:* Section 22002 provides additional funding for REAP. A key difference under IRA is the ability for the Agency to provide up to 50 percent of the cost of an activity carried out using grant funds. How should the Agency determine the level of grant for individual applications? Should there be a standard grant amount or a tiered approach? What criteria should drive a tiered approach?

*Question 8:* Section 22002 provides additional funding for underutilized technology projects and technical assistance for the purposes of applying to the program. What strategies should RD use to engage and encourage applications under this section?

**Listening Session**

Rural Development will hold the listening session on the dates listed in **DATES** section of this notice. Oral comments received from this listening session will be documented. All attendees of the listening sessions who submit oral comments may also are submit a written copy to help Rural Development accurately capture public input. In addition, stakeholders and the public who do not wish to attend or speak during the listing session are invited to submit written comments which must be received by the date indicated in the **DATES** section of this notice.

At the listening session, the focus is for Rural Development to hear from the public; this is not a discussion with Rural Development officials or a question-and-answer session. As noted above, the purpose is to receive public input that Rural Development can factor into decisions it needs to make in order to implement the IRA.

Each listening session will begin with brief opening remarks from USDA leadership in Rural Development. Individual speakers providing oral comments are requested to be succinct (the agency reserves the right to announce a time limitation at the beginning of each session based on attendance) as we do not know at this time how many participants there will be. As noted above, speakers providing oral comments may also provide a written copy of their comments. (See the **ADDRESSES** section above for information about submitting written comments.)

Rural Development will be using the Zoom platform to host the virtual listening session.

**Andrew Berke,**

*Administrator, Rural Utilities Service.*

**Karama Neal,**

*Administrator, Rural Business-Cooperative Service.*

[FR Doc. 2022–23519 Filed 10–27–22; 8:45 am]

**BILLING CODE 3410–XY–P**

## COMMISSION ON CIVIL RIGHTS

### Notice of Public Meeting of the Maryland Advisory Committee

**AGENCY:** Commission on Civil Rights.

**ACTION:** Announcement of planning meeting.

**SUMMARY:** Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a meeting of the Maryland Advisory Committee to the Commission will convene by Zoom virtual platform and conference call on Thursday, December 8, 2022, at 12:00 p.m. ET, for project planning.

**DATES:** Thursday, December 8, 2022, at 12:00 p.m. ET.

*Public Zoom Conference Link (video and audio): https://tinyurl.com/ycxd3xdj;* password, if needed: USCCR–MD.

*If Phone Only:* 1–551–285 1373; Meeting ID: 161 853 1651#.

**FOR FURTHER INFORMATION CONTACT:** Melissa Wojnaroski at *mwojnaroski@usccr.gov.*

**SUPPLEMENTARY INFORMATION:** The meeting is available to the public through the web link above. If joining only via phone, callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Individuals who are deaf, deafblind and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with conference details found through registering at the web link above. To request additional accommodations, please email *mwojnaroski@usccr.gov* at least 10 days prior to the meeting.

Members of the public are invited to make statements during the open comment period of the meeting or submit written comments. The comments must be received in the regional office approximately 30 days after each scheduled meeting. Written comments may be emailed to Melissa Wojnaroski at *mwojnaroski@usccr.gov.* Persons who desire additional information may contact Melissa Wojnaroski at *mwojnaroski@usccr.gov.*

Records and documents discussed during the meeting will be available for public viewing as they become available at *www.facadatabase.gov.* Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact Evelyn Bohor at *ebohor@usccr.gov.*

**Agenda**

*Thursday, December 8, 2022, at 12:00 p.m. ET*

- Welcome and Rollcall
- Discussion: Project Planning
- Open Comment
- Adjournment

Dated: October 24, 2022.

**David Mussatt,**

*Supervisory Chief, Regional Programs Unit.*

[FR Doc. 2022–23478 Filed 10–27–22; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF COMMERCE

### Foreign-Trade Zones Board

**[B–46–2022]**

### Foreign-Trade Zone 59—Lincoln, Nebraska: Application for Expansion of Subzone 59B: CNH Industrial America LLC: Grand Island, Nebraska

*Correction*

In Notice Document 2022–21361, appearing on page 59775, in the issue of Monday, October 3, 2022, make the following corrections:

1. On page 59775, in the second column, in the third paragraph, beginning on the sixth line, the text reading ''[INSERT DATE 40 DAYS AFTER DATE OF PUBLICATION IN THE **Federal Register**]'' should read ''November 14, 2022''.

2. On page 59775, in the same column, in the same paragraph, beginning on the twelfth line, the text reading ''[INSERT DATE 55 DAYS AFTER DATE OF PUBLICATION IN THE **Federal Register**]'' should read ''November 28, 2022''.

[FR Doc. C1–2022–21361 Filed 10–24–22; 8:45 am]

**BILLING CODE 0099–10–D**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**[RTID 0648–XC502]**

### Marine Mammals; File No. 26725

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Notice; receipt of application.

**SUMMARY:** Notice is hereby given that Florian Graner, Ph.D., 4021 Beach Drive, Freeland, WA 98249, has applied in due form for a permit to conduct commercial or educational photography on humpback whales (*Megaptera novaeangliae*) and Hawaiian spinner dolphins (*Stenella longirostris*).

**DATES:** Written, telefaxed, or email comments must be received on or before November 28, 2022.

**ADDRESSES:** These documents are available upon written request via email to *NMFS.Pr1Comments@noaa.gov.*

Written comments on this application should be submitted via email to *NMFS.Pr1Comments@noaa.gov.* Please include File No. 26725 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request via email to *NMFS.Pr1Comments@noaa.gov.* The request should set forth the specific reasons why a hearing on this application would be appropriate.

**FOR FURTHER INFORMATION CONTACT:** Amy Hapeman or Erin Markin, Ph.D., (301) 427–8401.

**SUPPLEMENTARY INFORMATION:** The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

The applicant proposes to film humpback whales and Hawaiian spinner dolphins in the waters off the coasts of Maui and Hawaii-Kona for a natural history documentary on the variety and diversity of the Hawaiian ecosystems. The applicant would film and observe up to 400 humpback whales and 1200 spinner dolphins annually topside from a vessel, using an unmanned aircraft system (UAS) or underwater by diving. Up to 250 short-finned pilot whales (*Globicephala macrorhynchus*) and 400 bottlenose dolphins (*Tursiops truncatus*) annually may be harassed and opportunistically filmed if in the vicinity of the target species. The permit would be valid from February 2023 through December 2024.

It has come to the agency's attention that the 2016 interim final humpback approach rule (50 CFR 216.19; 81 FR 62010, September 8, 2016) does not explicitly exempt permits issued under section 104(c)(6) of the MMPA from its prohibitions. It is not the agency's intent to preclude the issuance of permits or authorizations consistent with the requirements of the MMPA. We interpret the rule to allow issuance of these permits. Consistent with this interpretation, it has been our practice to continue to issue section 104(c)(6) permits that are in compliance with the MMPA's requirements and our review procedures. However, to eliminate any potential ambiguity, we intend to revise the rule to explicitly clarify that photography permits issued under section 104(c)(6) of the MMPA are exempt from the prohibitions on approach.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: October 25, 2022.

**Julia M. Harrison,**

*Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 2022–23554 Filed 10–27–22; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**[RTID 0648–XC501]**

### North Pacific Fishery Management Council; Public Meeting

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Notice of a hybrid meeting.

**SUMMARY:** The North Pacific Fishery Management Council (Council) Groundfish Plan Teams will meet November 14, 2022, through November 18, 2022.

**DATES:** The meetings will be held on Monday, November 14, 2022 through Friday, November 18, 2022, from 9 a.m. to 5 p.m., PDT.

**ADDRESSES:**

*Meeting address:* The meetings will be a hybrid meeting. The in-person component of the meeting will be held at the Alaska Fishery Science Center in the Traynor Room (2076) and Room 2039, 7600 Sand Point Way NE, Building 4, Seattle, WA 98115, or join the meeting online through the links at *https://meetings.npfmc.org/Meeting/Details/2961.*

*Council address:* North Pacific Fishery Management Council, 1007 W 3rd Ave., Anchorage, AK 99501–2252; telephone: (907) 271–2809. Instructions for attending the meeting are given under **SUPPLEMENTARY INFORMATION**, below.

**FOR FURTHER INFORMATION CONTACT:** Sara Cleaver, Council staff; email: *sara.cleaver@noaa.gov* or Diana Stram, Council staff; email *diana.stram@noaa.gov;* telephone: (907) 271–2809.

For technical support, please contact our administrative staff; email: *npfmc.admin@noaa.gov.*

**SUPPLEMENTARY INFORMATION:**

**Agenda**

*Monday, November 14, 2022, Through Friday, November 18, 2022*

The Bering Sea and Aleutian Islands (BSAI) and Gulf of Alaska (GOA) Groundfish Plan Teams will compile and review the annual BSAI and GOA Groundfish Stock Assessment and Fishery Evaluation (SAFE) reports, and recommend final groundfish Over Fishing Limit (OFL) and Allowable Biological Catches (ABCs) for 2023/24. The Plan Teams will also review the Economic Report and the Ecosystem Status Reports. The agenda is subject to change, and the latest version will be posted at *https://meetings.npfmc.org/Meeting/Details/2961* prior to the meeting, along with meeting materials.

**Connection Information**

You can attend the meeting online using a computer, tablet, or smartphone; or by phone only. Connection information will be posted online at: *https://meetings.npfmc.org/Meeting/Details/2961.*

**Public Comment**

Public comment letters should be submitted electronically via the electronic agenda at *https://meetings.npfmc.org/Meeting/Details/2961.*

*Authority:* 16 U.S.C. 1801 *et seq.*

Dated: October 25, 2022.

**Rey Israel Marquez,**

*Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 2022–23551 Filed 10–27–22; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**[RTID 0648–XC496]**

### Gulf of Mexico Fishery Management Council; Public Meeting

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Notice of a public meeting.

**SUMMARY:** The Gulf of Mexico Fishery Management Council will hold a one day in-person and virtual meeting (hybrid) of its Shrimp Advisory Panel (AP).

**DATES:** The meeting will convene Tuesday, November 15, 2022, 8:30 a.m.–5 p.m., EST. For agenda details, see **SUPPLEMENTARY INFORMATION.**

**ADDRESSES:** Registration information will be available on the Council's website by visiting *www.gulfcouncil.org* and clicking on the Shrimp AP meeting on the calendar.

*Council address:* Gulf of Mexico Fishery Management Council, 4107 W Spruce Street, Suite 200, Tampa, FL 33607; telephone: (813) 348–1630.

**FOR FURTHER INFORMATION CONTACT:** Dr. Matt Freeman, Economist, Gulf of Mexico Fishery Management Council; *matt.freeman@gulfcouncil.org,* telephone: (813) 348–1630.

**SUPPLEMENTARY INFORMATION:** The following items are on the agenda, though agenda items may be addressed out of order (changes will be noted on the Council's website when possible.)

**Tuesday, November 15, 2022; 8:30 a.m.–5 p.m. EST (7:30 a.m.–4 p.m. CST)**

Meeting will begin with Adoption of Agenda, Approval of Minutes from March 29, 2022, meeting, and Scope of Work. The AP will review Council Actions in Response to Motions from the March 2022 Shrimp AP Meeting, and June 2022 Council Meeting Motions. The AP will receive updates on the Florida Keys National Marine Sanctuary Expansion Proposal, Status of 2020 Gulf of Mexico Shrimp Effort and Landings Estimates, Draft Wind Energy Areas in the Gulf of Mexico and update on Research Track (SEDAR).

The AP will review the Recent Information on Sawfish in the Gulf; and receive any public testimony and discuss other business items.

—Meeting Adjourns

The in-person meeting will be broadcast via webinar. You may register by visiting *www.gulfcouncil.org* and clicking on the Shrimp Advisory Panel meeting on the calendar.

The Agenda is subject to change, and the latest version along with other meeting materials will be posted on *www.gulfcouncil.org* as they become available.

Although other non-emergency issues not on the agenda may come before the Advisory Panel for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during this meeting. Actions will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take-action to address the emergency at least 5 working days prior to the meeting.

**Special Accommodations**

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid or accommodations should be directed to Kathy Pereira, *kathy.pereira@gulfcouncil.org,* at least 5 days prior to the meeting date.

*Authority:* 16 U.S.C. 1801 *et seq.*

Dated: October 25, 2022.

**Rey Israel Marquez,**

*Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 2022–23552 Filed 10–27–22; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**[RTID 0648–XC500]**

### Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Notice; public meeting.

**SUMMARY:** The MAFMC will hold a public joint meeting (webinar) of its Mackerel, Squid, and Butterfish (MSB) Committee and Advisory Panel to consider potential follow-up actions regarding the disapproved *Illex* Permit Amendment.

**DATES:** The meeting will be held on Wednesday, November 16, 2022, from 9 a.m. to 11 a.m.

**ADDRESSES:** Webinar connection information will be posted to the calendar prior to the meeting at *www.mafmc.org.*

*Council address:* Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331; *www.mafmc.org.*

**FOR FURTHER INFORMATION CONTACT:** Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

**SUPPLEMENTARY INFORMATION:** In September 2022, NOAA Fisheries disapproved an Amendment to the MSB fishery management plan that would have reduced excess capacity in the *Illex* fishery. This meeting will consider potential follow-up actions by the Council.

**Special Accommodations**

The meeting is physically accessible to people with disabilities. Requests for

sign language interpretation or other auxiliary aid should be directed to Shelley Spedden, (302) 526–5251, at least 5 days prior to the meeting date.

*Authority:* 16 U.S.C. 1801 *et seq.*

Dated: October 25, 2022.

**Rey Israel Marquez,**

*Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 2022–23550 Filed 10–27–22; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**[RTID 0648–XC465]**

### Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to the Atlantic Shores Offshore Wind Energy Projects Offshore of New Jersey; Extension of Public Comment Period

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Notice; extension of public comment period.

**SUMMARY:** The National Marine Fisheries Service (NMFS) is extending the public comment period on the Notice of Receipt (NOR) of Atlantic Shores' application under the Marine Mammal Protection Act (MMPA) requesting authorization to take marine mammals, by Level A harassment and Level B harassment, incidental to the Atlantic Shores Offshore Wind Energy Project, offshore of New Jersey. The comment period for the Notice of Receipt of Atlantic Shores' application that published on September 29, 2022 closes on October 31, 2022. At the request of a commenter, NMFS is extending the public comment period to provide the public with additional time to submit information and to comment on Atlantic Shores' application.

**DATES:** The comment period for the notice published on September 29, 2022, at 87 FR 59061, is extended. Comments and information must be received no later than November 15, 2022. Comments received prior to and between the close of the first public comment period and the end of the extended comment period will be considered timely received.

**ADDRESSES:** Comments on the applications should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service. Physical comments should be sent to 1315 East-West Highway, Silver Spring, MD 20910 and electronic comments should be sent to *ITP.Potlock@noaa.gov.*

*Instructions:* NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments received electronically, including all attachments, must not exceed a 25-megabyte file size. Attachments to electronic comments will be accepted in Microsoft Word or Excel or Adobe PDF file formats only. All comments received are a part of the public record and will generally be posted online at *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act* without change. All personal identifying information (*e.g.,* name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

**FOR FURTHER INFORMATION CONTACT:** Kelsey Potlock, Office of Protected Resources, NMFS, (301) 427–8401. An electronic copy of Atlantic Shores' application may be obtained online at: *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act.* In case of problems accessing these documents, please call the contact listed above.

**SUPPLEMENTARY INFORMATION:**

#### Background

On September 29, 2022, we published a Notice of Receipt (NOR) regarding an adequate and complete application received by Atlantic Shores, who has requested NMFS to authorize the taking of marine mammals incidental to the construction of two offshore wind energy projects located off of New Jersey in and around lease area OCS–A–0499 (87 FR 59061). The NOR allowed for a 30-day public comment period, which is scheduled to close on October 31, 2022. On October 3, 2022, we received a request from the Save Long Beach Island, Inc. Coalition for Wind Without Impact (Save LBI) for a 15-day extension of the public comment period. The request indicated that Save LBI needed more time to conduct their review of the available documents and provide comments. Given that the targeted publication date of the proposed rule is May 1, 2023 (per Title 41 of the Fixing America's Surface Transportation Act (FAST–41); *https://www.permits.performance.gov/permitting-project/atlantic-shores-south*) and the requested extension would not interfere with any of the intermediate milestones, NMFS has elected to provide additional time (15 additional days) for public comment.

NMFS is extending the public comment period from an original end date of October 31, 2022, (87 FR 59061) to November 15, 2022, per this notice. No information has changed and all information that was previously described in the Background section, the Summary of Request section, and the Specified Activities section of the prior notice (87 FR 59061, September 29, 2022) remain applicable to this notice and the activities proposed by Atlantic Shores. Furthermore, all information remains available to the public on NMFS' website (*https://www.fisheries.noaa.gov/action/incidental-take-authorization-atlantic-shores-offshore-wind-llc-construction-atlantic-shores*). All comments and information submitted previously regarding Atlantic Shores' projects will be fully considered in preparation of the proposed rule and do not need to be resubmitted.

Dated: October 25, 2022.

**Kimberly Damon-Randall,**

*Director, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 2022–23523 Filed 10–27–22; 8:45 am]

**BILLING CODE 3510–22–P**

## COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

### Procurement List; Proposed Additions

**AGENCY:** Committee for Purchase From People Who Are Blind or Severely Disabled.

**ACTION:** Proposed Additions to the Procurement List.

**SUMMARY:** The Committee is proposing to add service(s) to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

**DATES:** Comments must be received on or before: November 27, 2022.

**ADDRESSES:** Committee for Purchase From People Who Are Blind or Severely Disabled, 355 E Street SW, Washington, DC 20024.

**FOR FURTHER INFORMATION CONTACT:** For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 785–6404, or email *CMTEFedReg@AbilityOne.gov.*

**SUPPLEMENTARY INFORMATION:** This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3. Its

purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

**Additions**

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the service(s) listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following service(s) are proposed for addition to the Procurement List for delivery by the nonprofit agencies listed:

*Service(s)*

*Service Type:* Contractor Operated Parts Store
*Mandatory for:* Sierra Army Depot, Herlong, CA
*Designated Source of Supply:* South Texas Lighthouse for the Blind, Corpus Christi, TX
*Contracting Activity:* DEPT OF THE ARMY, W6QK SIAD CONTR OFF

*Service Type:* Janitorial and Snow Removal
*Mandatory for:* FAA, ATBM, ATCT, Base Building and Interconnecting Link Walkway, South Burlington, VT
*Designated Source of Supply:* Northern New England Employment Services, Portland, ME
*Contracting Activity:* FEDERAL AVIATION ADMINISTRATION, 697DCK REGIONAL ACQUISITIONS SVCS

*Service Type:* Custodial Service
*Mandatory for:* U.S. Railroad Retirement Board, U.S. Railroad Retirement Board Headquarters, Chicago, IL
*Designated Source of Supply:* Bona Fide Conglomerate, Inc., El Cajon, CA
*Contracting Activity:* RAILROAD RETIREMENT BOARD, RRB—ACQUISITION MGMT DIVISION

**Michael R. Jurkowski,**

*Acting Director, Business Operations.*

[FR Doc. 2022–23535 Filed 10–27–22; 8:45 am]

**BILLING CODE 6353–01–P**

## CONSUMER PRODUCT SAFETY COMMISSION

**[Docket No. CPSC–2009–0073]**

## Agency Information Collection Activities; Submission for OMB Review; Comment Request; Virginia Graeme Baker Pool and Spa Safety Act; Compliance Form

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Notice.

**SUMMARY:** As required by the Paperwork Reduction Act of 1995, the Consumer Product Safety Commission (CPSC or Commission), announces that the Commission has submitted to the Office of Management and Budget (OMB) a request for extension of approval of a collection of information regarding a form used to verify whether pools and spas are in compliance with the Virginia Graeme Baker Pool and Spa Safety Act. The OMB previously approved the collection of information under OMB Control No. 3041–0142. On August 17, 2022, CPSC published a notice in the **Federal Register** announcing the agency's intent to seek this extension. CPSC received no comments in response to that notice. Therefore, by publication of this notice, the Commission announces that CPSC has submitted to the OMB a request for extension of approval of this collection of information.

**DATES:** Written comments on this request for extension of approval of information collection requirements should be submitted by November 28, 2022.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to: *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. In addition, written comments that are sent to OMB also should be submitted electronically at: *http://www.regulations.gov,* under Docket No. CPSC–2009–0073.

**FOR FURTHER INFORMATION CONTACT:** Cynthia Gillham, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; (301) 504–7991, or by email to: *cgillham@cpsc.gov.*

**SUPPLEMENTARY INFORMATION:** On August 17, 2022, CPSC published a notice in the **Federal Register** announcing the agency's intent to seek an extension for this information collection. 87 FR 50612. CPSC received no comments in response to that notice. Accordingly, CPSC seeks to renew the following currently approved collection of information:

*Title:* Virginia Graeme Baker Pool and Spa Safety Act Verification of Compliance Form.

*OMB Number:* 3041–0142.

*Type of Review:* Renewal of collection.

*Frequency of Response:* On occasion.

*Affected Public:* Public pools and spa facilities.

*Estimated Number of Respondents:* 50 pools or facilities.

*Estimated Time per Response:* CPSC staff or the designated State or local government official will take an estimated 3 hours to inspect a pool or spa facility.

*Total Estimated Annual Burden:* The total testing burden hours are 150 (50 inspections × 3 hours per inspection). We estimate there will be 50 inspections conducted throughout the fiscal year based on CPSC plans for inspections, past compliance rates and trends, as well as available staff resources. We estimate that hourly compensation for the time required for inspecting is $64.02 (U.S. Bureau of Labor Statistics, ''Employer Costs for Employee Compensation,'' March 2022, Table 4, total compensation for management, professional, and related workers in private service-producing industries: *https://www.bls.gov/news.release/ecec.t04.htm*). The total annual cost of time to inspect all facilities is estimated to be $9,603 ($64.02 × 150).

**General Description of Collection**

The Virginia Graeme Baker Pool and Spa Safety Act (Act), 15 U.S.C. 8001–8008, applies to public swimming pools and spas, and it requires that each swimming pool and spa drain cover manufactured, distributed, or entered into commerce in the United States shall conform to the entrapment protection standards of the ASME/ANSI A112.19.8 performance standard or any successor standard regulating such swimming pool or drain cover under section 1404(b) of the Act.

On August 5, 2011, the CPSC published a final rule incorporating by reference ANSI/APSP–16 2011 as the successor standard, effective September 6, 2011. 76 FR 47436. On May 24, 2019, the CPSC published a direct final rule incorporating by reference ANSI/APSP–16 2017 as the next successor standard. 84 FR 24021. The Act requires that, in addition to having the anti-entrapment devices or systems, each public pool and spa in the United States with a single main drain other than an unblockable drain shall be equipped with one or more of the following devices or systems designed to prevent entrapment by pool or spa drains: a safety vacuum release system, suction-limiting vent system, gravity drainage system, automatic pump shut-off system or drain disablement. The CPSC will collect information through the verification of compliance form to identify drain covers, pools, and spas that do not meet the performance requirements in ANSI/APSP–16 2017 and the Act. CPSC staff or the designated State or local government official will take approximately 3 hours to inspect the pool and fill out the checklist on the verification of

compliance form. The 2022 VGBA Form they will use is available for viewing at *https://www.regulations.gov* under docket number, CPSC–2009–0073, ''Supporting and Related Material.''

**Alberta E. Mills,**

*Secretary, Consumer Product Safety Commission.*

[FR Doc. 2022–23556 Filed 10–27–22; 8:45 am]

**BILLING CODE 6355–01–P**

## COURT SERVICES AND OFFENDER SUPERVISION AGENCY FOR THE DISTRICT OF COLUMBIA

### SES Performance Review Board

**AGENCY:** Court Services and Offender Supervision Agency for the District of Columbia.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given of the appointment of new members to the Court Services and Offender Supervision Services for the District of Columbia (CSOSA) and the Pretrial Services Agency for the District of Columbia (PSA), Senior Executive Service (SES) Performance Review Board (PRB). PSA is an independent agency within CSOSA. The PRB assures consistency, stability, and objectivity in the appraisal process.

**DATES:** November 1, 2022 to February 2025.

**FOR FURTHER INFORMATION CONTACT:** William Layne, Deputy Chief of Staff, Court Services and Offender Supervision Agency for the District of Columbia, 633 Indiana Ave. NW, Suite 1200, Washington, DC 20004, (202) 220–5637.

**SUPPLEMENTARY INFORMATION:** Section 4314(c)(1) of Title 5 of the United States Code requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management, one or more SES Performance Review Boards (PRB). (Section 4314(c)(4) requires that notice of appointment of PRB members be published in the **Federal Register**. The PRB is responsible for making recommendations to the appointing and awarding authority on the performance appraisal ratings and performance awards for SES employees. Members of the PRB will serve a term that shall begin on November 1, 2022. The following executives have been designated as members of the Performance Review Board for CSOSA and PSA:

Lisa Greene, Chief of Staff for CSOSA
Reggie James, Reginald James, Associate Director for the Office of Administration for CSOSA
Paul Girardo, Associate Director for the Office of Financial Management for CSOSA
Leslie Cooper, Director for PSA
Victor Valentino Davis, Assistant Director for Defendant Engagement and Systems Support for PSA
Karen L. Lellock, Assistant Director, Management and Administration for PSA

Dated: October 24, 2022.

**David J. Cumberbatch,**

*Federal Register Liaison.*

[FR Doc. 2022–23462 Filed 10–27–22; 8:45 am]

**BILLING CODE 3129–04–P**

## DEPARTMENT OF DEFENSE

### Office of the Secretary

### TRICARE; Notice of TRICARE Plan Program Changes for Calendar Year 2023

**AGENCY:** Office of the Secretary of Defense, Department of Defense (DoD).

**ACTION:** TRICARE plan program changes for calendar year 2023.

**SUMMARY:** This notice provides information regarding TRICARE plan program changes for Calendar Year 2023.

**DATES:** TRICARE health plan information in this notice is valid for services during calendar year (CY) 2023 (January 1, 2023–December 31, 2023).

**ADDRESSES:** Defense Health Agency, TRICARE Health Plan Division, 7700 Arlington Boulevard, Suite 5101, Falls Church, Virginia 22042–5101.

**FOR FURTHER INFORMATION CONTACT:** Ms. Debra Fisher, (703) 275–6224.

**SUPPLEMENTARY INFORMATION:** A final rule published in the **Federal Register** (FR) on February 15, 2019 (84 FR 4326–4333) established the requirement for the Director, Defense Health Agency (DHA), to provide public notice to TRICARE program beneficiaries with a summary of changes to the TRICARE program each calendar year in connection with the annual open season enrollment period.

**Announcement of Open Season**

Open Season is an annual period when beneficiaries can enroll in or make changes to their healthcare, dental and vision coverage for the next calendar year.

The TRICARE Open Season runs from November 14, 2022, through December 13, 2022, during which time beneficiaries can enroll in or change their TRICARE Prime or TRICARE Select plan.

The Federal Employee Dental and Vision Insurance Program (FEDVIP) Open Season runs from November 14, 2022, through December 12, 2022. The U.S. Office of Personnel Management offers FEDVIP enrollment to qualified beneficiaries of the Military Health System, including TRICARE for Life beneficiaries. During the FEDVIP Open Season beneficiaries may enroll in or make changes to their dental and vision plans.

Any changes beneficiaries make during open season will take effect on January 1, 2023. If a beneficiary remains eligible and does not make any changes during Open Season, then their coverage will stay the same for 2023.

**Annual Announcements**

The following TRICARE program features are subject to a year-to-year determination and are announced each year prior to the annual TRICARE Open Season.

*Urgent Care Visits:* Except for most Active Duty Service members, there continues to be no limit to the number of urgent care visits a TRICARE Prime enrollee may receive without a referral for Plan Year 2023. They may receive urgent care from any TRICARE-authorized urgent care center (UCC), either network or non-network. They may also receive urgent care from any TRICARE network provider. If the TRICARE Prime enrollee seeks care from a non-network TRICARE authorized provider (outside of a TRICARE-authorized UCC), the usual TRICARE Prime Point of Service deductible and cost-shares shall apply. Beneficiaries may also call the Military Health System Nurse Advice Line (NAL) for health care guidance from a specially trained registered nurse. The NAL is available 24/7 to all TRICARE beneficiaries in the United States (U.S.) except those enrolled in the US Family Health Plan. Beneficiaries who live overseas can call the NAL for health care advice when traveling in the U.S., but must coordinate care with their Overseas Regional Call Center. For additional information, call the servicing TRICARE contractor or visit *https://www.tricare.mil/ContactUs/CallUs/NAL.*

*Prime Service Area Changes:* Prime Service Areas (PSAs) are geographic areas around military Medical Treatment Facilities and Base Realignment and Closure sites. PSAs ensure medical readiness of active duty members by adding to the capability and capacity of military hospitals and

clinics. There is no change to geographic locations where TRICARE Prime will be offered.

*Coronavirus Disease 2023 (COVID–19) Continued Response:* A temporary waiver to the referral requirement remains in effect for TRICARE Prime enrollees, not including Active Duty Service Members (ADSMs), so they may receive COVID–19 vaccines, a clinical preventive service, from any TRICARE Basic (medical) program authorized non-network provider without incurring POS charges where applicable. This waiver will expire when the President of the United States declares the national emergency is terminated. As part of the COVID–19 response, the following temporary changes for care and treatment continue to be in effect: temporary coverage of the treatment use of investigational drugs under expanded access when for the treatment of COVID–19; temporary coverage of National Institute for Allergy and Infectious Disease (NIAID) sponsored clinical trials when for the prevention or treatment of COVID–19 or its associated sequalae; temporary interstate and international licensing, which allows the temporary waiver of licensing requirements for providers practicing (both in person and via telehealth) in a state or host-nation in which they are not licensed, when licensed in another state or nation and such practice is permitted by state, federal, or host-nation law; and temporary coverage of temporary facilities registered with Medicare's Hospitals Without Walls initiative. These temporary changes remain in effect until the President of the United States issues a declaration that the Public Health Emergency has terminated, unless terminated, extended, or otherwise modified in a final rule published in the **Federal Register**.

**What's New**

The following changes or improvements to the TRICARE program benefits apply to calendar year 2023 (although, some changes were implemented in 2022):

*Telephonic Office Visit:* Introduced during the COVID–19 pandemic, the telephonic office visit (audio-only telehealth) benefit was made permanent for all TRICARE enrollees effective July 1, 2022. A telephonic office visit is a TRICARE-covered service provided via a telephone call between an established TRICARE patient and his or her TRICARE-authorized provider. TRICARE can cover telephonic office visits for otherwise covered medically necessary and appropriate care that does not require face-to-face, hands-on treatment or visual evaluation. However, not all TRICARE covered services are appropriate for telephonic office visits. For example, evaluation of a skin lesion would require visual evaluation that cannot be completed via a telephone-only visit. Similarly, the services rendered through an intensive outpatient program would likewise be inappropriate to administer via telephone only. Another example, removal of a cast, would require hands-on treatment and would not be suitable for a telephonic visit.

*Female Contraception and Sterilization:* Active Duty service Members and TRICARE health plan enrollees enjoy access to a comprehensive range of contraceptive care under the TRICARE Program. Effective July 28, 2022, DHA eliminated cost-shares and copayments for reversible medical contraceptives as preventive services under TRICARE Prime and TRICARE Select. Reversible medical contraceptives include the FDA-approved implant, shot, and intrauterine devices. Beneficiaries can request refunds from their servicing TRICARE contractor on or after October 17, 2022, for any cost-share or copayment paid for these services performed on or after the effective date of July 28, 2022. DHA cannot eliminate cost-shares and/or copayments for daily use prescription birth control pills because TRICARE Pharmacy Program cost-sharing is mandated by law.

However, effective January 1, 2023, TRICARE Prime and Select beneficiaries seeking female surgical sterilization services (*i.e.,* surgical procedure where the fallopian tubes are cut, tied, or blocked to permanently prevent pregnancy) will also enjoy cost-share and copayment free access to these preventive services when performed by a TRICARE network provider.

*Comprehensive Autism Care Demonstration*

The Comprehensive Autism Care Demonstration (ACD) for Applied Behavior Analysis (ABA) services for TRICARE beneficiaries diagnosed with Autism Spectrum Disorder (ASD) has been extended through December 31, 2028. The ACD renders clinically necessary and appropriate ABA services for the core symptoms of ASD.

**Planned Changes**

Effective January 1, 2023, the annual premium increase for Continued Health Care Benefit Program (CHCBP) will transition from a Fiscal Year basis (October 1 each year) to a Calendar Year basis (January 1 each year). This change aligns CHCBP with the premium-based TRICARE health plans for uniformity in premium collections and reduces complexity for beneficiaries.

For more information, visit *tricare.mil/changes* or call the servicing TRICARE contractor.

**Appendix A**

Certain TRICARE enrollee out-of-pocket costs (enrollment fees, premiums, catastrophic caps, deductibles, and copayments) are adjusted annually by Federal law and regulations based on the annual Cost of Living Adjustment (COLA) applied to Uniformed Service member retired pay. A difference in copayments remains between those who joined a Uniformed Service before January 1, 2018 (Group A), and those who joined on or after that date (Group B).

The retiree COLA was announced October 2022. The COLA increase was 8.7 percent. Beneficiary out-of-pocket expenses impacted by the 2023 COLA will be posted to the *tricare.mil/changes* web page before TRICARE Open Season starts November 14, 2022.

PREMIUMS FOR CALENDAR YEAR 2023

| TRICARE Young Adult (TYA) | TRICARE Reserve Select (TRS) | TRICARE Retired Reserve (TRR) | Continued Health Care Benefit Program (CHCBP) |
|---|---|---|---|
| TYA Prime Individual $570.00 monthly. | TRS Member-Only $48.47 monthly. | TRR Member-Only $549.35 monthly. | CHCBP Single $1,654.00 quarterly |
| TYA Select Individual $291.00 monthly. | TRS Member & Family $239.69 monthly. | TRR Member & Family $1,320.76 monthly. | CHCBP Family $4,134.00 quarterly |

**Pharmacy Out-of-Pocket Expenses for CY 2023**

TRICARE Pharmacy copayments continue January 1, 2023 unchanged from 2022:

PHARMACY COPAYMENTS FOR CALENDAR YEAR 2023 *

| Year | Retail network generic formulary 30-day supply | Retail network brand-name formulary 30-day supply | Mail order generic formulary 90-day supply | Mail order brand-name formulary 90-day supply | Mail order & retail network non-formulary 90-day supply |
|---|---|---|---|---|---|
| 2023 | $14 | $38 | $12 | $34 | $68 ** |

* Active Duty Service Members enjoy a $0 copay for covered drugs at any pharmacy.
** For all beneficiaries except active duty service members, select brand-name maintenance medications (taken for long-term conditions) may only be filled twice at retail and then must be filled via home delivery or military pharmacy.

Dated: October 24, 2022.

**Aaron T. Siegel,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 2022–23465 Filed 10–27–22; 8:45 am]

**BILLING CODE 5001–06–P**

## DEPARTMENT OF DEFENSE

### Office of the Secretary

### Defense Science Board; Notice of Federal Advisory Committee Meeting

**AGENCY:** Under Secretary of Defense for Research and Engineering, Department of Defense (DoD).

**ACTION:** Notice of Federal Advisory Committee meeting.

**SUMMARY:** The DoD is publishing this notice to announce that the following Federal Advisory Committee meeting of the Defense Science Board (DSB) will take place.

**DATES:** Closed to the public Monday, November 14, 2022 from 8:30 a.m. to 4:30 p.m. Closed to the public Tuesday, November 15, 2022 from 8:30 a.m. to 5:00 p.m. Closed to the public Wednesday, November 16, 2022 from 8:30 a.m. to 5:00 p.m. Closed to the public Thursday, November 17, 2022 from 8:30 a.m. to 5:00 p.m. Closed to the public Friday, November 18, 2022 from 9:00 a.m. to 12:00 p.m.

**ADDRESSES:** The address of the closed meeting is the Naval Academy, Annapolis, Maryland 21402.

**FOR FURTHER INFORMATION CONTACT:** Mr. Kevin Doxey, Designated Federal Officer (DFO), (703) 571–0081 (Voice), (703) 697–1860 (Facsimile), *kevin.a.doxey.civ@mail.mil* (Email). Mailing address is Defense Science Board, 3140 Defense Pentagon, Room 3B888A, Washington, DC 20301–3140. Website: *http://www.acq.osd.mil/dsb/.* The most up-to-date changes to the meeting agenda can be found on the website.

**SUPPLEMENTARY INFORMATION:** This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) (Title 5 United States Code (U.S.C), Appendix), the Government in the Sunshine Act (5 U.S.C. 552b), and 41 Code of Federal Regulations (CFR) 102–3.140 and 102–3.150.

*Purpose of the Meeting:* The mission of the DSB is to provide independent advice and recommendations on matters relating to the DoD's scientific and technical enterprise. The objective of the meeting is to obtain, review, and evaluate classified information related to the DSB's mission. DSB membership will meet to discuss the 2022 DSB Summer Study on Technology Superiority (''the DSB Summer Study'').

*Agenda:* The DSB Summer Study meeting will begin on Monday, November 14, 2022 from 8:30 a.m. with administrative opening remarks from Mr. Kevin Doxey, the Executive Director and DFO, and a classified overview of the objectives of the Summer Study from Dr. Eric Evans, the DSB Chair. Next, the DSB members will meet in a plenary session to discuss classified concepts, capabilities, and strategies that may enhance the military technological advantage of the United States. Following break, the DSB members will meet in small groups to discuss classified concepts, capabilities, and strategies that may enhance the military technological advantage of the United States. The meeting will adjourn at 5:00 p.m. On Tuesday, November 15, 2022, beginning at 8:30 a.m., the DSB members will meet in small groups to discuss classified concepts, capabilities, and strategies that may enhance the military technological advantage of the United States. Following break, the DSB members will meet in small groups to discuss classified concepts, capabilities, and strategies that may enhance the military technological advantage of the United States. The meeting will adjourn at 5:00 p.m. On Wednesday, November 16, 2022, beginning at 8:30 a.m., the DSB members will meet in a plenary session to discuss classified concepts, capabilities, and strategies that may enhance the military technological advantage of the United States. Following break, the DSB members will meet in small groups to discuss classified concepts, capabilities, and strategies that may enhance the military technological advantage of the United States. The meeting will adjourn at 5:00 p.m. On Thursday, November 17, 2022 beginning at 8:30 a.m., the DSB members will meet in small groups to discuss classified concepts, capabilities, and strategies that may enhance the military technological advantage of the United States. Following break, the DSB members will meet in small groups to discuss classified concepts, capabilities, and strategies that may enhance the military technological advantage of the United States. The meeting will adjourn at 5:00 p.m. On Friday, November 18, 2022 beginning at 9:00 a.m., the DSB members will meet in a plenary session to discuss classified concepts, capabilities, and strategies that may enhance the military technological advantage of the United States. DSB will vote on the 2022 Summer Study on Technology Superiority findings and recommendations. The meeting will adjourn at 12:00 p.m.

*Meeting Accessibility:* In accordance with section 10(d) of the FACA and 41 CFR 102–3.155, the DoD has determined that the DSB meeting will be closed to the public. Specifically, the Under Secretary of Defense for Research and Engineering, in consultation with the DoD Office of the General Counsel, has determined in writing that the meeting will be closed to the public because it will consider matters covered by 5

U.S.C. 552b(c)(1). The determination is based on the consideration that it is expected that discussions throughout will involve classified matters of national security concern. Such classified material is so intertwined with the unclassified material that it cannot reasonably be segregated into separate discussions without defeating the effectiveness and meaning of the overall meetings. To permit the meeting to be open to the public would preclude discussion of such matters and would greatly diminish the ultimate utility of the DSB's findings and recommendations to the Secretary of Defense and to the Under Secretary of Defense for Research and Engineering.

*Written Statements:* In accordance with section 10(a)(3) of the FACA and 41 CFR 102–3.105(j) and 102–3.140, interested persons may submit a written statement for consideration by the DSB at any time regarding its mission or in response to the stated agenda of a planned meeting. Individuals submitting a written statement must submit their statement to the DSB DFO at the email provided in the **FOR FURTHER INFORMATION CONTACT** section of this notice at any point; however, if a written statement is not received at least three calendar days prior to the meeting, which is the subject of this notice, then it may not be provided to or considered by the DSB until a later date.

Dated: October 24, 2022.

**Aaron T. Siegel,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 2022–23467 Filed 10–27–22; 8:45 am]

**BILLING CODE 5001–06–P**

## DEPARTMENT OF EDUCATION

**[Docket No.: ED–2022–SCC–0098]**

### Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; GEPA Section 427 Guidance for All Grant Applications

**AGENCY:** Office of the Secretary (OS), Department of Education (ED).

**ACTION:** Notice.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of a currently approved information collection.

**DATES:** Interested persons are invited to submit comments on or before November 28, 2022.

**ADDRESSES:** Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection request (ICR) by selecting ''Department of Education'' under ''Currently Under Review,'' then check the ''Only Show ICR for Public Comment'' checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the ''View Information Collection (IC) List'' link. Supporting statements and other supporting documentation may be found by clicking on the ''View Supporting Statement and Other Documents'' link.

**FOR FURTHER INFORMATION CONTACT:** For specific questions related to collection activities, please contact Cleveland Knight, 202–987–0064.

**SUPPLEMENTARY INFORMATION:** The Department, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed ICR that is described below. The Department is especially interested in public comments addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public record.

*Title of Collection:* GEPA Section 427 Guidance for All Grant Applications.

*OMB Control Number:* 1894–0005.

*Type of Review:* A revision of a currently approved collection.

*Respondents/Affected Public:* State, Local, and Tribal Governments.

*Total Estimated Number of Annual Responses:* 12,816.

*Total Estimated Number of Annual Burden Hours:* 38,448.

*Abstract:* On October 20, 1994, the Improving America's Schools Act, Public Law 103–382 (The Act), became law. The Act added a provision to the General Education Provisions Act (GEPA), section 427. Section 427 of GEPA requires an applicant for assistance under Department programs to develop and describe in the grant application the steps it proposes to take to ensure equitable access to, and equitable participation in, its proposed project for students, teachers, and other program beneficiaries. Applicants have responded to the GEPA 427 requirements for approximately the last 27 years, and the current form expires in June 2023. In response to the Agency's Equity Plan resulting from the President's Executive Order 13985, we now propose to update that form by expanding the number of questions from one to four.

These four questions are intended to help applicants for Department grant funds to be more intentional and specific as to identifying barriers to equitable access and how they will address those barriers consistent with the requirements of section 427 of GEPA. As with the existing form, applicants retain the flexibility to determine and define for themselves the barriers to ''equitable access'' and ''equitable participation'' based on the design of their proposed grant projects and the participants and community the project proposes to serve.

Dated: October 25, 2022.

**Stephanie Valentine,**

*PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.*

[FR Doc. 2022–23528 Filed 10–27–22; 8:45 am]

**BILLING CODE 4000–01–P**

## DEPARTMENT OF EDUCATION

**[Docket No.: ED–2022–SCC–0133]**

### Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; 2024 Teaching and Learning International Survey (TALIS 2024) International Field Test Questionnaire Revision

**AGENCY:** Institute of Educational Sciences (IES), Department of Education (ED).

**ACTION:** Notice.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of a currently approved information collection.

**DATES:** Interested persons are invited to submit comments on or before November 28, 2022.

**ADDRESSES:** Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection request (ICR) by selecting ''Department of Education'' under ''Currently Under Review,'' then check the ''Only Show ICR for Public Comment'' checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the ''View Information Collection (IC) List'' link. Supporting statements and other supporting documentation may be found by clicking on the ''View Supporting Statement and Other Documents'' link.

**FOR FURTHER INFORMATION CONTACT:** For specific questions related to collection activities, please contact Carrie Clarady, 202–245–6347.

**SUPPLEMENTARY INFORMATION:** The Department, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed ICR that is described below. The Department is especially interested in public comments addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public record.

*Title of Collection:* 2024 Teaching and Learning International Survey (TALIS 2024) International Field Test Questionnaire Revision.

*OMB Control Number:* 1850–0888.

*Type of Review:* A revision of a currently approved collection.

*Respondents/Affected Public:* Individuals and households.

*Total Estimated Number of Annual Responses:* 2,683.

*Total Estimated Number of Annual Burden Hours:* 3,133.

*Abstract:* The Teaching and Learning International Survey (TALIS) is an international survey of teachers and principals focusing on the working conditions of teachers and the teaching and learning practices in schools. The United States will administer TALIS for the third time in 2024, having participated in 2013 and 2018. TALIS 2024 is sponsored by the Organization for Economic Cooperation and Development (OECD). TALIS is steered by the TALIS Governing Board (TGB), comprising representatives from the OECD member countries, and implemented internationally by organizations contracted by the OECD (referred to as the ''international consortium'' or ''IC''). In the U.S., TALIS 2024 is conducted by the National Center for Education Statistics (NCES) of the Institute of Education Sciences, U.S. Department of Education.

TALIS 2024 is focused on teachers' professional environment, teaching conditions, and their impact on school and teacher effectiveness. TALIS 2024 will address teacher training and professional development, teacher appraisal, school climate, school leadership, instructional approaches, pedagogical practices, and teaching experience with and support for teaching diverse populations.

OECD has scheduled the main study to occur in the Northern hemisphere from February through March 2024 and in the Southern hemisphere from June through August 2024. To prepare for the main study, several TALIS countries will conduct pilot studies in February 2022; the U.S. will not participate. Countries will also conduct a field test in the first quarter of 2023, primarily to evaluate newly developed questionnaire items and school recruitment materials; the U.S. will participate in the field test. To meet the international data collection schedule for the field test, U.S. recruitment activities need to begin by August 2022 and U.S. questionnaires must be finalized by December 2022.

TALIS 2024 includes the core TALIS teacher and principal surveys that are required for each participating country, as well as an optional Teacher Knowledge Survey (TKS). The TKS is intended to better understand the teacher pedagogical knowledge base at the national level. The US is including the TKS in the upcoming TALIS 2024 field test and will evaluate these results to determine the feasibility of including TKS as part of the US Main Study.

The previous submission (OMB #1850–0888 v.8) requested approval for: (1) recruitment and pre-survey activities for the 2023 field test sample; (2) administration of the field test; and (3) school recruitment and pre-survey activities for the 2024 main study sample. That package was approved in August 2022. This submission requests approval for the final international versions of the principal and teacher instruments approved for the TALIS 2024 Field Test. The final U.S. adaptations of the 2024 core TALIS and TKS field test questionnaires that will be administered in the TALIS 2024 U.S. Field Test will be submitted to OMB as a non-substantive change request in Winter 2022/23.

Dated: October 25, 2022.

**Stephanie Valentine,**

*PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.*

[FR Doc. 2022–23527 Filed 10–27–22; 8:45 am]

**BILLING CODE 4000–01–P**

## DEPARTMENT OF EDUCATION

**[Docket No.: ED–2022–SCC–0134]**

## Agency Information Collection Activities; Comment Request; National Evaluation of Title III Implementation

**AGENCY:** Institute of Educational Sciences (IES), Department of Education (ED).

**ACTION:** Notice.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, ED is proposing a new information collection.

**DATES:** Interested persons are invited to submit comments on or before December 27, 2022.

**ADDRESSES:** To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2022–SCC–0134. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the

information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the PRA Coordinator of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W208C, Washington, DC 20202–8240.

**FOR FURTHER INFORMATION CONTACT:** For specific questions related to collection activities, please contact Tracy Rimdzius, 202–245–7283.

**SUPPLEMENTARY INFORMATION:** The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

*Title of Collection:* National Evaluation of Title III Implementation.

*OMB Control Number:* 1850–NEW.

*Type of Review:* A new information collection.

*Respondents/Affected Public:* State, Local, and Tribal Governments.

*Total Estimated Number of Annual Responses:* 3,301.

*Total Estimated Number of Annual Burden Hours:* 574.

*Abstract:* The data collection described in this submission includes state-, district-, and school-level surveys for the National Evaluation of Title III Implementation. This study is designed to provide information to policymakers, administrators, and educators about state and local practices for serving English learners (ELs), both through implementation of Title III, Part A of the Elementary and Secondary Education Act (ESEA) and more generally. The surveys will collect information on criteria for identifying and reclassifying ELs, instructional models and strategies for ELs, strategies for promoting EL teacher quality, and supports for EL parents and families.

Dated: October 25, 2022.

**Juliana Pearson,**

*PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.*

[FR Doc. 2022–23558 Filed 10–27–22; 8:45 am]

**BILLING CODE 4000–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Project No. 3509–042]**

### Little Falls Hydroelectric Associates, LP; Notice of Settlement Agreement and Soliciting Comments

Take notice that the following settlement agreement has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Settlement Agreement.

b. *Project No.:* 3509–042.

c. *Date filed:* October 11, 2022.

d. *Applicant:* Little Falls Hydroelectric Associates, LP (Little Falls Associates).

e. *Name of Project:* Little Falls Hydroelectric Project (Little Falls Project).

f. *Location:* The existing project is located on the Mohawk River, in the City of Little Falls, Herkimer County, New York. The project does not occupy federal land.

g. *Filed Pursuant to:* Rule 602 of the Commission's Rules of Practice and Procedure, 18 CFR 385.602.

h. *Applicant Contact:* David H. Fox, Director, Licensing and Compliance, Little Falls Hydroelectric Associates, LP, Eagle Creek Renewable Energy, 7315 Wisconsin Avenue, Suite 1100W, Bethesda, MD 20814, email—*david.fox@eaglecreekre.com;* Jody J. Smet, Vice President, Regulatory Affairs, Little Falls Hydroelectric Associates, LP, Eagle Creek Renewable Energy, 7315 Wisconsin Avenue, Suite 1100W, Bethesda, MD 20814, email—*jody.smet@eaglecreekre.com.*

i. *FERC Contact:* Monir Chowdhury at (202) 502–6736 or email at *monir.chowdhury@ferc.gov.*

j. *Deadline for filing comments:* November 14, 2022. Reply comments due November 24, 2022.

The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–3509–042.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. Little Falls Associates filed the Settlement Agreement on behalf of itself, the U.S. Fish and Wildlife Service, and the New York State Department of Environmental Conservation. The purpose of the Settlement Agreement is to resolve, among the signatories, issues related to operational, fisheries, wildlife, water quality, and recreation resources associated with issuance of a new license and water quality certification for the project. Specifically, the Settlement Agreement includes proposed protection, mitigation, and enhancements measures to address bypassed reach minimum flow, streamflow and water level monitoring, downstream fish passage enhancements,

recreation facility enhancements, invasive species management, and bald eagle protection. Little Falls Associates states that the terms of the Settlement Agreement are an integrated and indivisible set of measures intended to address and balance non-power and power values relating to the project and requests that the Commission approve the Settlement Agreement and incorporate the proposed measures set forth in section 3 into any new license issued.

l. A copy of the Settlement Agreement may be viewed on the Commission's website at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number, excluding the last three digits, in the docket number field to access the document (*i.e.,* P–3509). At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC Online Support.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Dated: October 24, 2022.

**Debbie-Anne A. Reese,**

*Deputy Secretary.*

[FR Doc. 2022–23504 Filed 10–27–22; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

*Docket Numbers:* EC23–10–000.

*Applicants:* Carson Hybrid Energy Storage LLC, Enery Holdings LLC, Carson Hybrid Energy Center LLC.

*Description:* Joint Application for Authorization Under Section 203 of the Federal Power Act of Carson Hybrid Energy Storage LLC, et al.

*Filed Date:* 10/21/22.

*Accession Number:* 20221021–5218.

*Comment Date:* 5 p.m. ET 11/14/22.

*Docket Numbers:* EC23–11–000.

*Applicants:* Washington County Power, LLC.

*Description:* Application for Authorization Under Section 203 of the Federal Power Act of Washington County Power, LLC.

*Filed Date:* 10/21/22.

*Accession Number:* 20221021–5221.

*Comment Date:* 5 p.m. ET 11/14/22.

Take notice that the Commission received the following electric rate filings:

*Docket Numbers:* ER10–1410–006; ER10–1823–004; ER16–1750–009; ER16–2601–007; ER17–2292–007; ER17–2381–006; ER19–1656–006; ER20–2123–004; ER20–2768–004.

*Applicants:* Greensville County Solar Project, LLC, Hardin Solar Energy LLC, Wilkinson Solar LLC, Scott-II Solar LLC, Southampton Solar, LLC, Summit Farms Solar, LLC, Eastern Shore Solar LLC, Dominion Energy Marketing, Inc., Virginia Electric and Power Company.

*Description:* Notice of Change in Status of Virginia Electric and Power Company, et al.

*Filed Date:* 10/21/22.

*Accession Number:* 20221021–5217.

*Comment Date:* 5 p.m. ET 11/14/22.

*Docket Numbers:* ER10–1618–017; ER10–1631–019; ER10–1854–019; ER10–1892–022; ER10–2678–020; ER10–2729–014; ER10–2739–035; ER10–2744–020; ER11–3320–019; ER13–2316–017; ER14–19–018; ER14–1219–014; ER16–1652–022; ER16–1732–013; ER16–2405–013; ER16–2406–014; ER17–989–012; ER17–990–012; ER17–992–012; ER17–993–012; ER17–1946–012; ER18–95–009; ER20–660–009; ER20–1440–005; ER21–202–001; ER21–1133–002; ER22–425–002; ER22–1241–001.

*Applicants:* REV Energy Marketing, LLC, Enerwise Global Technologies, LLC, Hummel Station, LLC, Centrica Business Solutions Optimize, LLC, Yards Creek Energy, LLC, Bolt Energy Marketing, LLC, Buchanan Energy Services Company, LLC, Helix Ironwood, LLC, Bath County Energy, LLC, Springdale Energy, LLC, Gans Energy, LLC, Chambersburg Energy, LLC, Rockford Power, LLC, Rockford Power II, LLC, Aurora Generation, LLC, LifeEnergy, LLC, Armstrong Power, LLC, West Deptford Energy, LLC, Seneca Generation, LLC, LSP University Park, LLC, Riverside Generating Company, L.L.C., LS Power Marketing, LLC, Buchanan Generation, LLC, Troy Energy, LLC, Columbia Energy LLC, Doswell Limited Partnership, University Park Energy, LLC, Rolling Hills Generating, L.L.C.

*Description:* Notice of Change in Status of Rolling Hills Generating, L.L.C., et al.

*Filed Date:* 10/21/22.

*Accession Number:* 20221021–5224.

*Comment Date:* 5 p.m. ET 11/14/22.

*Docket Numbers:* ER18–2358–005.

*Applicants:* GridLiance High Plains LLC, Southwest Power Pool, Inc.

*Description:* Compliance filing: Southwest Power Pool, Inc. submits tariff filing per 35: GridLiance—Compliance Filing in Response to Order issued in ER18–2358 to be effective 9/22/2022.

*Filed Date:* 10/24/22.

*Accession Number:* 20221024–5091.

*Comment Date:* 5 p.m. ET 11/14/22.

*Docket Numbers:* ER23–163–000.

*Applicants:* Illinois Power Resources Generating, LLC.

*Description:* Tariff Amendment: IPRG Notice of Cancellation of Reactive Rate Schedule to be effective 1/1/2023.

*Filed Date:* 10/21/22.

*Accession Number:* 20221021–5197.

*Comment Date:* 5 p.m. ET 11/14/22.

*Docket Numbers:* ER23–164–000.

*Applicants:* Nevada Power Company.

*Description:* § 205(d) Rate Filing: Rate Schedule No. 96 2nd Amended & Restated Navajo WTS Operating Agreement to be effective 12/21/2022.

*Filed Date:* 10/21/22.

*Accession Number:* 20221021–5202.

*Comment Date:* 5 p.m. ET 11/14/22.

*Docket Numbers:* ER23–165–000.

*Applicants:* ISO New England Inc., New England Power Company.

*Description:* § 205(d) Rate Filing: ISO New England Inc. submits tariff filing per 35.13(a)(2)(iii): New England Power Company; Revisions to Schedule 21–NEP to be effective 1/1/2023.

*Filed Date:* 10/24/22.

*Accession Number:* 20221024–5045.

*Comment Date:* 5 p.m. ET 11/14/22.

*Docket Numbers:* ER23–166–000.

*Applicants:* Energy Storage Resources, LLC.

*Description:* Baseline eTariff Filing: Baseline new to be effective 12/24/2022.

*Filed Date:* 10/24/22.

*Accession Number:* 20221024–5074.

*Comment Date:* 5 p.m. ET 11/14/22.

*Docket Numbers:* ER23–167–000.

*Applicants:* Cranberry Point Energy Storage, LLC.

*Description:* Baseline eTariff Filing: Baseline new to be effective 12/24/2022.

*Filed Date:* 10/24/22.

*Accession Number:* 20221024–5076.

*Comment Date:* 5 p.m. ET 11/14/22.

*Docket Numbers:* ER23–168–000.

*Applicants:* Cross Town Energy Storage, LLC.

*Description:* Baseline eTariff Filing: Baseline new to be effective 12/24/2022.

*Filed Date:* 10/24/22.

*Accession Number:* 20221024–5078.

*Comment Date:* 5 p.m. ET 11/14/22.

*Docket Numbers:* ER23–169–000.

*Applicants:* Midcontinent Independent System Operator, Inc.

*Description:* § 205(d) Rate Filing: 2022–10–24_Tariff True-Up for Seasonal and Accreditation Construct to be effective 9/1/2022.

*Filed Date:* 10/24/22.

*Accession Number:* 20221024–5083.

*Comment Date:* 5 p.m. ET 11/14/22.

*Docket Numbers:* ER23–170–000.

*Applicants:* Idaho Power Company.

*Description:* Compliance filing: Order 864 Compliance Filing Letter to be effective 1/27/2020.

*Filed Date:* 10/24/22.

*Accession Number:* 20221024–5086.

*Comment Date:* 5 p.m. ET 11/14/22.

*Docket Numbers:* ER23–171–000.

*Applicants:* Cheyenne Light, Fuel and Power Company.

*Description:* § 205(d) Rate Filing: Filing of E&P Agreement with Roundhouse Renewable Energy II, LLC to be effective 10/24/2022.

*Filed Date:* 10/24/22.

*Accession Number:* 20221024–5102.

*Comment Date:* 5 p.m. ET 11/14/22.

*Docket Numbers:* ER23–172–000.

*Applicants:* AEP Texas Inc.

*Description:* § 205(d) Rate Filing: AEPTX-Noria Hondo Solar Generation Interconnection Agreement to be effective 10/12/2022.

*Filed Date:* 10/24/22.

*Accession Number:* 20221024–5110.

*Comment Date:* 5 p.m. ET 11/14/22.

*Docket Numbers:* ER23–173–000.

*Applicants:* AEP Texas Inc.

*Description:* § 205(d) Rate Filing: AEPTX-Bordertown BESS Generation Interconnection Agreement to be effective 10/12/2022.

*Filed Date:* 10/24/22.

*Accession Number:* 20221024–5113.

*Comment Date:* 5 p.m. ET 11/14/22.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: October 24, 2022.

**Debbie-Anne A. Reese,**

*Deputy Secretary.*

[FR Doc. 2022–23507 Filed 10–27–22; 8:45 am]

**BILLING CODE 6717–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

**Filings Instituting Proceedings**

*Docket Numbers:* RP23–55–000.

*Applicants:* East Cheyenne Gas Storage, LLC.

*Description:* § 4(d) Rate Filing: ECGS 2022–10–21 GT&C Section 35 Revisions to be effective 11/1/2022.

*Filed Date:* 10/21/22.

*Accession Number:* 20221021–5168.

*Comment Date:* 5 p.m. ET 11/2/22.

*Docket Numbers:* RP23–56–000.

*Applicants:* Iroquois Gas Transmission System, L.P.

*Description:* § 4(d) Rate Filing: 10.24.22 Negotiated Rates—Castleton Commodities Merchant Trading R–4010–32 to be effective 11/1/2022.

*Filed Date:* 10/24/22.

*Accession Number:* 20221024–5024.

*Comment Date:* 5 p.m. ET 11/7/22.

*Docket Numbers:* RP23–57–000.

*Applicants:* Iroquois Gas Transmission System, L.P.

*Description:* § 4(d) Rate Filing: 10.24.22 Negotiated Rates—Castleton Commodities Merchant Trading R–4010–33 to be effective 11/1/2022.

*Filed Date:* 10/24/22.

*Accession Number:* 20221024–5029.

*Comment Date:* 5 p.m. ET 11/7/22.

*Docket Numbers:* RP23–58–000.

*Applicants:* Iroquois Gas Transmission System, L.P.

*Description:* § 4(d) Rate Filing: 10.24.22 Negotiated Rates—Castleton Commodities Merchant Trading R–4010–34 to be effective 11/1/2022.

*Filed Date:* 10/24/22.

*Accession Number:* 20221024–5030.

*Comment Date:* 5 p.m. ET 11/7/22.

*Docket Numbers:* RP23–59–000.

*Applicants:* Iroquois Gas Transmission System, L.P.

*Description:* § 4(d) Rate Filing: 10.24.22 Negotiated Rates—Castleton Commodities Merchant Trading R–4010–35 to be effective 11/1/2022.

*Filed Date:* 10/24/22.

*Accession Number:* 20221024–5035.

*Comment Date:* 5 p.m. ET 11/7/22.

*Docket Numbers:* RP23–60–000.

*Applicants:* Iroquois Gas Transmission System, L.P.

*Description:* § 4(d) Rate Filing: 10.24.22 Negotiated Rates—Castleton Commodities Merchant Trading R–4010–36 to be effective 11/1/2022.

*Filed Date:* 10/24/22.

*Accession Number:* 20221024–5037.

*Comment Date:* 5 p.m. ET 11/7/22.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: October 24, 2022.

**Debbie-Anne A. Reese,**

*Deputy Secretary.*

[FR Doc. 2022–23505 Filed 10–27–22; 8:45 am]

**BILLING CODE 6717–01–P**

## ENVIRONMENTAL PROTECTION AGENCY

**[FRL OP–OFA–041]**

### Environmental Impact Statements; Notice of Availability

*Responsible Agency:* Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EIS)

Filed October 17, 2022 10 a.m. EST Through October 24, 2022 10 a.m. EST

Pursuant to 40 CFR 1506.9.

*Notice:* Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxapps.epa.gov/cdx-enepa-II/public/action/eis/search.*

*EIS No. 20220152, Final, USCG, ND,* BNSF Railway Bridge 196.6 Project Morton and Burleigh Counties, North Dakota, Review Period Ends: 11/28/2022, Contact: Rob McCaskey 314–269–2381.

*EIS No. 20220153, Draft, FERC, NC,* Southside Reliability Enhancement Project, Comment Period Ends: 12/12/2022, Contact: Office of External Affairs 866–208–3372.

*EIS No. 20220154, Draft Supplement, USFS, ID,* Stibnite Gold Project, Comment Period Ends: 01/10/2023, Contact: Brian Harris 208–634–0784.

*EIS No. 20220155, Final, BOEM, AK,* Outer Continental Shelf (OCS) Alaska Region, Cook Inlet Planning Area, Oil and Gas Lease Sale 258, Review Period Ends: 11/28/2022, Contact: Casey Rowe 907–312–3788.

*EIS No. 20220156, Draft, BOEM, CA,* Programmatic Environmental Impact Statement for Oil and Gas Decommissioning Activities on the Pacific Outer Continental Shelf, Comment Period Ends: 12/12/2022, Contact: Richard Yarde 805–384–6379.

**Amended Notice**

*EIS No. 20220086, Draft Supplement, NMFS, WA,* The Makah Tribe Request to Hunt Gray Whales, Comment Period Ends: 11/03/2022, Contact: Grace Ferrara 206–526–6172. Revision to FR Notice Published 08/12/2022; Extending the Comment Period from 10/14/2022 to 11/03/2022.

*EIS No. 20220122, Draft, CHSRA, CA,* California High-Speed Rail Authority Palmdale to Burbank Project Section: Draft Environmental Impact Report/Environmental Impact Statement, Comment Period Ends: 12/01/2022, Contact: Scott Rothenberg 916–403–6936. Revision to FR Notice Published 09/02/2022; Extending the Comment Period from 11/01/2022 to 12/01/2022.

Dated: October 24, 2022.

**Julie Roemele,**

*Acting Director, NEPA Compliance Division, Office of Federal Activities.*

[FR Doc. 2022–23500 Filed 10–27–22; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

**[FRL–10263–01–ORD]**

## Ambient Air Monitoring Reference and Equivalent Methods; Designation of One New Equivalent Method

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of the designation of a new equivalent method for monitoring ambient air quality.

**SUMMARY:** Notice is hereby given that the Environmental Protection Agency (EPA) has designated one new equivalent method for measuring concentrations of Particulate Matter in the 2.5-micron range ($PM_{2.5}$) in ambient air.

**FOR FURTHER INFORMATION CONTACT:** Robert Vanderpool, Air Methods and Characterization Division (MD–D205–03), Center for Environmental Measurements and Modeling, U.S. EPA, Research Triangle Park, North Carolina 27711. Phone: 919–541–7877. Email: *Vanderpool.Robert@epa.gov.*

**SUPPLEMENTARY INFORMATION:** In accordance with regulations at 40 CFR part 53, the EPA evaluates various methods for monitoring the concentrations of those ambient air pollutants for which EPA has established National Ambient Air Quality Standards (NAAQS) as set forth in 40 CFR part 50. Monitoring methods that are determined to meet specific requirements for adequacy are designated by the EPA as either reference or equivalent methods (as applicable), thereby permitting their use under 40 CFR part 58 by States and other agencies for determining compliance with the NAAQS. A list of all reference or equivalent methods that have been previously designated by EPA may be found at *http://www.epa.gov/ttn/amtic/criteria.html.*

The EPA hereby announces the designation of one new equivalent method for measuring concentrations of Particulate Matter in the 2.5-micron range ($PM_{2.5}$) in ambient air. This designation is made under the provisions of 40 CFR part 53, as amended on October 26, 2015 (80 FR 65291–65468).

The new equivalent method for $PM_{2.5}$ is an automated method (analyzer) utilizing an optically based measurement principle. This newly designated equivalent method is identified as follows:

EQPM–0922–260 ''Ambilabs Model 2WIN $PM_{2.5}$ FEM Monitor'' Optically based continuous ambient particulate analyzer operated at a volumetric flow rate of 2 Lpm, equipped with Ambilabs omnidirectional sampling inlet (P/N: M9003011), an Ambilabs 2 Lpm sharp cut cyclone inlet (P/N: A001025), and an Ambilabs ambient temperature sensor (P/N: AL–2WIN–TEMP) configured for operation with firmware version 1.36 or later, and operated in accordance with the Ambilabs 2WIN operations manual. The 2WIN $PM_{2.5}$ FEM Monitor is set for red and blue scattering coefficients and the internal sample conditioning must be set for an RH < 35%. The Monitor can be operated either outside in an Ambilabs environmental enclosure (P/N: Neph Shelter) or as tabletop or wall mount in an AC controlled shelter. This designation applies to $PM_{2.5}$ measurements only.

This application for an equivalent method determination for this $PM_{2.5}$ method was received by the Office of Research and Development on July 12, 2022. This analyzer is commercially available from the applicant, Ambilabs, 100 Elm Street, Warren, RI 02885.

A representative test analyzer was tested in accordance with the applicable test procedures specified in 40 CFR part 53, as amended on October 26, 2015. After reviewing the results of those tests and other information submitted by the applicant, EPA has determined, in accordance with part 53, that this method should be designated as an equivalent method.

As a designated equivalent method, this method is acceptable for use by states and other air monitoring agencies under the requirements of 40 CFR part 58, Ambient Air Quality Surveillance. For such purposes, this method must be used in strict accordance with the operation or instruction manual associated with the method and subject to any specifications and limitations (*e.g.,* configuration or operational settings) specified in the designated method description (see the identification of the method above).

Use of the method also should be in general accordance with the guidance and recommendations of applicable sections of the ''Quality Assurance Handbook for Air Pollution Measurement Systems, Volume I,'' EPA/600/R–94/038a and ''Quality Assurance Handbook for Air Pollution Measurement Systems, Volume II, Ambient Air Quality Monitoring Program,'' EPA–454/B–13–003, (both available at *http://www.epa.gov/ttn/amtic/qalist.html*). Provisions concerning modification of such methods by users are specified under Section 2.8 (Modifications of Methods by Users) of Appendix C to 40 CFR part 58.

Consistent or repeated noncompliance with any of these conditions should be reported to: Director, Air Methods and Characterization Division (MD–D205–03), Center for Environmental Measurements and Modeling, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

Designation of this equivalent method is intended to assist the States in establishing and operating their air quality surveillance systems under 40 CFR part 58. Questions concerning the commercial availability or technical

aspects of the method should be directed to the applicant.

**Alice Gilliland,**

*Director (Acting), Center for Environmental Measurements and Modeling.*

[FR Doc. 2022–23524 Filed 10–27–22; 8:45 am]

**BILLING CODE 6560–50–P**

## FEDERAL COMMUNICATIONS COMMISSION

**[OMB 3060–XXXX; FR ID 111329]**

### Information Collection Being Submitted for Review and Approval to Office of Management and Budget

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice and request for comments.

**SUMMARY:** As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.'' The Commission may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

**DATES:** Written comments and recommendations for the proposed information collection should be submitted on or before December 1, 2022.

**ADDRESSES:** Comments should be sent to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Your comment must be submitted into *www.reginfo.gov* per the above instructions for it to be considered. In addition to submitting in *www.reginfo.gov* also send a copy of your comment on the proposed information collection to Nicole Ongele, FCC, via email to *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

**FOR FURTHER INFORMATION CONTACT:** For additional information or copies of the information collection, contact Nicole Ongele at (202) 418–2991. To view a copy of this information collection request (ICR) submitted to OMB: (1) go to the web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

**SUPPLEMENTARY INFORMATION:** As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

*OMB Control Number:* 3060–XXXX.

*Title:* Performance Evaluation of Numbering Administration Vendor(s).

*Form Number:* N/A.

*Type of Review:* New information collection.

*Respondents:* Business or other for-profit entities, Not-for-profit entities, and State, Local and Tribal Governments.

*Number of Respondents and Responses:* 6,161 respondents and 6,161 responses.

*Estimated Time per Response:* 0.25 hours.

*Frequency of Response:* Annual reporting requirement.

*Obligation to Respond:* Voluntary.

*Total Annual Burden:* 1,540 hours.

*Total Annual Cost:* No cost.

*Privacy Impact Assessment:* Personally identifiable information (PII) in the form of business contact information will be collected and maintained in accordance with the FCC–2, Business Contacts and Certifications, System of Records Notice (SORN), posted at *https://www.fcc.gov/managing-director/privacy-transparency/privacy-act-information.* There is no intention by the Numbering Administration Oversight Working Group (NAOWG), North American Numbering Council (NANC), or the Commission to make this business contact information publicly available.

*Nature and Extent of Confidentiality:* Participants must share their business contact information to respond to the survey. This information will be protected as described in the FCC–2, Business Contacts and Certifications SORN, posted at *https://www.fcc.gov/managing-director/privacy-transparency/privacy-act-information.* Participation in each survey is voluntary and any participant can decline to participate at any time.

*Needs and Uses:* The Commission is requesting Office of Management and Budget (OMB) approval for this new information collection. This collection of information is an annual performance satisfaction survey of its vendor(s) acting as administrators for various telephone number management functions.

These functions may be performed by one or multiple vendors under one or multiple contracts. The vendor(s) act pursuant to their contract(s) with the Federal Communications Commission (FCC) and the FCC's numbering rules. *See* 47 CFR 52.1 *et seq.*

The survey will be designed and administered by the Numbering Administration Oversight Working Group (NAOWG) of the North American Numbering Council (NANC). The NANC is a Federal Advisory Committee established under the Federal Advisory Committee Act. The NANC advises the FCC and makes recommendations, reached through consensus, that foster efficient and impartial number administration. The NANC is composed of representatives of telecommunications carriers, regulators, cable providers, Voice Over Internet

Protocol (VoIP) providers, industry associations, vendors, and consumer advocates. Working groups, including the NAOWG, made up of industry experts, have been established by the NANC to assist in its efforts. The NANC charter can be found at *https://docs.fcc.gov/public/attachments/DOC-375774A1.pdf.*

The relevant contract(s) require that the Commission and/or its designee shall develop and conduct a performance survey for each administrator. The results of this consumer satisfaction survey will provide the FCC with indicators on how well the vendor(s) are acting as the North American Numbering Program Administrator (NANPA), Pooling Administrator (PA), Routing Number Administrator (RNA) and Reassigned Numbering Database Administrator (RNDA) is meeting its contractual obligations and accomplishing its mission as the NANPA/PA/RNA/RNDA.

Federal Communications Commission.

**Marlene Dortch,**

*Secretary, Office of the Secretary.*

[FR Doc. 2022–23539 Filed 10–27–22; 8:45 am]

**BILLING CODE 6712–01–P**

## FEDERAL RESERVE SYSTEM

### Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than November 14, 2022.

*A. Federal Reserve Bank of Dallas* (Karen Smith, Director, Applications) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *Rosalie Miller Acree 1999 GST Trust FBO Michalyn Miller Ordeneaux (''Trust FBO Michalyn Miller Ordeneaux''); Rosalie Miller Acree 1999 GST Trust FBO Jacalyn Miller DeLange (''Trust FBO Jacalyn Miller DeLange''); Jacalyn Miller DeLange, individually and as co-trustee of the Trust FBO Michalyn Miller Ordeneaux and the Trust FBO Jacalyn Miller DeLange; Michalyn Miller Ordeneaux, individually and as co-trustee of the Trust FBO Michalyn Miller Ordeneaux and the Trust FBO Jacalyn Miller DeLange; Michalyn Miller Ordeneaux 2004 GST Trust, Roddy Keith Ordeneaux and Michala Ordeneaux Denton as co-trustees; and Jacalyn Miller DeLange Trust, Lindsey Miller DeLange Hagan, as trustee, all of Pearland, Texas;* as a group acting in concert, to retain voting shares of Coastal Bancshares, Inc., Pearland, Texas, and thereby indirectly retain voting shares of Pearland State Bank, Pearland, Texas, and First National Bank of Alvin, Alvin, Texas.

*B. Federal Reserve Bank of Kansas City* (Jeffrey Imgarten, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *The Heather A. Dews Children's Trust, Randy Dews, as trustee, Kylie Dews, as voting proxy, and certain minor children of Roger Cattle, all of Lincoln, Nebraska;* to join the Cattle Family Group, a group acting in concert, to retain voting shares of Cattle Crossing, Inc., and thereby indirectly retain voting shares of Cattle Bank & Trust, both of Seward, Nebraska.

Board of Governors of the Federal Reserve System.

**Michele Taylor Fennell,**

*Deputy Associate Secretary of the Board.*

[FR Doc. 2022–23538 Filed 10–27–22; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Agency for Healthcare Research and Quality, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project ''Supporting and Evaluating the Dissemination and Implementation of PCOR to Improve Non-Surgical Treatment of Urinary Incontinence Among Women in Primary Care.''

**DATES:** Comments on this notice must be received by December 27, 2022.

**ADDRESSES:** Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at *doris.lefkowitz@AHRQ.hhs.gov.*

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

**FOR FURTHER INFORMATION CONTACT:** Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

**Proposed Project**

**Supporting and Evaluating the Dissemination and Implementation of PCOR To Improve Non-Surgical Treatment of Urinary Incontinence Among Women in Primary Care**

AHRQ's Improve Non-surgical Treatment of Urinary Incontinence Among Women in Primary Care (INTUIT–PC) initiative, now named the Managing Urinary Incontinence (MUI) initiative, addresses important gaps in urinary incontinence (UI) care for women in the primary care setting. As part of the MUI initiative, AHRQ is funding five cooperative agreement (U18) grantees to develop primary care extension services to disseminate and implement improved nonsurgical treatment of UI for women—including screening, diagnosis, management, and specialty referral—within primary care practices in separate regions of the United States.

AHRQ is also conducting a project to support the MUI cooperative agreements and evaluate the initiative, which includes:

- Support of the five U18 MUI cooperative agreements in the form of a learning community, technical assistance, and other resources to assist grantees to disseminate and implement patient centered outcomes research (PCOR) for nonsurgical treatment of urinary incontinence for women in primary care.

• A rigorous mixed methods process and outcome evaluation of the grantees' dissemination and implementation strategies.

This evaluation is being conducted by AHRQ through its contractor, RAND, pursuant to AHRQ's authority to carry out the PCOR dissemination activities described in section 937 of the Public Health Service Act. 42 U.S.C. 299b—37.

**Method of Collection**

To achieve the goals of this multisite evaluation, AHRQ is requesting OMB approval for three years of data collection by the evaluator. The evaluator's primary data collection is requested to achieve the goals of the multisite evaluation and includes the following data collection activities:

(1) Focus groups with practice facilitators who are employed by the MUI U18 grantees to provide direct technical assistance to primary care practices

(2) Semi-structured interviews with leaders and staff of primary care practices participating in the MUI U18 studies

Practice facilitator focus groups. Practice facilitators (also known as practice coaches) perform a critical role in enabling primary care practices to implement evidence-based improvements. The purpose of the annual focus groups with practice facilitators is to gather their insights on challenges assisting various types of primary care practices, the resources needed to promote improvement in primary care practices, and the effectiveness of different dissemination and implementation strategies used by the MUI U18 studies. The evaluator aims to conduct a virtual focus group with 8–10 practice facilitators for each of the five U18 studies, for an expected total of 45 focus group participants per year.

Practice leader/staff semi-structured interviews. The goal of the MUI U18 studies is to disseminate and implement evidence-based UI treatment for women within primary care practices. The purpose of the semi-structured interviews with leaders and staff of primary care practices is to collect data from the practices' perspective on the barriers and facilitators to implementing evidence-based UI treatment for women in primary care, as well as on the utility of the technical assistance and resources provided to practices by the grant studies. The evaluator aims to conduct 4–8 in-person individual interviews in one practice per each U18 study (average of 1 interviews × on average 6 participants × 1 practice × 5 grants = 30 interviews), and 1 telephone interview with 1–2 participants per interview for two additional practices per each grant study (1 interview × on average 1.5 participants × 2 practices × 5 grants = 15 interviews), for an expected total of 45 interview participants per year.

**Estimated Annual Respondent Burden**

Exhibit A.1a shows the estimated annualized burden hours for the respondents' time to complete the Practice Facilitator Focus Groups and Practice Leader/Staff Semi-Structured Interviews. For the three-year clearance period, the estimated annualized burden hours for the interviews are $2,190.50.

EXHIBIT A.1a—ESTIMATED ANNUALIZED BURDEN HOURS

| Form name | Number of respondents | Number of responses per respondent | Hours per response | Total burden hours |
|---|---|---|---|---|
| Practice Facilitator Focus Groups | 45 | 1 | 1 | 45 |
| Practice Leader/Staff Semi-Structured Interviews | 45 | 1 | 1 | 45 |
| Total | 90 | N/A | N/A | 90 |

EXHIBIT A.1b—ESTIMATED ANNUALIZED COST BURDEN

| Form name | Number of respondents | Total burden hours | Average hourly wage rate * | Total cost burden |
|---|---|---|---|---|
| Practice Facilitator Focus Groups | 45 | 45 | [a] $28.01 | $1,260.45 |
| Practice Leader/Staff Semi-Structured Interviews | 45 | 45 | [a] 28.01 | 1,260.45 |
| Total | 90 | 90 | 24.34 | 2,520.90 |

* Mean hourly wage for All Occupations (00–0000).

Occupational Employment Statistics, May 2021 National Occupational Employment and Wage Estimates United States, U.S. Department of Labor, Bureau of Labor Statistics.

**Request for Comments**

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: October 24, 2022.

**Marquita Cullom,**

*Associate Director.*

[FR Doc. 2022–23506 Filed 10–27–22; 8:45 am]

**BILLING CODE 4160–90–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifier: CMS–10830]**

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by December 27, 2022.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

**FOR FURTHER INFORMATION CONTACT:** William N. Parham at (410) 786–4669.

**SUPPLEMENTARY INFORMATION:**

**Contents**

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10830—Data Collection to Support CMS Burden Reduction and Health Informatics Efforts

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

**Information Collection**

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Data Collection to Support CMS Burden Reduction and Health Informatics Efforts; *Use:* CMS seeks to establish a generic clearance that will be used to permit quick turnaround data collection projects that support CMS efforts to infuse customer perspectives, apply innovative solutions, advance standards and information technology (IT) interoperability, advance health equity, and respond to emerging priorities. CMS will utilize a range of methodologies through this generic clearance including surveys, focus groups, stakeholder/key informant interviews, cognitive interviews, site visits, and usability testing. Data collected under this generic clearance will support CMS and OBRHI efforts to reduce the burden of CMS regulations, sub-regulations, and policies as well as increasing the use of digital health tools to improve the customer experience. Obtaining feedback from CMS stakeholders is a core component of OBRHI's work to assist CMS in improving service delivery.

*Form number:* CMS–10830 (OMB control number: 0938–New); *Frequency:* Occasionally; *Affected Public:* Private Sector (Businesses or other for-profits and Not-for-profit institutions); *Number of Respondents:* 15,648; *Number of Responses:* 15,648; *Total Burden Hours:* 5,034. (For questions regarding this collection contact Réna McClain at 410–786–3975).

Dated: October 24, 2022.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2022–23485 Filed 10–27–22; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifier: CMS–10731, CMS–10825 and CMS–10439]**

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden,

ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by December 27, 2022.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

**FOR FURTHER INFORMATION CONTACT:** William N. Parham at (410) 786–4669.

**SUPPLEMENTARY INFORMATION:**

**Contents**

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10731 Generic Clearance for CMS and Medicare Administrative Contractor (MAC) Generic Customer Experience

CMS–10825 List of Screening Instruments for Housing Stability, Food Security, and Transportation Questions on Health Risk Assessments

CMS–10439 Data Collection to Support Eligibility Determinations for Small Businesses in the Small Business Health Options Program

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

**Information Collection**

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Generic Clearance for CMS and Medicare Administrative Contractor (MAC) Generic Customer Experience; *Use:* The Centers for Medicare & Medicaid Services (CMS) is requesting approval to collect generic feedback from respondents including, but not limited to Medicare providers, Medicare suppliers, provider or supplier staff, billers, credentialing agencies, researchers, clearinghouses, consultants, and attorneys. These surveys will give us insights into customers' perceptions and opinions and will be used to improve customer experiences and communications materials; however, the results will not be generalized to the population of study.

Improving agency programs requires ongoing systemic review of service delivery and program operations compared to defined standards. We'll use multiple methods to collect, analyze, and interpret information from this generic clearance to find the strengths and weaknesses of our current services. We'll use this feedback to inform process improvements or maintain service quality offered to providers and stakeholders. *Form Number:* CMS–10731 (OMB control number: 0938–New); *Frequency:* Occasionally; *Affected Public:* Private sector (business or other for-profits); *Number of Respondents:* 997,100; *Total Annual Responses:* 997,100; *Total Annual Hours:* 50,000. (For policy questions regarding this collection contact Alyssa Schaub-Rimel at 410–786–4660.)

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* List of Screening Instruments for Housing Stability, Food Security, and Transportation Questions on Health Risk Assessments; *Use:* This information collection request is for the new regulation at 42 CFR 422.101(f)(1)(i) requiring that all MA SNP health risk assessments (HRAs) include at least one question from a list of screening instruments specified by CMS in sub-regulatory guidance on each of three domains (housing stability, food security, and access to transportation) beginning in CY 2024. This new requirement will help better identify the risk factors that may inhibit enrollees from accessing care and achieving optimal health outcomes and independence and enable MA SNPs to take these risk factors into account in enrollee individualized care plans. This information collection request provides the list of CMS-specified Social Determinants of Health (SDOH) screening instruments available for SNPs to meet the new requirement.

We note that the scope of the information collection currently approved under OMB control number 0938–1422 (CMS–10799) listed in the January 2022 proposed rule was too broad to include a discussion of the new regulation at 42 CFR 422.101(f)(1)(i) and the information collection requirements contained therein. Also, we did not finalize our proposal to require SNPs to use a standardized set of questions based on comments received from on the January 2022 proposed rule titled ''Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs'' (87 FR 1842). Therefore, in accordance with the implementing regulations of the PRA at 5 CFR 1320, we did not include this information collection in OMB control number 0938–1422 (CMS–10799) and are conducting a standard PRA clearance process to obtain public comment on the list of SDOH screening instruments described in the May 2022 final rule. *Form Number:* CMS–10731 (OMB control number: 0938-New); *Frequency:* Occasionally; *Affected Public:* Private sector (business or other for-profits); *Number of Respondents:* 174; *Total Annual Responses:* 174; *Total Annual Hours:* 167. (For policy questions regarding this collection contact Michelle Conway at 202–260–7752.)

3. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Data Collection to Support Eligibility Determinations for Small Businesses in the Small Business

Health Options Program; *Use:* On March 23, 2010, the President signed into law H.R. 3590, the Patient Protection and Affordable Care Act, Public Law 111–148, as amended by the Health Care and Education Reconciliation Act of 2010, Public Law 111–152. The Patient Protection and Affordable Care Act (PPACA) expands access to health insurance coverage through improvements to the Medicaid and Children's Health Insurance (CHIP) programs, the establishment of Affordable Insurance Exchanges (Exchanges), and the coordination between Medicaid, CHIP, and Exchanges. Small business employers may participate in and provide health coverage through the Small Business Health Options Program (SHOP), so long as the small business employer obtains a positive eligibility determination from SHOP. Employers will work with SHOP-registered agents/brokers or Issuers offering Qualified Health Plans (QHPs) and Qualified Dental Plans (SADPs), to enroll in SHOP coverage and to select coverage options to offer their employees. SHOP Exchanges became operational on October 1, 2013.

HHS has developed a single, streamlined form that employers use to obtain a SHOP eligibility determination, which is included as an appendix to this Information Collection Request. 45 CFR 155.731 provides more detail about this ''single employer application,'' which is used to determine employer eligibility. Since publication of the last package, no updates have been made in regulation concerning what information should be collected on the single employer application to determine employer eligibility under 45 CFR 155.731. When an employer completes the SHOP Eligibility Determination Form, the form and its results are retained by SHOP for future use, if needed (*e.g.,* reconciliation with issuer records, SHOP employer appeals, etc.). *Form Number:* CMS–10439 (OMB control number 0938–1193); *Frequency:* Annually; *Affected Public:* Private Sector (business or other for-profits, not-for-profit institutions); *Number of Respondents:* 2,100; *Number of Responses:* 2,100; *Total Annual Hours:* 336. (For questions regarding this collection contact Elliot Klein at 410–786–0415).

Dated: October 25, 2022.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2022–23553 Filed 10–27–22; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Community Living

### Agency Information Collection Activities: Proposed Collection; Public Comment Request; Evaluation of the National Paralysis Resource Center (NPRC) and Performance Management Support, OMB Control Number 0985–New

**AGENCY:** Administration for Community Living, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This information collection (IC) request solicits comments on the information collection requirements relating to the Evaluation of the National Paralysis Resource Center (NPRC) and Performance Management Support.

**DATES:** Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by December 27, 2022.

**ADDRESSES:** Submit electronic comments on the collection of information to: Amanda Cash, 202–795–7369 *Amanda.Cash@acl.hhs.gov.* Submit written comments on the collection of information to Administration for Community Living, 330 C Street SW, Washington, DC 20201, Attention: Amanda Cash.

**FOR FURTHER INFORMATION CONTACT:** Amanda Cash, 202–795–7369, *Amanda.Cash@acl.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. The PRA requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

(1) whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility.

(2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates.

(3) ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

The Administration for Community Living (ACL) is conducting process and outcome evaluations of the National Paralysis Resource Center (NPRC) to understand how and to what extent the NPRC is meeting its goals. The NPRC provides resources to people living with paralysis, their caregivers, and their support network. ACL is responsible for oversight of the NPRC, which has been administered by the Christopher and Dana Reeve Foundation since its authorization in 2009. This data collection effort will be focused on evaluating specific major activities of the NPRC: (a) the Quality of Life (QOL) Grants Program; (b) the Peer and Family Support Program (PFSP); and (c) the Promotional Activities, Outreach, and Collaboration program. This evaluation seeks to identify barriers and challenges to operating the NPRC, document best practices for other Resource Centers, and recommend areas for improvement.

Specifically, this IC will help ACL to understand *how* each major NPRC activity aims to achieve the following goals, and *to what extent* the activities affect related outcomes:

a. Improving the health and quality of life of individuals living with paralysis of all ages, their families, and their support network
b. Raising awareness of members of the target populations about paralysis

c. Increasing access of members of the target populations to services relevant to individuals with paralysis
d. Increasing the empowerment, confidence, and independence of individuals living with paralysis
e. Strengthening support networks for individuals living with paralysis
f. Improving and increasing opportunities for community living for individuals living with paralysis and their caretakers

To gain an in-depth understanding of the perspectives of mentors and peers participating in the PFSP, QOL program subgrantees, and people who serve as regional champions in the Promotional Activities, Outreach, and Collaboration program, eight focus groups will be conducted with no more than eight people per focus group. Additionally, a web-based survey will be administered to a maximum of 330 PFSP peers, 150 PFSP mentors, and 850 people served by QOL subgrantees to understand respondents' experiences with the NPRC.

This data will contribute to documenting how each of the NPRC's major activities are delivered and the extent to which they improve the quality of life of people living with paralysis, their caregivers, and their support networks.

Findings can inform practice for the NPRC and other Resource Centers. This evaluation will also help to identify how the NPRC can better meet the stated goals of the Department of Health and Human Services (HHS) to, ''protect and strengthen equitable access to high quality and affordable healthcare,'' and to, ''strengthen social well-being, equity, and economic resilience.'' [1]

The proposed data collection tools may be found on the ACL website for review at: *https://www.acl.gov/about-acl/public-input.*

*Estimated Program Burden:* ACL estimates the burden of this collection of information as follows:

The eight focus groups together will include no more than 64 total individuals representing three major activities of the NPRC: the QOL Grants Program; the PFSP; and the Promotional Activities, Outreach, and Collaboration program. The burden for their participation is estimated at 1.5 hours per participant, for a total of 96 hours.

A maximum of 150 PFSP mentors, 330 PFSP peers, and 850 people served by QOL subgrantee programs are expected to respond to the web-based survey, for a total of 1,330 respondents. The approximate burden for survey completion is 15 minutes for the peer mentor survey, and 10 minutes for the peer survey and QOL end-user survey per respondent.

This results in a total survey burden estimate of 14,050 minutes (234.17 hours). The estimated survey completion burden includes time to review the instructions, read the questions, and complete responses.

| Respondent/data collection activity | Number of respondents | Responses per respondent | Hours per response | Annual burden hours * |
|---|---|---|---|---|
| Focus groups | 64 | 1 | 1.50 | 96.00 |
| Survey—Peer Mentor | 150 | 1 | 0.25 | 37.50 |
| Survey—Peers | 330 | 1 | 0.17 | 55.00 |
| Survey—Quality of Life End-User | 850 | 1 | 0.17 | 141.67 |
| Total | 1,394 | 1 | 2.09 | 330.17 |

* Annual burden hours were calculated from total minutes for each activity divided by sixty.

Dated: October 24, 2022.

**Alison Barkoff,**

*Acting Administrator and Assistant Secretary for Aging.*

[FR Doc. 2022–23484 Filed 10–27–22; 8:45 am]

**BILLING CODE 4154–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2022–D–1261]**

### Clostridioides difficile Infection: Developing Drugs for Treatment, Reduction of Recurrence, and Prevention; Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''*Clostridioides difficile* Infection: Developing Drugs for Treatment, Reduction of Recurrence, and Prevention.'' The purpose of this draft guidance is to assist sponsors in the clinical development of drugs for the treatment of *Clostridioides difficile* infection (CDI), reduction of recurrence, or prevention of CDI.

**DATES:** Submit either electronic or written comments on the draft guidance by December 27, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

[1] *FY 2023 Evaluation Plan* (p. 3). (2022). U.S. Department of Health & Human Services. *https://aspe.hhs.gov/reports/fy-2023-hhs-evaluation-plan.*

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* All submissions received must include the Docket No. FDA–2022–D–1261 for ''*Clostridioides difficile* Infection: Developing Drugs for Treatment, Reduction of Recurrence, and Prevention.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Ramya Gopinath, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6154, Silver Spring, MD 20993, 240–402–5328.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''*Clostridioides difficile* Infection: Developing Drugs for Treatment, Reduction of Recurrence, and Prevention.'' The purpose of this draft guidance is to assist sponsors in the clinical development of drugs for treatment, reduction of recurrence, or prevention of CDI. Specifically, this guidance addresses FDA's current thinking regarding clinical trial design considerations such as trial populations and efficacy endpoints for treatment of CDI, reduction of recurrence, and prevention.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''*Clostridioides difficile* Infection: Developing Drugs for Treatment, Reduction of Recurrence, and Prevention.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information relating to regulations found in 21 CFR parts 58, 312, 314, and 601 have been approved under OMB control numbers 0910–0119, 0910–0014, 0910–0001, and 0910–0338, respectively.

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov*.

Dated: October 24, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–23457 Filed 10–27–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket Nos. FDA–2013–N–0370; FDA–2011–D–0893; and FDA–2013–N–0093]**

### Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information

collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

| Title of collection | OMB control No. | Date approval expires |
|---|---|---|
| Infant Formula Requirements | 0910–0256 | 3/31/2023 |
| Export of Medical Devices; Foreign Letters of Approval | 0910–0264 | 10/31/2025 |
| Center for Devices and Radiological Health Appeals Processes | 0910–0738 | 10/31/2025 |
| Review Transparency & Communication for New Molecular Entity NDAs & Original BLAs | 0910–0746 | 10/31/2025 |

Dated: October 24, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–23510 Filed 10–27–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Enrollment and Re-Certification of Covered Entities in the 340B Drug Pricing Program, OMB Number 0915–0327—Revision.

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

**DATES:** Comments on this ICR should be received no later than November 28, 2022.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the Acting HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–9094.

**SUPPLEMENTARY INFORMATION:**

*Information Collection Request Title:* Enrollment and Re-Certification of Covered Entities in the 340B Drug Pricing Program, OMB No. 0915–0327—Revision.

*Abstract:* Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service (PHS) Act, which instructs HHS to enter into a Pharmaceutical Pricing Agreement (PPA) with manufacturers of covered outpatient drugs. Manufacturers are required by section 1927(a)(5)(A) of the Social Security Act to enter into agreements with the Secretary of HHS (Secretary) that comply with section 340B of the PHS Act if they participate in the Medicaid Drug Rebate Program. When a drug manufacturer signs a PPA, it is opting into the 340B Drug Pricing Program (340B Program), and it agrees to the statutory requirement that prices charged for covered outpatient drugs to covered entities will not exceed statutorily defined 340B ceiling prices. When an eligible covered entity voluntarily decides to enroll and participate in the 340B Program, it accepts responsibility for ensuring compliance with all provisions of the 340B Program, including all associated costs. Covered entities that choose to participate in the 340B Program must comply with the requirements of section 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) of the PHS Act prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate. Further, section 340B(a)(5)(B) of the PHS Act prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the covered entity. A 60-day notice was published in the **Federal Register** on June 14, 2022, vol. 87, No. 114; pp. 35983–85. There were five comments. Some comments addressed policy issues that are outside the scope of this information collection request. HRSA responded to technical comments that pertained to the ICR and revised the draft instruments based on the comments received.

*Need and Proposed Use of the Information:* To ensure the ongoing responsibility to administer the 340B Program while maintaining efficiency, transparency and integrity, HRSA developed a process of registration for covered entities to enable it to address specific statutory mandates. Specifically, section 340B(a)(9) of the PHS Act requires HRSA to notify manufacturers of the identities of covered entities and of their status pertaining to certification and annual recertification in the 340B Program pursuant to section 340B(a)(7) and the establishment of a mechanism to prevent duplicate discounts as outlined at section 340B(a)(5)(A)(ii) of the PHS Act.

In addition, section 340B(a)(1) of the PHS Act requires each participating manufacturer to enter into an agreement with the Secretary in order to offer covered outpatient drugs to 340B covered entities.

Finally, section 340B(d)(1)(B)(i) of the PHS Act requires the development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities.

HRSA is requesting approval for existing information collections. HRSA notes that the previously approved collections are mostly unchanged, except several forms have been revised to increase program efficiency and integrity. Below are descriptions of each of the forms and revisions that are captured in both the registration and pricing component of the 340B Office of Pharmacy Affairs Information System (OPAIS).

**Enrollment/Registration/Recertification**

To enroll and certify the eligibility of federally funded grantees and other safety net health care providers, HRSA requires covered entities to submit administrative information (*e.g.,* shipping and billing arrangements, Medicaid participation), certifying information (*e.g.,* Medicare Cost Report information, documentation supporting the hospital's selected classification), and attestation from appropriate grantee level or covered entity level authorizing officials and primary contacts. To maintain accurate records, HRSA requests covered entities submit modifications to any administrative information that they submitted when initially enrolling into the 340B Program. Covered entities participating in the 340B Program have an ongoing responsibility to immediately notify HRSA in the event of any change in eligibility for the 340B Program. No less than on an annual basis, covered entities need to certify the accuracy of the information provided and continued maintenance of their eligibility and to comply with statutory mandates of the 340B Program.

Registration and annual recertification information is entered into the 340B OPAIS by covered entities and verified by HRSA staff according to 340B Program requirements. In response to the comments received, HRSA has made technical and other revisions to the draft instruments and discusses the revisions below.

1. 340B Program Registrations & Recertifications for Hospitals (applies to all hospital types): In September 2017, HRSA launched 340B OPAIS, which among other things, removed the attestation requirement from the Government Official for the classification of a parent hospital, but it was still required for the covered entity to enter the Government Official contact information. As covered entities are no longer required to obtain this attestation, HRSA is removing the requirement for the covered entity to enter the Government Official contact information in 340B OPAIS. During the first public review of this ICR, commenters agreed with removing the Government Official contact information for a parent hospital.

2. 340B Registrations & Recertifications for Ryan White Covered Entities: Previously, HRSA requested that Ryan White covered entities provide a Notice of Funding Opportunity (NOFO) number at the time of registration and recertification. After reevaluation, HRSA has determined that the NOFO number is an unnecessary component to determine the eligibility of a Ryan White covered entity's registration. Since the NOFO number correlates to the Ryan White covered entity's Federal Grant Number, which is already required to be entered in 340B OPAIS during registration, the NOFO number is not needed. During the first public review of this ICR, commenters agreed with removing the requirement for Ryan White covered entities to provide a NOFO number at the time of registration and recertification.

3. 340B Registration, Recertification & Change Requests for Shipping Address: In the 60-day notice (87 FR 35,983, June 14, 2022), HRSA proposed to include clarifying information for covered entities to complete the shipping address section in 340B OPAIS. This information was added to assist covered entities in determining the exact shipping address location and relationship to the covered entity. In response to comments submitted during the first public review of this ICR, HRSA is removing this section from the instrument and will plan to release guidance on shipping address locations in the future.

4. 340B Program Registrations, Recertifications & Change Requests for Hospitals (applies to rural referral centers and sole community hospital covered entity types): HRSA proposed to revise the 340B OPAIS registration for the rural referral centers and sole community hospital covered entity types. If applicable, 340B OPAIS will prompt the covered entity for documentation that supports eligibility, which will be attached as part of its registration, recertification or change request submission. Currently, the request for the supporting eligibility documentation is obtained during the submission review process; therefore, this requirement would not change the burden on the covered entities.

5. 340B Program Registrations and Recertification for Authorizing Official Certification/Attestation: In the 60-day notice (87 FR 35,983, June 14, 2022), HRSA proposed to make revisions to the Authorizing Official certification by removing the requirement that any contract pharmacy arrangement is performed in accordance with OPA requirements and guidelines. Several commenters questioned why HRSA was removing this statement from the Authorizing Official's certification of a covered entity's registration or recertification in the 340B Program. HRSA removed this information as it was duplicative with information found on other instruments (*e.g.,* the contract pharmacy registration form) and already existed on the registration and recertification documentation. HRSA believes that this revision will reduce burden on covered entities.

6. 340B Program Change Requests for Hospitals: HRSA proposed inclusion of hospital qualification information such as, the Disproportionate Share Adjustment Percentage, control type, hospital classification, and contract start date to be changed under a change request submission as well as during recertification. This requirement would not change the burden on the covered entities, as this is an option to change the information by the hospital.

7. 340B Primary Contact and Authorizing Official Information: HRSA removed the FAX number field. This does not change the burden on covered entities, as this was an optional field.

8. 340B Program Recertifications & Change Requests for Hospitals: HRSA proposed clarifying when a covered entity would initiate a name change in 340B OPAIS. If applicable, 340B OPAIS will prompt the covered entity for documentation that supports the name change, which will be attached as part of its recertification or change request submission. In response to comments received, HRSA has made general technical and editorial revisions to this instrument.

9. Medicaid Billing Information: In the 60-day notice (87 FR 35,983, June 14, 2022), HRSA proposed to make a minor clarification regarding whether a 340B drug to an outpatient at a pharmacy or as part of a medical encounter. In response to comments submitted during the first public review of this ICR and after further consideration, HRSA is removing this section from the instrument and will plan to release future guidance on this issue.

**Contract Pharmacy Certification**

In order to ensure that drug manufacturers and drug wholesalers recognize contract pharmacy arrangements, covered entities that elect to utilize one or more contract pharmacies are required to submit general information about their contract pharmacy arrangements and certify that signed agreements are in place with those contract pharmacies.

**Pharmaceutical Pricing Agreement and Addendum**

Section 340B(a)(1) of the PHS Act provides that a manufacturer who sells covered outpatient drugs to eligible covered entities must sign a Pharmaceutical Pricing Agreement (the ''Agreement'') with the Secretary in which the manufacturer agrees to charge a price for covered outpatient drugs that

will not exceed the average manufacturer price (''AMP'') decreased by a rebate percentage. In addition, section 340B(a)(1) of the PHS Act includes specific requirements, which have been incorporated in the PPA with manufacturers of covered outpatient drugs. In particular, section 340B(a)(1) includes the following requirements:

I. ''Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the ''ceiling price'') and

II. ''. . . shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.''

The burden imposed on manufacturers by submission of the PPA and PPA Addendum is low as the information is readily available.

**Pricing Data Submission, Validation and Dissemination**

In order to implement section 340B(d)(1)(B)(i)(II) of the PHS Act, HRSA developed a system to calculate 340B ceiling prices prospectively from data obtained from the Centers for Medicare & Medicaid Services as well as a third-party commercial database. However, in order to conduct the comparison required under the statute, manufacturers must submit the quarterly pricing data as required by section 340B(d)(1)(B)(i)(II). The 340B OPAIS securely collects the following data from manufacturers on a quarterly basis: AMP, unit rebate amount, package size, case pack size, unit type, national drug code, labeler code, product code, period of sale (year and quarter), Food and Drug Administration product name, labeler name, wholesale acquisition cost, and the manufacturer determined ceiling price for each covered outpatient drug produced by a manufacturer subject to a PPA. The burden imposed on manufacturers is low because the information requested is readily available and utilized by manufacturers in other areas.

*Likely Respondents:* Drug manufacturers and covered entities.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

| Form name | Number of respondents | Number of responses per respondent | Total responses | Hours per respondent | Total burden hours |
|---|---|---|---|---|---|
| **Hospital Enrollment, Additions & Recertifications** | | | | | |
| 340B Program Registrations & Certifications for Hospitals * | 131 | 1 | 131 | 2.00 | 262 |
| Certifications to Enroll Hospital Outpatient Facilities * | 620 | 7 | 4340 | 0.50 | 2170 |
| Hospital Annual Recertifications * | 2618 | 10 | 26180 | 0.25 | 6545 |
| **Registrations and Recertifications for Covered Entities Other Than Hospitals** | | | | | |
| 340B Registrations for Community Health Centers * | 679 | 1 | 679 | 1.00 | 679 |
| 340B Registrations for STD/TB Clinics * | 864 | 1 | 864 | 1.00 | 864 |
| 340B Registrations for Various Other Eligible Covered Entity Types * | 166 | 1 | 166 | 1.00 | 166 |
| Community Health Center Annual Recertifications * | 1277 | 7 | 8939 | 0.25 | 2235 |
| STD & TB Annual Recertifications * | 4033 | 1 | 4033 | 0.25 | 1008 |
| Annual Recertification for covered entities other than Hospitals, Community Health Centers, and STD/TB Clinics * | 4472 | 1 | 4472 | 0.25 | 1118 |
| **Contracted Pharmacy Services Registration & Recertifications** | | | | | |
| Contracted Pharmacy Services Registration | 3446 | 11 | 37906 | 1.00 | 37906 |
| **Other Information Collections** | | | | | |
| Submission of Administrative Changes for any Covered Entity * | 19322 | 1 | 19322 | 0.25 | 4831 |
| Submission of Administrative Changes for any Manufacturer * | 350 | 1 | 350 | 0.50 | 175 |
| Pharmaceutical Pricing Agreement and PPA Addendum | 200 | 1 | 200 | 1.00 | 200 |
| Total | 38,178 | | 99,542 | | 58,159 |

* Minor revisions since last the OMB submission, but burden was not affected.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information

technology to minimize the information collection burden.

**Maria G. Button,**

*Director, Executive Secretariat.*

[FR Doc. 2022–23518 Filed 10–27–22; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Allergy and Infectious Diseases Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Allergy and Infectious Diseases Special Emphasis Panel, which was published in the **Federal Register** on October 11, 2022, FR Doc 2022–22017, 87 FR 61342.

Amendment to change panel name from NIAID Clinical Trial Planning Grant (R34 Clinical Trial Not Allowed) to NIAID Clinical Trial Planning Grant (R34 Clinical Trial Not Allowed) and Implementation Cooperative Agreement (U01 Clinical Trial Required). The meeting is closed to the public.

Dated: October 25, 2022.

**Tyeshia M. Roberson-Curtis,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2022–23541 Filed 10–27–22; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Allergy and Infectious Diseases; Amended Notice of Closed Meeting

Notice is hereby given of a change in the meeting of the National Institute of Allergy and Infectious Diseases Special Emphasis Panel NIAID Investigator Initiated Program Project Applications (P01 Clinical Trial Not Allowed) which was published in the **Federal Register** on September 30, 2022, FR Doc 2022–21261, 87 FR 59446.

Amendment to change meeting date from October 26, 2022, to November 14, 2022. The meeting is closed to the public.

Dated: October 25, 2022.

**Tyeshia M. Roberson-Curtis,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2022–23540 Filed 10–27–22; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Environmental Health Sciences; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, NIEHS.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend as well as those who need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting website (*http://videocast.nih.gov/*).

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Board of Scientific Counselors, NIEHS.

*Date:* December 4, 2022.

*Closed:* 7:00 p.m. to 8:30 p.m.

*Agenda:* Discussion of BSC Reviews.

*Place:* National Institute of Environmental Health Science, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

*Open:* December 5, 2022, 9:00 a.m. to 12:05 p.m.

*Agenda:* Meeting Overview and Q & A Sessions (Calcium Signaling in Health & Disease Group, Inositol Signaling Group, and Molecular Endocrinology Group).

*Place:* National Institute of Environmental Health Science, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

*Closed:* December 5, 2022, 12:05 p.m. to 1:05 p.m.

*Agenda:* To review and evaluate personnel qualifications and performance, and competence of individual investigators.

*Place:* National Institute of Environmental Health Science, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

*Open:* December 5, 2022, 1:05 p.m. to 2:45 p.m.

*Agenda:* Q & A Sessions (Nucleolar Integrity Group and Metabolism, Genes and Environment Group).

*Place:* National Institute of Environmental Health Science, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

*Closed:* December 5, 2022, 3:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate personnel qualifications and performance, and competence of individual investigators.

*Place:* National Institute of Environmental Health Science, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

*Open:* December 5, 2022, 4:00 p.m. to 4:50 p.m.

*Agenda:* Q & A Sessions (In Vivo Neurobiology Group and Neurobiology Group).

*Place:* National Institute of Environmental Health Science, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

*Closed:* December 5, 2022, 4:50 p.m. to 5:05 p.m.

*Agenda:* To review and evaluate personnel qualifications and performance, and competence of individual investigators.

*Place:* National Institute of Environmental Health Science, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

*Open:* December 6, 2022, 8:45 a.m. to 9:35 a.m.

*Agenda:* Q & A Session (Mechanism of Mutation Group and Genome Integrity & Structural Biology Group).

*Place:* National Institute of Environmental Health Science, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

*Closed:* December 6, 2022, 9:50 a.m. to 10:05 a.m.

*Agenda:* To review and evaluate personnel qualifications and performance, and competence of individual investigators.

*Place:* National Institute of Environmental Health Science, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

*Open:* December 6, 2022, 10:05 a.m. to 12:00 p.m.

*Agenda:* Poster Session.

*Place:* National Institute of Environmental Health Science, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

*Closed:* December 6, 2022, 1:00 p.m. to 5:30 p.m.

*Agenda:* Session with Fellows and Staff Scientists; Review of Flow Cytometry Center Molecular Genomics Core Laboratory and Fluorescence Microscopy and Imaging Center; BSC Discussion & completion of Individual Review Assignments; Debriefing to NIEHS/DIR Leadership.

*Place:* National Institute of Environmental Health Science, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709 (Hybrid Meeting).

*Contact Person:* Darryl C. Zeldin, Scientific Director & Principal Investigator, Division of Intramural Research, National Institute of Environmental Sciences, NIH, 111 T. W. Alexander Drive, Mail drop MSC A2–09, Research Triangle Park, NC 27709, 919–541–1169, *zeldin@niehs.nih.gov*.

Any interested person may file written comments with the committee by forwarding

the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has procedures at *https://www.nih.gov/about-nih/visitor-information/campus-access-security* for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

*Additional Health and Safety Guidance:* Before attending a meeting at an NIH facility, it is important that visitors review the NIH COVID–19 Safety Plan at *https://ors.od.nih.gov/sr/dohs/safety/NIH-covid-19-safety-plan/Pages/default.aspx* and the NIH testing and assessment web page at *https://ors.od.nih.gov/sr/dohs/safety/NIH-covid-19-safety-plan/COVID-assessment-testing/Pages/visitor-testing-requirement.aspx* for information about requirements and procedures for entering NIH facilities, especially when COVID–19 community levels are medium or high. In addition, the Safer Federal Workforce website has FAQs for visitors at *https://www.saferfederalworkforce.gov/faq/visitors/.* Please note that if an individual has a COVID–19 diagnosis within 10 days of the meeting, that person must attend virtually. (For more information please read NIH's Requirements for Persons after Exposure at *https://ors.od.nih.gov/sr/dohs/safety/NIH-covid-19-safety-plan/COVID-assessment-testing/Pages/persons-after-exposure.aspx* and What Happens When Someone Tests Positive at *https://ors.od.nih.gov/sr/dohs/safety/NIH-covid-19-safety-plan/COVID-assessment-testing/Pages/test-positive.aspx.* Anyone from the public can attend the open portion of the meeting virtually via the NIH Videocasting website (*http://videocast.nih.gov*). Please continue checking these websites, in addition to the committee website listed below, for the most up to date guidance as the meeting date approaches.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: October 24, 2022.

**David Freeman,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2022–23452 Filed 10–27–22; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Board on Medical Rehabilitation Research.

The meeting will be held as a virtual meeting and is open to the public. Individuals who plan to view the virtual meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting will be videocast and can be accessed from the NIH Videocasting website (*http://videocast.nih.gov*).

*Name of Committee:* National Advisory Board on Medical Rehabilitation Research.

*Date:* December 5–6, 2022.

*Time:* December 5, 2022, 10:00 a.m. to 5:00 p.m.

*Agenda:* NICHD Director's report; NCMRR Director's report; Update from NABMRR Liaison to the NICHD Advisory Council; STRIVE Action Plan update; Report from NABMRR Research Infrastructure Working Group; Discussion of Stakeholder Engagement; Research Talk: Cognitive Rehabilitation and the use of Virtual Reality.

*Place:* Eunice Kennedy Shriver National Institute of Child, Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2116, Bethesda, MD 20892–7510 (Virtual Meeting).

*Time:* December 6, 2022, 10:00 a.m. to 2:00 p.m.

*Agenda:* Updates from NIDILRR; NIH Policy Updates; Global Health and World Disability Day; Discussion on Telerehabilitation; Planning for Next Board Meeting in May 2023.

*Place:* Eunice Kennedy Shriver National Institute of Child, Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2116, Bethesda, MD 20892–7510 (Virtual Meeting).

*Contact Person:* Ralph M. Nitkin, Ph.D., Deputy, National Center for Medical Rehabilitation, and Director, Biological Sciences and Career Development Program, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2116, Bethesda, MD 20892–7510, (301) 402–4206, *nitkinr@mail.nih.gov*.

Information is also available on the Institute's/Center's home page: *https://www.nichd.nih.gov/about/advisory/nabmrr,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: October 24, 2022.

**David W. Freeman,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2022–23453 Filed 10–27–22; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

**[Docket No. USCG–2019–0882]**

### BNSF Railway Bridge Across the Missouri River Between Bismarck and Mandan, North Dakota; Final Environmental Impact Statement

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of availability for a Final Environmental Impact Statement.

**SUMMARY:** The Coast Guard announces the availability of a Final Environmental Impact Statement (EIS) for the proposed replacement of the BNSF Railway Bridge across the Missouri River between Bismarck and Mandan, North Dakota. This was prepared in compliance with the National Environmental Policy Act of 1969 (NEPA) and Council on Environmental Quality implementing regulations, and the National Historic Preservation Act (NHPA). This final EIS evaluates the potential environmental consequences of permitting the replacement of the existing BNSF Railway Bridge across the Missouri River between the cities of Bismarck and Mandan, ND, or the construction of a bridge adjacent to the existing bridge. The applicant proposes to remove the existing structure, which is eligible for listing on the National Register of Historic Places. The Coast Guard analyzed proposed alternatives, through the NEPA and NHPA processes, which included alternatives to construct the new bridge while retaining the existing bridge. The Coast Guard is making the final EIS available to the public on this docket. Section 4.0 of the final EIS identifies the preferred alternative, which is to construct a new bridge with 200-foot spans, and piers 20 feet upstream of the existing bridge, and to remove the existing structure.

**DATES:** The Coast Guard intends to issue a Record of Decision on November 28, 2022.

**FOR FURTHER INFORMATION CONTACT:** For information about this document call or

email Rob McCaskey, Coast Guard District 8 Project Officer; telephone: 314–269–2381, or email: *HQS-SMB-CG-BRG@uscg.mil.*

**Discussion**

On January 8, 2020, the Coast Guard published a notice of intent to prepare an EIS (85 FR 930). On June 7, 2021, we published a notice of availability for a draft EIS seeking public comments, and announcement of a virtual meeting (86 FR 30323) for the BNSF Railway Bridge across the Missouri River between the cities of Bismarck and Mandan, ND. Lastly, on June 14, 2021, we published a notice of extension to the public comment period (86 FR 31509), which extended the comment period to July 26, 2021.

The notice of availability solicited substantive and relevant comments related to the draft EIS. On June 30, 2021, the Coast Guard held a virtual public meeting to receive written and oral comments on the draft EIS. Public comments yielded very few substantive changes. We are now providing notice of the availability of the final EIS.

We developed a final EIS that addresses impacts associated with the alternatives mentioned in section 2.0 of the draft EIS. These impacts include those environmental control laws listed in appendix B of the Coast Guard's Bridge Permit Application Guide (available at *https://www.dco.uscg.mil/Portals/9/DCO%20Documents/5pw/Office%20of%20Bridge%20Programs/BPAG%20COMDTPUB%20P16591%203D_Sequential%20Clearance%20Final(July2016).pdf*), as well as those impacts associated with floodplain rise, impacts to the Bismarck Water Reservoir and the Missouri River Natural Area. The final EIS also includes responses to all substantive and relevant comments received during the public comment period and virtual public meeting.

The Coast Guard, as lead agency, held 21 consultation meetings with stakeholders to satisfy the requirements of section 106 of the NHPA (54 U.S.C. 306108). On January 15, 2021, the Coast Guard and consulting parties signed a Programmatic Agreement to address the adverse effect on the existing historic bridge, and to provide third parties the opportunity to develop additional alternatives that would allow for retention of the bridge. The additional alternative presented during this process was not technically or economically feasible, so the Coast Guard and consulting parties developed a Memorandum of Agreement, which dictates mitigation measures for removal of the existing bridge. A consulting party, the Friends of the Rail Bridge, initiated termination of the Programmatic Agreement on February 22, 2022, and after additional consultation meetings, it was terminated on June 19, 2022. The Memorandum of Agreement was signed on September 27, 2022, and is available in appendix B of the final EIS.

This notice is issued under authority of NEPA, 42 U.S.C. 4321 *et seq.,* Council on Environmental Quality implementing regulations in 40 CFR parts 1500 through 1508, and 5 U.S.C. 552(a).

**Brian L. Dunn,**

*Chief, U.S. Coast Guard, Office of Bridge Programs.*

[FR Doc. 2022–23466 Filed 10–27–22; 8:45 am]

**BILLING CODE 9110–04–P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Docket ID FEMA–2022–0002; Internal Agency Docket No. FEMA–B–2283]**

### Proposed Flood Hazard Determinations

**AGENCY:** Federal Emergency Management Agency, Department of Homeland Security.

**ACTION:** Notice.

**SUMMARY:** Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

**DATES:** Comments are to be submitted on or before January 26, 2023.

**ADDRESSES:** The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location *https://hazards.fema.gov/femaportal/prelimdownload* and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–2283, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

**FOR FURTHER INFORMATION CONTACT:** Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

**SUPPLEMENTARY INFORMATION:** FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution

process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *https://www.floodsrp.org/pdfs/srp_overview.pdf*.

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location *https://hazards.fema.gov/femaportal/prelimdownload* and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

**Nicholas A. Shufro,**

*Assistant Administrator for Risk Management (Acting), Federal Emergency Management Agency, Department of Homeland Security.*

| Community | Community map repository address |
|---|---|
| **Morgan County, Indiana and Incorporated Areas**<br>**Project: 12–05–8945S Preliminary Date: May 13, 2022** | |
| City of Martinsville | Martinsville City Hall, 59 South Jefferson Street, Martinsville, IN 46151. |
| Unincorporated Areas of Morgan County | Morgan County Administration Building, 180 South Main Street, Martinsville, IN 46151. |
| **Waseca County, Minnesota and Incorporated Areas**<br>**Project: 18–05–0017S Preliminary Date: September 30, 2021** | |
| City of Elysian | City Hall, 110 West Main Street, Elysian, MN 56028. |
| City of Janesville | City Hall, 101 North Mott Street, Janesville, MN 56048. |
| City of Waseca | City Hall, 508 South State Street, Waseca, MN 56093. |
| Unincorporated Areas of Waseca County | Waseca County Courthouse, 307 North State Street, Waseca, MN 56093. |
| **Bradford County, Pennsylvania (All Jurisdictions)**<br>**Project: 16–03–0615S Preliminary Date: June 17, 2022** | |
| Borough of Athens | Municipal Building, 2 South River Street, Athens, PA 18810. |
| Borough of Sayre | Borough Office, 110 West Packer Avenue, Sayre, PA 18840. |
| Borough of Wyalusing | Borough Hall, 50 Senate Street, Wyalusing, PA 18853. |
| Township of Asylum | Asylum Township Building, 19981 Route 187, Towanda, PA 18848. |
| Township of Athens | Athens Township Municipal Building, 45 Herrick Avenue, Sayre, PA 18840. |
| Township of Burlington | Burlington Township Building, 2030 Weed Hill Road, Towanda, PA 18848. |
| Township of Litchfield | Litchfield Township Municipal Building, 1391 Hill Road, Sayre, PA 18840. |
| Township of North Towanda | North Towanda Township Office, 292 Old Mills Road, Towanda, PA 18848. |
| Township of Sheshequin | Sheshequin Township Office, 1774 North Middle Road, Ulster, PA 18850. |
| Township of Standing Stone | Standing Stone Township Building, 35165 Route 6, Wysox, PA 18854. |
| Township of Terry | Terry Township Building, 1876 Rienze Road, Wyalusing, PA 18853. |
| Township of Towanda | Township Office, 44 Chapel Street, Towanda, PA 18848. |
| Township of Ulster | Municipal Building, 23849 Route 220, Ulster, PA 18850. |
| Township of Wilmot | Wilmot Township Municipal Building, 4861 Route 187, Sugar Run, PA 18846. |
| Township of Wyalusing | Township Building, 41908 Route 6, Wyalusing, PA 18853. |
| Township of Wysox | Township Building, 103 Lake Road, Wysox, PA 18854. |

[FR Doc. 2022–23543 Filed 10–27–22; 8:45 am]

**BILLING CODE 9110–12–P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Docket ID FEMA–2022–0002; Internal Agency Docket No. FEMA–B–2284]**

### Changes in Flood Hazard Determinations

**AGENCY:** Federal Emergency Management Agency, Department of Homeland Security.

**ACTION:** Notice.

**SUMMARY:** This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Federal Regulations. The currently effective community number is shown in the table below and must be used for all new policies and renewals.

**DATES:** These flood hazard determinations will be finalized on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Insurance and Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

**ADDRESSES:** The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

**FOR FURTHER INFORMATION CONTACT:** Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

**SUPPLEMENTARY INFORMATION:** The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

**Nicholas A. Shufro,**

*Assistant Administrator for Risk Management (Acting), Federal Emergency Management Agency, Department of Homeland Security.*

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Online location of letter of map revision | Date of modification | Community No. |
|---|---|---|---|---|---|---|
| Colorado: | | | | | | |
| Boulder ..... | City of Lafayette (21–08–1058P). | The Honorable J.D. Mangat, Mayor, City of Lafayette, 1290 South Public Road, Lafayette, CO 80026. | City Hall, 1290 South Public Road, Lafayette, CO 80026. | *https://msc.fema.gov/portal/advanceSearch.* | Dec. 29, 2022 .... | 080026 |
| Boulder ..... | Unincorporated areas of Boulder County (21–08–1058P). | The Honorable Matt Jones, Chair, Boulder County Board of Commissioners, P.O. Box 471, Boulder, CO 80306. | Boulder County Transportation Department, 2525 13th Street, Suite 203, Boulder, CO 80304. | *https://msc.fema.gov/portal/advanceSearch.* | Dec. 29, 2022 .... | 080023 |
| Weld ..... | Unincorporated areas of Weld County (21–08–1198P). | The Honorable Scott James, Chair, Weld County Board of Commissioners, P.O. Box 758, Greeley, CO 80632. | Weld County Commissioner's Office, 1150 O Street, Greeley, CO 80631. | *https://msc.fema.gov/portal/advanceSearch.* | Jan. 9, 2023 ..... | 080266 |
| Florida: | | | | | | |

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Online location of letter of map revision | Date of modification | Community No. |
|---|---|---|---|---|---|---|
| Lee | Unincorporated areas of Lee County (22–04–1445P). | Roger Desjarlais, Manager, Lee County, 2120 Main Street, Fort Myers, FL 33901. | Lee County Building Department, 1500 Monroe Street, Fort Myers, FL 33901. | *https://msc.fema.gov/portal/advanceSearch.* | Jan. 5, 2023 | 125124 |
| Manatee | Unincorporated areas of Manatee County (22–04–0251P). | Scott Hopes, Administrator, Manatee County, 1112 Manatee Avenue West, Bradenton, FL 34205. | Manatee County Development Services Department, 1112 Manatee Avenue West, Bradenton, FL 34205. | *https://msc.fema.gov/portal/advanceSearch.* | Jan. 3, 2023 | 120153 |
| Manatee | Unincorporated areas of Manatee County (22–04–0770P).. | Scott Hopes, Manatee County Administrator, 1112 Manatee Avenue West, Bradenton, FL 34205. | Manatee County Development Services Department, 1112 Manatee Avenue West, Bradenton, FL 34205. | *https://msc.fema.gov/portal/advanceSearch.* | Jan. 25, 2023 | 120153 |
| Monroe | Unincorporated areas of Monroe County (22–04–3484P). | The Honorable David Rice, Mayor, Monroe County Board of Commissioners, 9400 Overseas Highway, Suite 210, Marathon, FL 33050. | Monroe County Building Department, 2798 Overseas Highway, Suite 300, Marathon, FL 33050. | *https://msc.fema.gov/portal/advanceSearch.* | Jan. 3, 2023 | 125129 |
| Monroe | Unincorporated areas of Monroe County (22–04–4636P). | The Honorable David Rice, Mayor, Monroe County Board of Commissioners, 9400 Overseas Highway, Suite 210, Marathon, FL 33050. | Monroe County Building Department, 2798 Overseas Highway, Suite 300, Marathon, FL 33050. | *https://msc.fema.gov/portal/advanceSearch.* | Feb. 2, 2023 | 125129 |
| Volusia | City of Deland (22–04–2131P). | Michael F. Pleus, Manager, City of Deland, 120 South Florida Avenue, Deland, FL 32720. | Public Services Department, 1102 South Garfield Avenue, Deland, FL 32724. | *https://msc.fema.gov/portal/advanceSearch.* | Jan. 13, 2023 | 120307 |
| Volusia | Unincorporated areas of Volusia County (22–04–2131P). | George Recktenwald, Manager, Volusia County, 123 West Indiana Avenue, Deland, FL 32730. | Volusia County Thomas C. Kelly Administration Center, 123 West Indiana Avenue, Deland, FL 32730. | *https://msc.fema.gov/portal/advanceSearch.* | Jan. 13, 2023 | 125155 |
| Idaho: | | | | | | |
| Gooding | City of Gooding (21–10–1380P). | The Honorable Diane Houser, Mayor, City of Gooding, 308 5th Avenue West, Gooding, ID 83330. | Public Works Department, 308 5th Avenue West, Gooding, ID 83330. | *https://msc.fema.gov/portal/advanceSearch.* | Jan. 20, 2023 | 160064 |
| Gooding | Unincorporated areas of Gooding County (21–10–1380P). | The Honorable Mark Bolduc, Chair, Gooding County Board of Commissioners, P.O. Box 417, Gooding, ID 83330. | Gooding County Planning and Zoning Department, 714 Main Street, Gooding, ID 83330. | *https://msc.fema.gov/portal/advanceSearch.* | Jan. 20, 2023 | 160227 |
| New Mexico: Bernalillo. | City of Albuquerque (22–06–0212P). | The Honorable Timothy M. Keller, Mayor, City of Albuquerque, P.O. Box 1293, Albuquerque, NM 87103. | Planning Department, 600 2nd Street Northwest, Albuquerque, NM 87102. | *https://msc.fema.gov/portal/advanceSearch.* | Jan. 18, 2023 | 350002 |
| North Dakota: | | | | | | |
| Walsh | City of Grafton (21–08–0925P). | The Honorable Chris West, Mayor, City of Grafton, P.O. Box 578, Grafton, ND 58237. | City Hall, 5 East 4th Street, Grafton, ND 58237. | *https://msc.fema.gov/portal/advanceSearch.* | Jan. 19, 2023 | 380137 |
| Walsh | Township of Grafton (21–08–0925P). | The Honorable Lawrence Burianek, Chair, Township of Grafton, 117 Westwood Drive, Grafton, ND 58237. | Walsh County Administrative Building, 638 Cooper Avenue, Suite 2, Grafton, ND 58237. | *https://msc.fema.gov/portal/advanceSearch.* | Jan. 19, 2023 | 380302 |
| Walsh | Township of Oakwood (21–08–0925P). | The Honorable Mark Gourde, Chair, Township of Oakwood, 15387 County Road 11, Grafton, ND 58237. | Walsh County Administrative Building, 638 Cooper Avenue, Suite 2, Grafton, ND 58237. | *https://msc.fema.gov/portal/advanceSearch.* | Jan. 19, 2023 | 380303 |
| Oklahoma: Grady | City of Chickasha (22–06–1362P). | The Honorable Chris Mosley, Mayor, City of Chickasha, 117 North 4th Street, Chickasha, OK 73018. | Community Development Department, 117 North 4th Street, Chickasha, OK 73018. | *https://msc.fema.gov/portal/advanceSearch.* | Jan. 6, 2023 | 400234 |
| South Carolina: | | | | | | |
| Darlington | Unincorporated areas of Darlington County (22–04–2654P). | Marion C. Stewart, III, Administrator, Darlington County, 1 Public Square, Room 210, Darlington, SC 29532. | Darlington County Planning Department, 1 Public Square, Darlington, SC 29532. | *https://msc.fema.gov/portal/advanceSearch.* | Jan. 12, 2023 | 450060 |

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Online location of letter of map revision | Date of modification | Community No. |
|---|---|---|---|---|---|---|
| Richland | Unincorporated areas of Richland County (22–04–1306P). | The Honorable Paul Livingston, Chair, Richland County Council, 2308 Park Street, Columbia, SC 29201. | Richland County Floodplain Management Department, 2020 Hampton Street, 1st Floor, Columbia, SC 29204. | *https://msc.fema.gov/portal/advanceSearch.* | Dec. 19, 2022 | 450170 |
| Tennessee: Hamilton. | Unincorporated areas of Hamilton County (21–04–5804P). | The Honorable Weston Wamp, Mayor, Hamilton County, 625 Georgia Avenue, Chattanooga, TN 37402. | Hamilton County Engineering Department, Development Resource Center, 1250 Market Street, Suite 3046, Chattanooga, TN 37402. | *https://msc.fema.gov/portal/advanceSearch.* | Jan. 25, 2023 | 470071 |
| Texas: | | | | | | |
| Bexar | City of San Antonio (21–06–3257P). | The Honorable Ron Nirenberg, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, TX 78283. | Transportation and Capitol Improvements Department, Storm Water Division, 1901 South Alamo Street, 2nd Floor, San Antonio, TX 78204. | *https://msc.fema.gov/portal/advanceSearch.* | Jan. 9, 2023 | 480045 |
| Bexar | City of San Antonio, (22–06–1766P). | The Honorable Ron Nirenberg, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, TX 78283. | Transportation and Capitol Improvements Department, Storm Water Division, 1901 South Alamo Street, 2nd Floor, San Antonio, TX 78204. | *https://msc.fema.gov/portal/advanceSearch.* | Dec. 19, 2022 | 480045 |
| Bexar | Unincorporated areas of Bexar County (22–06–0468P). | The Honorable Nelson W. Wolff, Bexar County Judge, 101 West Nueva Street, 10th Floor, San Antonio, TX 78205. | Bexar County Public Works Department, 1948 Probandt Street, San Antonio, TX 78214. | *https://msc.fema.gov/portal/advanceSearch.* | Jan. 3, 2023 | 480035 |
| Bexar | Unincorporated areas of Bexar County (22–06–1766P). | The Honorable Nelson W. Wolff, Bexar County Judge, 101 West Nueva Street, 10th Floor, San Antonio, TX 78205. | Bexar County Public Works Department, 1948 Probandt Street, San Antonio, TX 78214. | *https://msc.fema.gov/portal/advanceSearch.* | Dec. 19, 2022 | 480035 |
| Comal | Unincorporated areas of Comal County (22–06–0468P). | The Honorable Sherman Krause, Comal County Judge, 100 Main Plaza, New Braunfels, TX 78130. | Comal County Engineering Department, 195 David Jonas Drive, New Braunfels, TX 78132. | *https://msc.fema.gov/portal/advanceSearch.* | Jan. 3, 2023 | 485463 |
| Dallas | City of Garland (22–06–0786P). | The Honorable Scott LeMay, Mayor, City of Garland, P.O. Box 469002, Garland, TX 75046. | Engineering Department, 800 Main Street, 3rd Floor, Garland, TX 75040. | *https://msc.fema.gov/portal/advanceSearch.* | Jan. 3, 2023 | 485471 |
| Denton | City of Fort Worth (22–06–0030P). | The Honorable Mattie Parker, Mayor, City of Fort Worth, 200 Texas Street, Fort Worth, TX 76102. | Department of Transportation and Public Works, 200 Texas Street, Fort Worth, TX 76102. | *https://msc.fema.gov/portal/advanceSearch.* | Jan. 23, 2023 | 480596 |
| Denton | Unincorporated areas of Denton County (22–06–0030P). | The Honorable Andy Eads, Denton County Judge, 1 Courthouse Drive, Suite 3100, Denton, TX 76208. | Denton County Public Works Department, Engineering Department, 1505 East McKinney Street, Suite 175, Denton, TX 76209. | *https://msc.fema.gov/portal/advanceSearch.* | Jan. 23, 2023 | 480774 |
| Erath | City of Stephenville (22–06–0024P). | Jason King, Manager, City of Stephenville, 298 West Washington Street, Stephenville, TX 76401. | Department of Public Works, 298 West Washington Street, Stephenville, TX 76401. | *https://msc.fema.gov/portal/advanceSearch.* | Jan. 17, 2023 | 480220 |
| Tarrant | City of Benbrook, (22–06–0792P). | The Honorable Jason Ward, Mayor, City of Benbrook, 911 Winscott Road, Benbrook, TX 76126. | Department of Public Works, 8401 Laguna Palms Way, Benbrook, TX 76126. | *https://msc.fema.gov/portal/advanceSearch.* | Feb. 2, 2023 | 480586 |
| Virginia: Loudoun | Unincorporated areas of Loudoun County (22–03–0311P). | Tim Hemstreet, Administrator, Loudoun County, 1 Harrison Street Southeast, 5th Floor, Leesburg, VA 20175. | Loudoun County Government Center, 1 Harrison Street Southeast, 3rd Floor, Leesburg, VA 20175. | *https://msc.fema.gov/portal/advanceSearch.* | Dec. 19, 2022 | 510090 |

[FR Doc. 2022–23544 Filed 10–27–22; 8:45 am]

BILLING CODE 9110–12–P

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Docket ID FEMA–2022–0002]**

### Changes in Flood Hazard Determinations

**AGENCY:** Federal Emergency Management Agency, Department of Homeland Security.

**ACTION:** Notice.

**SUMMARY:** New or modified Base (1-percent annual chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or regulatory floodways (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports, currently in effect for the listed communities.

**DATES:** Each LOMR was finalized as in the table below.

**ADDRESSES:** Each LOMR is available for inspection at both the respective Community Map Repository address listed in the table below and online through the FEMA Map Service Center at *https://msc.fema.gov.*

**FOR FURTHER INFORMATION CONTACT:** Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

**SUPPLEMENTARY INFORMATION:** The Federal Emergency Management Agency (FEMA) makes the final flood hazard determinations as shown in the LOMRs for each community listed in the table below. Notice of these modified flood hazard determinations has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65. The currently effective community number is shown and must be used for all new policies and renewals.

The new or modified flood hazard information is the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP).

This new or modified flood hazard information, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.

This new or modified flood hazard determinations are used to meet the floodplain management requirements of the NFIP. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA Map Service Center at *https://msc.fema.gov.*

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

**Nicholas A. Shufro,**

*Assistant Administrator for Risk Management (Acting), Federal Emergency Management Agency, Department of Homeland Security.*

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Date of modification | Community No. |
|---|---|---|---|---|---|
| Colorado: Denver (FEMA Docket No.: B–2251). | City and County of Denver (22–08–0130P). | The Honorable Michael B. Hancock, Mayor, City and County of Denver, 1437 Bannock Street, Room 350, Denver, CO 80202. | Department of Transportation and Infrastructure, 201 West Colfax Avenue, Department 608, Denver, CO 80202. | Oct. 14, 2022 | 080046 |
| Delaware: Sussex (FEMA Docket No.: B–2259). | Unincorporated areas of Sussex County (22–03–0052P). | The Honorable Michael H. Vincent, President, Sussex County Council, P.O. Box 589, Georgetown, DE 19947. | Sussex County Planning and Zoning Department, 2 The Circle, Georgetown, DE 19947. | Oct. 13, 2022 | 100029 |
| Florida: | | | | | |
| Broward (FEMA Docket No.: B–2253). | City of Oakland Park (22–04–0596P). | The Honorable Michael E. Carn, Mayor, City of Oakland Park, 3650 Northeast 12th Avenue, Oakland Park, FL 33334. | City Hall, 3650 Northeast 12th Avenue, Oakland Park, FL 33334. | Oct. 11, 2022 | 120050 |
| Collier (FEMA Docket No.: B–2251). | City of Marco Island (22–04–2823P). | Mike McNees, Manager, City of Marco Island, 50 Bald Eagle Drive, Marco Island, FL 34145. | Building Services Department, 50 Bald Eagle Drive, Marco Island, FL 34145. | Oct. 11, 2022 | 120426 |
| Duval (FEMA Docket No.: B–2251). | City of Jacksonville Beach (22–04–0750P). | The Honorable Christine Hoffman, Mayor, City of Jacksonville Beach, 11 North 3rd Street, Jacksonville Beach, FL 32250. | Planning and Development Department, 11 North 3rd Street, Jacksonville Beach, FL 32250. | Sep. 28, 2022 | 120078 |
| Lee (FEMA Docket No.: B–2251). | City of Bonita Springs (22–04–0173P). | The Honorable Rick Steinmeyer, Mayor, City of Bonita Springs, 9101 Bonita Beach Road, Bonita Springs, FL 34135. | Community Development Department, 9220 Bonita Beach Road, Bonita Springs, FL 34135. | Sep. 23, 2022 | 120680 |
| Manatee (FEMA Docket No.: B–2251). | Unincorporated areas of Manatee County (21–04–2233P). | The Honorable Kevin Van Ostenbridge, Chair, Manatee County Board of Commissioners, 1112 Manatee Avenue West, Bradenton, FL 34205. | Manatee County Building and Development Services Department, 1112 Manatee Avenue West, Bradenton, FL 34205. | Oct. 14, 2022 | 120153 |
| Monroe (FEMA Docket No.: B–2251). | Unincorporated areas of Monroe County (22–04–0860P). | The Honorable David Rice, Mayor, Monroe County Board of Commissioners, 1100 Simonton Street, Key West, FL 33040. | Monroe County Building Department, 2798 Overseas Highway, Suite 300, Marathon, FL 33050. | Sep. 22, 2022 | 125129 |

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Date of modification | Community No. |
|---|---|---|---|---|---|
| Monroe (FEMA Docket No.: B–2251). | Unincorporated areas of Monroe County (22–04–2418P). | The Honorable David Rice, Mayor, Monroe County Board of Commissioners, 1100 Simonton Street, Key West, FL 33040. | Monroe County Building Department, 2798 Overseas Highway, Suite 300, Marathon, FL 33050. | Oct. 3, 2022 | 125129 |
| Osceola (FEMA Docket No.: B–2251). | City of St. Cloud (20–04–5566P). | Bill Sturgeon, Manager, City of St. Cloud, 1300 9th Street, St. Cloud, FL 34769. | Building Department, 1300 9th Street, St. Cloud, FL 34769. | Oct. 3, 2022 | 120191 |
| Polk (FEMA Docket No.: B–2251). | Unincorporated areas of Polk County (22–04–0291X). | Bill Beasley, Manager, Polk County, 330 West Church Street, Bartow, FL 33831. | Polk County Land Development Division, 330 West Church Street, Bartow, FL 33831. | Oct. 13, 2022 | 120261 |
| Sarasota (FEMA Docket No.: B–2253). | City of Sarasota (22–04–2558P). | The Honorable Erik Arroyo, Mayor, City of Sarasota, 1565 1st Street, Room 101, Sarasota, FL 34236. | Development Services Department, 1565 1st Street, Sarasota, FL 34236. | Oct. 11, 2022 | 125150 |
| Seminole (FEMA Docket No.: B–2251). | City of Lake Mary (22–04–0236P). | Kevin Smith, Manager, City of Lake Mary, 100 North Country Club Road, Lake Mary, FL 32795. | Municipal Services Complex, 911 Wallace Court, Lake Mary, FL 32746. | Oct. 3, 2022 | 120416 |
| Kentucky: Jefferson (FEMA Docket No.: B–2251). | Louisville-Jefferson County Metro Government (21–04–5654P). | The Honorable Greg Fischer, Mayor, Louisville-Jefferson County, Metro Government, 527 West Jefferson Street, Louisville, KY 40202. | Louisville-Jefferson County Metropolitan Sewer District, 700 West Liberty Street, Louisville, KY 40203. | Sep. 26, 2022 | 210120 |
| Louisiana: Lafayette (FEMA Docket No.: B–2268). | City of Youngsville (21–06–3256P). | The Honorable Ken Ritter, Mayor, City of Youngsville, 305 Iberia Street, Youngsville, LA 70592. | City Hall, 305 Iberia Street, Youngsville, LA 70592. | Oct. 14, 2022 | 220358 |
| Maryland: Prince George's (FEMA Docket No.: B–2251). | Unincorporated areas of Prince George's County (21–03–1450P). | The Honorable Angela D. Alsobrooks, Executive, Prince George's County, 1301 McCormick Drive, Suite 4000, Largo, MD 20774. | Prince George's County Department of Permitting Inspections and Enforcement, 9400 Peppercorn Place, Suite 230, Largo, MD 20774. | Sep. 23, 2022 | 245208 |
| New Hampshire: Carroll (FEMA Docket No.: B–2259). | Town of Jackson (22–01–0604P). | The Honorable Barbara Campbell, Chair, Town of Jackson Board of Selectmen, 54 Main Street, Jackson, NH 03846. | Building Department, 54 Main Street, Jackson, NH 03846. | Oct. 11, 2022 | 330014 |
| North Carolina: Durham (FEMA Docket No.: B–2251). | Unincorporated areas of Durham County (21–04–5308P). | The Honorable Brenda Howerton, Chair, Durham County Board of Commissioners, 200 East Main Street, Durham, NC 27701. | Durham County Planning Department, 101 City Hall Plaza, Durham, NC 27701. | Sept. 21, 2022 | 370085 |
| Oklahoma: Canadian and Oklahoma (FEMA Docket No.: B–2253). | City of Oklahoma City (21–06–3298P). | The Honorable David Holt, Mayor, City of Oklahoma City, 200 North Walker Avenue, 3rd Floor, Oklahoma City, OK 73102. | Public Works Department, 420 West Main Street, Suite 700, Oklahoma City, OK 73102. | Oct. 14, 2022 | 405378 |
| Pennsylvania: | | | | | |
| Philadelphia (FEMA Docket No.: B–2253). | City of Philadelphia (21–03–1283P). | The Honorable Jim Kenney, Mayor, City of Philadelphia, 1400 John F. Kennedy Boulevard, Room 215, Philadelphia, PA 19107. | Department of Licenses and Inspections, 1401 John F. Kennedy Boulevard, 11th Floor, Philadelphia, PA 19102. | Sep. 26, 2022 | 420757 |
| Philadelphia (FEMA Docket No.: B–2253). | Township of Lower Merion (21–03–1283P). | Ernie B. McNeely, Manager, Township of Lower Merion, 75 East Lancaster Avenue, Ardmore, PA 19003. | Township Hall, 75 East Lancaster Avenue, Ardmore, PA 19003. | Sep. 26, 2022 | 420701 |
| South Carolina: | | | | | |
| Sumter (FEMA Docket No.: B–2253). | City of Sumter (22–04–2326P). | The Honorable David P. Merchant, Mayor, City of Sumter, 21 North Main Street, Sumter, SC 29151. | Sumter City-County Planning Department, 12 West Liberty Street, Sumter, SC 29150. | Sep. 30, 2022 | 450184 |
| Sumter (FEMA Docket No.: B–2253). | Unincorporated areas of Sumter County (22–04–2326P). | The Honorable James T. McCain, Jr., Chair, Sumter County Council, 13 East Canal Street, Sumter, SC 29150. | Sumter City-County Planning Department, 12 West Liberty Street, Sumter, SC 29150. | Sep. 30, 2022 | 450182 |
| Texas: | | | | | |
| Bexar (FEMA Docket No.: B–2253). | Unincorporated areas of Bexar County (21–06–2900P). | The Honorable Nelson W. Wolff, Bexar County Judge, 101 West Nueva Street, 10 Floor, San Antonio, TX 78205. | Bexar County Public Works Department, 1948 Probandt Street, San Antonio, TX 78214. | Oct. 3, 2022 | 480035 |
| Collin (FEMA Docket No.: B–2253). | City of Anna (21–06–3396P). | The Honorable Nate Pike, Mayor, City of Anna, P.O. Box 776, Anna, TX 75409. | Public Works Department, 3223 North Powell Parkway, Anna, TX 75409. | Sep. 26, 2022 | 480132 |
| Collin (FEMA Docket No.: B–2253). | Unincorporated areas of Collin County (21–06–3396P). | The Honorable Chris Hill, Collin County Judge, 2300 Bloomdale Road, Suite 4192, McKinney, TX 75071. | Collin County Engineering Department, 4690 Community Avenue, Suite 200, McKinney, TX 75071. | Sep. 26, 2022 | 480130 |
| Denton (FEMA Docket No.: B–2251). | City of Fort Worth (22–06–0847P). | The Honorable Mattie Parker, Mayor, City of Fort Worth, 200 Texas Street, Fort Worth, TX 76102. | Transportation and Public Works Department, Engineering Vault, 200 Texas Street, Fort Worth, TX 76102. | Oct. 11, 2022 | 480596 |

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Date of modification | Community No. |
|---|---|---|---|---|---|
| Hays (FEMA Docket No.: B–2253). | City of Buda (21–06–2861P). | The Honorable Lee Urbanovsky, Mayor, City of Buda, 405 East Loop Street, Building 100, Buda, TX 78610. | Engineering Department, 405 East Loop Street, Building 100, Buda, TX 78610. | Oct. 13, 2022 | 481640 |
| Hays (FEMA Docket No.: B–2253). | Unincorporated areas of Hays County (21–06–2861P). | The Honorable Ruben Becerra, Hays County Judge, 111 East San Antonio Street, Suite 300, San Marcos, TX 78666. | Hays County Office of Development Services, 2171 Yarrington Road, Suite 100, Kyle, TX 78640. | Oct. 13, 2022 | 480321 |
| Johnson (FEMA Docket No.: B–2251). | City of Burleson (21–06–3092P). | The Honorable Chris Fletcher, Mayor, City of Burleson, 141 West Renfro Street, Burleson, TX 76028. | City Hall, 141 West Renfro Street, Burleson, TX 76028. | Oct. 6, 2022 | 485459 |
| Tarrant (FEMA Docket No.: B–2251). | City of Fort Worth (21–06–2361P). | The Honorable Mattie Parker, Mayor, City of Fort Worth, 200 Texas Street, Fort Worth, TX 76102. | Transportation and Public Works Department, Engineering Vault, 200 Texas Street, Fort Worth, TX 76102. | Sep. 29, 2022 | 480596 |
| Tarrant (FEMA Docket No.: B–2251). | Unincorporated areas of Tarrant County (21–06–2361P). | The Honorable B. Glen Whitley, Tarrant County Judge, 100 East Weatherford Street, Room 502A, Fort Worth, TX 76196. | Tarrant County Administration Building, 100 East Weatherford Street, Fort Worth, TX 76196. | Sep. 29, 2022 | 480582 |
| Tarrant (FEMA Docket No.: B–2253). | City of Mansfield (22–06–0409P). | The Honorable Michael A. Evans, Mayor, City of Mansfield, 1200 East Broad Street, Mansfield, TX 76063. | Department of Zoning and Planning, 1200 East Broad Street, Mansfield, TX 76063. | Oct. 11, 2022 | 480606 |
| Williamson (FEMA Docket No.: B–2251). | City of Leander (21–06–2660P). | Mr. Richard B. Beverlin, III, Manager, City of Leander, 105 North Brushy Street, Leander, TX 78641. | Engineering Department, 201 North Brushy Street, Leander, TX 78641. | Oct. 14, 2022 | 481536 |
| Utah: Weber (FEMA Docket No.: B–2253). | Unincorporated areas of Weber County (21–08–1088P). | The Honorable Scott Jenkins, Chair, Weber County Commission, 2380 Washington Boulevard, Suite 360, Ogden, UT 84401. | Weber County Center, 2380 Washington Boulevard, Suite 360, Ogden, UT 84401. | Oct. 3, 2022 | 490187 |

[FR Doc. 2022–23548 Filed 10–27–22; 8:45 am]

**BILLING CODE 9110–12–P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Docket ID FEMA–2022–0002]**

### Changes in Flood Hazard Determinations

**AGENCY:** Federal Emergency Management Agency, Department of Homeland Security.

**ACTION:** Notice.

**SUMMARY:** New or modified Base (1-percent annual chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or regulatory floodways (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports, currently in effect for the listed communities.

**DATES:** Each LOMR was finalized as in the table below.

**ADDRESSES:** Each LOMR is available for inspection at both the respective Community Map Repository address listed in the table below and online through the FEMA Map Service Center at *https://msc.fema.gov.*

**FOR FURTHER INFORMATION CONTACT:** Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

**SUPPLEMENTARY INFORMATION:** The Federal Emergency Management Agency (FEMA) makes the final flood hazard determinations as shown in the LOMRs for each community listed in the table below. Notice of these modified flood hazard determinations has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65. The currently effective community number is shown and must be used for all new policies and renewals.

The new or modified flood hazard information is the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP).

This new or modified flood hazard information, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.

This new or modified flood hazard determinations are used to meet the floodplain management requirements of the NFIP. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA

Map Service Center at *https://msc.fema.gov.*

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

**Nicholas A. Shufro,**

*Assistant Administrator for Risk Management (Acting), Federal Emergency Management Agency, Department of Homeland Security.*

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Date of modification | Community No. |
|---|---|---|---|---|---|
| Arizona: | | | | | |
| Maricopa (FEMA Docket No.: B–2230). | City of Surprise (21–09–1333P). | The Honorable Skip Hall, Mayor, City of Surprise, 16000 North Civic Center Plaza, Surprise, AZ 85374. | Public Works Department, Engineering Development Services, 16000 North Civic Center Plaza, Surprise, AZ 85374. | Jul. 8, 2022 | 040053 |
| Maricopa (FEMA Docket No.: B–2246). | City of Surprise, (21–09–1794P). | The Honorable Skip Hall, Mayor, City of Surprise, 16000 North Civic Center Plaza, Surprise, AZ 85374. | Public Works Department, Engineering Development Services, 16000 North Civic Center Plaza, Surprise, AZ 85374. | Sep. 9, 2022 | 040053 |
| Maricopa (FEMA Docket No.: B–2230). | Unincorporated Areas of Maricopa County (21–09–1333P). | The Honorable Bill Gates, Chair, Board of Supervisors, Maricopa County, 301 West Jefferson Street, Phoenix, AZ 85003. | Flood Control District of Maricopa County, 2801 West Durango Street, Phoenix, AZ 85009. | Jul. 8, 2022 | 040037 |
| Maricopa (FEMA Docket No.: B–2246). | Unincorporated Areas of Maricopa County (21–09–1794P). | The Honorable Bill Gates, Chair, Board of Supervisors, Maricopa County, 301 West Jefferson Street, 10th Floor, Phoenix, AZ 85003. | Flood Control District of Maricopa County, 2801 West Durango Street, Phoenix, AZ 85009. | Sep. 9, 2022 | 040037 |
| Pinal (FEMA Docket No.: B–2237). | City of Maricopa, (21–09–0921P). | The Honorable Nancy Smith, Mayor, City of Maricopa, 39700 West Civic Center Plaza, Maricopa, AZ 85138. | City Hall, 39700 West Civic Center Plaza, Maricopa, AZ 85138. | Aug. 12, 2022 | 040052 |
| Pinal (FEMA Docket No.: B–2237). | Unincorporated Areas of Pinal County (21–09–0921P). | The Honorable Jeffrey McClure, Chair, Board of Supervisors, Pinal County, P.O. Box 827, Florence, AZ 85132. | Pinal County Engineering Division, 31 North Pinal Street, Building F, Florence, AZ 85132. | Aug. 12, 2022 | 040077 |
| Santa Cruz (FEMA Docket No.: B–2246). | Unincorporated Areas of Santa Cruz County (21–09–1881P). | The Honorable Manuel Ruiz, Chair, Board of Supervisors, Santa Cruz County, 2150 North Congress Street, Suite 119, Nogales, AZ 85621. | Santa Cruz County Flood Control District, Gabilondo-Zehentner Building, 275 Rio Rico Drive, Rio Rico, AZ 85648. | Sep. 6, 2022 | 040090 |
| Yavapai (FEMA Docket No.: B–2237). | Town of Prescott Valley (21–09–1013P). | The Honorable Kell Palguta, Mayor, Town of Prescott Valley, Civic Center, 7501 East Skoog Boulevard, 4th Floor, Prescott Valley, AZ 86314. | Town Hall, Engineering Division, 7501 East Civic Circle, Prescott Valley, AZ 86314. | Jul. 20, 2022 | 040121 |
| California: | | | | | |
| Fresno (FEMA Docket No.: B–2237). | City of Clovis, (21–09–1313P). | The Honorable Jose Flores, Mayor, City of Clovis, 1033 5th Street, Clovis, CA 93612. | City Clerk's Office, Civic Center, 1033 5th Street, Clovis, CA 93612. | Jul. 25, 2022 | 060044 |
| Los Angeles (FEMA Docket No.: B–2246). | Unincorporated Areas of Los Angeles County (21–09–0650P). | The Honorable Holly J Mitchell, Chair, Board of Supervisors, Los Angeles County, 500 West Temple Street Room 866, Los Angeles, CA 90012. | Los Angeles County Public Works Headquarters, Watershed Management Division, 900 South Fremont Avenue, Alhambra, CA 91803. | Sep. 6, 2022 | 065043 |
| Placer (FEMA Docket No.: B–2230). | City of Lincoln (21–09–1152P). | The Honorable Alyssa Silhi, Mayor, City of Lincoln, 600 6th Street, Lincoln, CA 95648. | Community Development Department, 600 6th Street, Lincoln, CA 95648. | Jun. 24, 2022 | 060241 |
| Riverside (FEMA Docket No.: B–2246). | City of Calimesa (21–09–0875P). | The Honorable William Davis, Mayor, City of Calimesa, 908 Park Avenue, Calimesa, CA 92320. | Planning Department, 908 Park Avenue, Calimesa, CA 92320. | Aug. 8, 2022 | 060740 |
| Riverside (FEMA Docket No.: B–2246). | City of Desert Hot Springs (21–09–1924P). | The Honorable Scott Matas, Mayor, City of Desert Hot Springs, 11999 Palm Drive, Desert Hot Springs, CA 92240. | Planning Department, 65950 Pierson Boulevard, Desert Hot Springs, CA 92240. | Sep. 23, 2022 | 060251 |
| Riverside (FEMA Docket No.: B–2246). | Unincorporated Areas of Riverside County (21–09–1924P). | The Honorable Jeff Hewitt, Chair, Board of Supervisors Riverside County, 4080 Lemon Street, 5th Floor, Riverside, CA 92501. | Riverside County Flood Control and Water Conservation District, 1995 Market Street, Riverside, CA 92501. | Sep. 23, 2022 | 060245 |
| San Diego (FEMA Docket No.: B–2230). | City of San Diego (21–09–1601P). | The Honorable Todd Gloria, Mayor, City of San Diego, 202 C Street, 11th Floor, San Diego, CA 92101. | Development Services Department, 1222 1st Avenue, MS 301, San Diego, CA 92101. | Jul. 1, 2022 | 060295 |
| San Diego (FEMA Docket No.: B–2237). | Unincorporated Areas of San Diego County (20–09–1857P). | The Honorable Nathan Fletcher, Chair, Board of Supervisors, San Diego County, 1600 Pacific Highway, Room 335, San Diego, CA 92101. | San Diego County Flood Control District, Department of Public Works, 5510 Overland Avenue, Suite 410, San Diego, CA 92123. | Aug. 19, 2022 | 060284 |
| Ventura (FEMA Docket No.: B–2246). | City of Oxnard (22–09–0194P). | The Honorable John C. Zaragoza, Mayor, City of Oxnard, 300 West 3rd Street, Oxnard, CA 93030. | Development Services Support Division, Service Center, 214 South C Street, Oxnard, CA 93030. | Sep. 6, 2022 | 060417 |

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Date of modification | Community No. |
|---|---|---|---|---|---|
| Ventura (FEMA Docket No: B–2246). | Unincorporated Areas of Ventura County (22–09–0194P). | The Honorable Carmen Ramirez, Chair, Board of Supervisors Ventura County, 800 South Victoria Avenue, Ventura, CA 93009. | Ventura County Public Works Agency, 800 South Victoria Avenue, Ventura, CA 93009. | Sep. 6, 2022 | 060413 |
| Yolo (FEMA Docket No.: B–2237). | City of Davis (20–09–2115P). | The Honorable Gloria Partida, Mayor, City of Davis, 23 Russell Boulevard, Suite 1, Davis, CA 95616. | City Hall, 23 Russell Boulevard, Davis, CA 95616. | Aug. 15, 2022 | 060424 |
| Florida: | | | | | |
| Bay (FEMA Docket No.: B–2230). | Unincorporated Areas of Bay County (21–04–1447P). | Commissioner Robert Carroll, Chair, District 2, Bay County, 840 West 11th Street, Panama City, FL 32401. | Bay County Planning and Zoning, 707 Jenks Avenue, Suite B, Panama City, FL 32401. | Jun. 23, 2022 | 120004 |
| Orange (FEMA Docket No.: B–2237). | City of Orlando (21–04–2426P). | The Honorable Buddy Dyer, Mayor, City of Orlando, P.O. Box 4990, Orlando, FL 32802. | City Hall, 400 South Orange Avenue, 1st Floor, Orlando, FL 32801. | Aug. 26, 2022 | 120186 |
| Orange (FEMA Docket No.: B–2237). | Unincorporated Areas of Orange County (21–04–2426P). | The Honorable Jerry L. Demings, Mayor, Orange County, 201 South Rosalind Avenue, 5th Floor, Orlando, FL 32801. | Orange County Stormwater Management Division, 4200 South Young Parkway, Orlando, FL 32839. | Aug. 26, 2022 | 120179 |
| St. Johns (FEMA Docket No.: B–2246). | Unincorporated Areas of St. Johns County (21–04–5482P). | Henry Dean, Chair, St. Johns County Board of County Commissioners, 500 San Sebastian View, St. Augustine, FL 32084. | St. Johns County Administration Building, 4020 Lewis Speedway, St. Augustine, FL 32084. | Sep. 13, 2022 | 125147 |
| Walton (FEMA Docket No.: B–2230). | Unincorporated Areas of Walton County (21–04–1447P). | Commissioner Trey Nick, Chair, District 4, Walton County, 263 Chaffin Avenue, DeFuniak Springs, FL 32433. | Walton County Planning and Development Services Department, 31 Coastal Centre Boulevard, Santa Rosa Beach, FL 32459. | Jun. 23, 2022 | 120317 |
| Idaho: | | | | | |
| Ada (FEMA Docket No.: B–2246). | City of Boise (21–10–1267P). | The Honorable Lauren McLean, Mayor, City of Boise, P.O. Box 500, Boise, ID 83701. | City Hall, 150 North Capitol Boulevard, Boise, ID 83701. | Sep. 14, 2022 | 160002 |
| Ada (FEMA Docket No.: B–2237). | Unincorporated Areas of Ada County (21–10–1055P). | Rod Beck, Chair, Ada County Board of Commissioners, 200 West Front Street, 3rd Floor, Boise, ID 83702. | Ada County Courthouse, 200 West Front Street, Boise, ID 83702. | Aug. 5, 2022 | 160001 |
| Bonneville (FEMA Docket No.: B–2237). | Unincorporated Areas of Bonneville County (22–10–0131P). | Roger Christensen, Chair, Bonneville County Board of Commissioners, 605 North Capital Avenue, Idaho Falls, ID 83402. | Bonneville County Courthouse, 605 North Capital Avenue, Idaho Falls, ID 83402. | Jul. 28, 2022 | 160027 |
| Fremont (FEMA Docket No.: B–2237). | Unincorporated Areas of Fremont County (21–10–1438P). | Commissioner Jordan Stoddard, Board of Fremont County Commissioners, 151 West 1st North, Room 10, St Anthony, ID 83445. | Fremont County Court House, 151 West 1st North, St. Anthony, ID 83445. | Aug. 1, 2022 | 160061 |
| Kootenai (FEMA Docket No.: B–2246). | Unincorporated Areas of Kootenai County, (21–10–0970P). | Chair Chris Fillios, Commissioner, District 2, Kootenai County, 451 Government Way, Coeur d'Alene, ID 83816. | Kootenai County Assessors Department, Kootenai County Court House, 451 Government Way, Coeur d'Alene, ID 83816. | Sep. 14, 2022 | 160076 |
| Illinois: | | | | | |
| Cook (FEMA Docket No.: B–2224). | Village of Wheeling (21–05–4442P). | The Honorable Patrick Horcher, Village President, Village of Wheeling, 2 Community Boulevard, Wheeling, IL 60090. | Village Hall, Community Development Engineering Division, 2 Community Boulevard, Wheeling, IL 60090. | Jun. 23, 2022 | 170173 |
| McHenry (FEMA Docket No.: B–2213). | Village of Algonquin, (21–05–4386P). | The Honorable Debby Sosine, Village President, Village of Algonquin, 2200 Harnish Drive, Algonquin, IL 60102. | Village Hall, 2200 Harnish Drive, Algonquin, IL 60102. | May 23, 2022 | 170474 |
| Putnam (FEMA Docket No.: B–2224). | Village of Hennepin (22–05–0122P). | The Honorable Kevin J. Coleman, Mayor, Village of Hennepin, 627 East High Street, Hennepin, IL 61327. | Village Hall, 627 East High Street, Hennepin, IL 61327. | Jun. 23, 2022. | 170570 |
| Randolph (FEMA Docket No.: B–2237). | Unincorporated Areas of Randolph County (22–05–0587P). | The Honorable Marc Kiehna, Chair, Board of Commissioners, Randolph County Courthouse, 1 Taylor Street, Chester, IL 62233. | Randolph County Courthouse, 1 Taylor Street, Chester, IL 62233. | Aug. 19, 2022 | 170575 |
| Will (FEMA Docket No.: B–2213). | City of Lockport, (19–05–4019P). | The Honorable Steven Streit, Mayor, City of Lockport, 222 East 9th Street, Lockport, IL 60441. | Public Works and Engineering Department, 17112 South Prime Boulevard, Lockport, IL 60441. | May 23, 2022 | 170703 |
| Will (FEMA Docket No.: B–2237). | City of Naperville (21–05–0302P). | The Honorable Steve Chirico, Mayor, City of Naperville, Municipal Center, 400 South Eagle Street, Naperville, IL 60540. | Municipal Center, 400 South Eagle Street, Naperville, IL 60540. | Jul. 28, 2022 | 170213 |
| Will (FEMA Docket No.: B–2213). | Unincorporated Areas of Will County (19–05–4019P). | The Honorable Jennifer Bertino-Tarrant, Will County Executive, Will County Office Building, 302 North Chicago Street, Joliet, IL 60432. | Will County Land Use Department, 58 East Clinton Street, Suite 100, Joliet, IL 60432. | May 23, 2022 | 170695 |

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Date of modification | Community No. |
|---|---|---|---|---|---|
| Will (FEMA Docket No.: B–2237). | Unincorporated Areas of Will County (21–05–0302P). | The Honorable Jennifer Bertino-Tarrant, Will County Executive, Will County Office Building, 302 North Chicago Street, Joliet, IL 60432. | Will County Land Use Department, 58 East Clinton Street, Suite 100, Joliet, IL 60432. | Jul. 28, 2022 | 170695 |
| Will (FEMA Docket No.: B–2237). | Village of Bolingbrook (21–05–4669P). | The Honorable Mary Alexander-Basta, Mayor, Village of Bolingbrook, 375 West Briarcliff Road, Bolingbrook, IL 60440. | Village Hall, 375 West Briarcliff Road, Bolingbrook, IL 60440. | Aug. 3, 2022 | 170812 |
| Will (FEMA Docket No.: B–2246). | Village of Plainfield, (22–05–0786P). | The Honorable John F. Argoudelis, Village President, Village of Plainfield, 24401 West Lockport Street, Plainfield, IL 60544. | Village Hall, 24401 West Lockport Street, Plainfield, IL 60544. | Sep. 7, 2022 | 170771 |
| Indiana: | | | | | |
| Hendricks, (FEMA Docket No.: B–2237). | Town of Danville, (21–05–2756P). | David Winters, President, Danville Town Council, 49 North Wayne Street, Danville, IN 46122. | Town of Danville, Planning Department, 147 West Main Street, Danville, IN 46122. | Aug. 12, 2022 | 180088 |
| Hendricks (FEMA Docket No.: B–2237). | Unincorporated Areas of Hendricks County (21–05–2756P). | Phyllis Palmer, President, Hendricks County Board of Commissioners, 49 North Wayne Street, Danville, IN 46122. | Hendricks County Government Center, 355 South Washington Street, Danville, IN 46122. | Aug. 12, 2022 | 180415 |
| Lake (FEMA Docket No.: B–2237). | Town of Cedar Lake (21–05–4556P). | The Honorable Randy Niemeyer, Town Council President, Town of Cedar Lake, 7408 Constitution Avenue, Cedar Lake, IN 46303. | Town Hall, 7408 Constitution Avenue, Cedar Lake, IN 46303. | Jul. 27, 2022 | 180127 |
| Tippecanoe (FEMA Docket No.: B–2246). | Unincorporated Areas of Tippecanoe County (21–05–3329P). | Commissioner Tom Murtaugh, Member, Tippecanoe County Board of Commissioners, 20 North 3rd Street, 1st Floor, Lafayette, IN 47901. | Tippecanoe County Office, 20 North 3rd Street, Lafayette, IN 47901. | Sep. 13, 2022 | 180428 |
| Kansas: | | | | | |
| Johnson (FEMA Docket No.: B–2246). | City of Mission (21–07–1200P). | Laura Smith, Administrator, City of Mission, 6090 Woodson Road, Mission, KS 66202. | City Hall, 6090 Woodson Road, Mission, KS 66202. | Sep. 14, 2022 | 200170 |
| Johnson (FEMA Docket No.: B–2237). | City of Olathe (21–07–0765P). | The Honorable John Bacon, Mayor, City of Olathe, 100 East Santa Fe Street, Olathe, KS 66061. | City Hall, 100 West Santa Fe Drive, Olathe, KS 66061. | Aug. 4, 2022 | 200173 |
| Michigan: | | | | | |
| Saginaw (FEMA Docket No.: B–2230). | City of Frankenmuth (21–05–3420P). | The Honorable Mary Anne Ackerman, Mayor, City of Frankenmuth, City and Township Government Center, 240 West Genesee Street, Frankenmuth, MI 48734. | City and Township Government Center, 240 West Genesee Street, Frankenmuth, MI 48734. | Jul. 7, 2022 | 260188 |
| Saginaw (FEMA Docket No.: B–2230). | Township of Frankenmuth (21–05–3420P). | Tim Hildner, Supervisor, Township of Frankenmuth, P.O. Box 245, Frankenmuth, MI 48734. | City and Township Government Center, 240 West Genesee Street, Frankenmuth, MI 48734. | Jul. 7, 2022 | 260895 |
| St. Clair (FEMA Docket No.: B–2237). | City of St. Clair (22–05–0188P). | The Honorable William Cedar, Jr., Mayor, City of St. Clair, 547 North Carney Drive, St. Clair, MI 48079. | City Hall, 547 North Carney Drive, St. Clair, MI 48079. | Jun. 1, 2022 | 260279 |
| Missouri: Jackson (FEMA Docket No.: B–2230). | City of Kansas City (21–07–1040P). | The Honorable Quinton Lucas, Mayor, City of Kansas City, City Hall, 414 East 12th Street, Kansas City, MO 64106. | Federal Office Building, 911 Walnut Street, Kansas City, MO 64106. | Jul. 6, 2022 | 290173 |
| Nevada: Douglas (FEMA Docket No.: B–2246). | Unincorporated Areas of Douglas County (21–09–1466P). | The Honorable Mark Gardner, Chair, Board of Commissioners, Douglas County, P.O. Box 218, Minden, NV 89423. | Douglas County, Community Development, 1594 Esmeralda Avenue, Minden, NV 89423. | Sep. 8, 2022 | 320008 |
| New Jersey: Mercer (FEMA Docket No.: B–2237). | Township of Ewing, (21–02–0942P). | The Honorable Bert Steinmann, Mayor, Township of Ewing, 2 Jake Garzio Drive, Ewing, NJ 08628. | Construction Office, 2 Jake Garzio Drive, Ewing, NJ 08628. | Aug. 18, 2022 | 345294 |
| New York: Westchester (FEMA Docket No.: B–2237). | Town of North Castle, (21–02–1100P). | Michael J Schiliro, Supervisor, Town of North Castle, 15 Bedford Road, Armonk, NY 10504. | Town Engineer, 200 South Greeley Avenue, Chappaqua, NY 10514. | Oct. 13, 2022 | 360923 |
| Ohio: | | | | | |
| Erie (FEMA Docket No.: B–2237). | Unincorporated Areas of Erie County (22–05–0959P). | Commissioner Patrick Shenigo, Erie County Board of Commissioners, 2900 Columbus Avenue, Sandusky, OH 44870. | Erie County Regional Planning Commission, 2900 Columbus Avenue, Sandusky, OH 44870. | Sep. 2, 2022 | 390153 |
| Lorain (FEMA Docket No.: B–2230). | City of Avon (21–05–4651P). | The Honorable Bryan K Jensen, Mayor, City of Avon, 36080 Chester Road, Avon, OH 44011. | City Hall, Planning Department, 36080 Chester Road, Avon, OH 44011. | Jul. 8, 2022 | 390348 |
| Lorain (FEMA Docket No.: B–2230). | City of North Ridgeville (21–05–4651P). | The Honorable Kevin Corcoran, Mayor, City of North Ridgeville, 7307 Avon Belden Road, North Ridgeville, OH 44039. | City Hall, 7307 Avon Belden Road, North Ridgeville, OH 44039. | Jul. 8, 2022 | 390352 |

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Date of modification | Community No. |
|---|---|---|---|---|---|
| Lucas (FEMA Docket No.: B–2246). | City of Toledo (21–05–2785P). | The Honorable Wade Kapszukiewicz, Mayor, City of Toledo, 1 Government Center, 640 Jackson Street, Toledo, OH 43604. | Department of Inspection, 1 Government Center, Suite 1600, Toledo, OH 43604. | Sep. 29, 2022 | 395373 |
| Summit (FEMA Docket No.: B–2230). | Unincorporated Areas of Summit County (21–05–3486P). | Executive Ilene Shapiro, Summit County, 175 South Main Street, 8th Floor, Akron, OH 44308. | Summit County Building Standards Department, 1030 East Tallmadge Avenue, Akron, OH 44310. | Jun. 9, 2022 | 390781 |
| Summit (FEMA Docket No.: B–2230). | Village of Reminderville, (21–05–3486P). | The Honorable Sam Alonso, Mayor, Village of Reminderville, 3382 Glenwood Boulevard, Reminderville, OH 44202. | Village Hall, 3382 Glenwood Boulevard, Reminderville, OH 44202. | Jun. 9, 2022 | 390855 |
| Warren (FEMA Docket No.: B–2237). | City of Mason (21–05–3113P). | The Honorable Kathy Grossmann, Mayor, City of Mason, 6000 Mason Montgomery Road, Mason, OH 45040. | Municipal Building, 6000 Mason Montgomery Road, Mason, OH 45040. | Aug. 22, 2022 | 390559 |
| Oregon: Lane (FEMA Docket No.: B–2246). | Unincorporated Areas of Lane County (22–10–0105P). | Commissioner Joe Berney, Lane County Board of County Commissioners, 125 East 8th Avenue, Eugene, OR 97401. | Lane County, Customer Service Center, 3050 North Delta Highway, Eugene, OR 97408. | Aug. 26, 2022 | 415591 |
| South Carolina: | | | | | |
| Jasper (FEMA Docket No.: B–2237). | City of Hardeeville, (21–04–0577P). | The Honorable Harry Williams, Mayor, City of Hardeeville, P.O. Box 609, Hardeeville, SC 29927. | City Hall, 205 Main Street, Hardeeville, SC 29927. | Jul. 28, 2022 | 450113 |
| Jasper (FEMA Docket No.: B–2237). | Unincorporated Areas of Jasper County (21–04–0577P). | Barbara Clark, Chair, Jasper County, P.O. Box 1659, Ridgeland, SC 29936. | Jasper County Planning and Building Services, 358 3rd Avenue, Room 202, Ridgeland, SC 29936. | Jul. 28, 2022 | 450112 |
| Texas: | | | | | |
| Dallas (FEMA Docket No.: B–2230). | City of Grand Prairie (21–06–2282P). | The Honorable Ron Jensen, Mayor, City of Grand Prairie, 300 West Main Street, Grand Prairie, TX 75050. | City Development Center, 205 West Church Street, Grand Prairie, TX 75050. | Jul. 11, 2022 | 485472 |
| Travis (FEMA Docket No.: B–2246). | City of Austin (21–06–2164P). | The Honorable Steve Adler, Mayor, City of Austin, P.O. Box 1088, Austin, TX 78767. | Watershed Engineering Division, 505 Barton Springs Road, 12th Floor, Austin, TX 78704. | Sep. 22, 2022 | 480624 |
| Washington: | | | | | |
| King (FEMA Docket No.: B–2246). | City of Issaquah (21–10–1197P). | The Honorable Mary Lou Pauly, Mayor, City of Issaquah, 130 East Sunset Way, Issaquah, WA 98027. | City Hall, 1775 12th Avenue Northwest, Issaquah, WA 98027. | Sep. 26, 2022 | 530079 |
| Pierce (FEMA Docket No.: B–2246). | City of Puyallup (21–10–0191P). | The Honorable Dean Johnson, Mayor, City of Puyallup, City Hall, 333 South Meridian, Puyallup, WA 98371. | City Hall, 333 South Meridian, Puyallup, WA 98371. | Sep. 8, 2022 | 530144 |
| Wisconsin: | | | | | |
| Kenosha (FEMA Docket No.: B–2237). | Village of Pleasant Prairie (21–05–4480P). | John P. Steinbrink, President, Village of Pleasant Prairie, 9915 39th Avenue, Pleasant Prairie, WI 53158. | Village Hall, 9915 39th Avenue, Pleasant Prairie, WI 53158. | Aug. 4, 2022 | 550613 |
| Kenosha (FEMA Docket No.: B–2230). | Village of Salem Lakes (21–05–3136P). | Diann Tesar, President, Village of Salem Lakes, P.O. Box 443, Salem, WI 53168. | Village Hall, 9814 Antioch Road, Salem, WI 53168. | Jun. 16, 2022 | 550505 |
| Milwaukee (FEMA Docket No.: B–2246). | City of Oak Creek (21–05–0691P). | The Honorable Daniel Bukiewicz, Mayor, City of Oak Creek, 8040 South 6th Street, Oak Creek, WI 53154. | City Hall, 8640 South Howell Avenue, Oak Creek, WI 53154. | Aug. 25, 2022 | 550279 |

[FR Doc. 2022–23545 Filed 10–27–22; 8:45 am]

**BILLING CODE 9110–12–P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

**[Docket ID FEMA–2008–0010]**

### Board of Visitors for the National Fire Academy

**AGENCY:** Federal Emergency Management Agency, Department of Homeland Security.

**ACTION:** Notice of open federal advisory committee meeting.

**SUMMARY:** The Board of Visitors for the National Fire Academy (Board) will meet virtually on Tuesday, December 6, 2022, to discuss and support the academic stature of the National Fire Academy. The meeting will be open to the public.

**DATES:** The meeting will take place on Tuesday, December 6, 2022, 2 p.m. to 4 p.m. Eastern Standard Time. Please note that the meeting may close early if the Board has completed its business.

**ADDRESSES:** Members of the public who wish to participate in the virtual conference should contact Deborah Gartrell-Kemp as listed in the **FOR FURTHER INFORMATION CONTACT** section by close of business on November 25, 2022, to obtain the call-in number and access code for the virtual meeting on December 6, 2022. For more information on services for individuals with disabilities or to request special assistance, contact Deborah Gartrell-Kemp as soon as possible. The Board is committed to ensuring all participants have equal access regardless of disability status. If you require a reasonable accommodation due to a disability to fully participate, please contact Deborah Gartrell-Kemp as listed

in the **FOR FURTHER INFORMATION CONTACT** section as soon as possible.

To facilitate public participation, we are inviting public comment on the issues to be considered by the Board as listed in the **SUPPLEMENTARY INFORMATION** section. Participants seeking to have their comments considered during the meeting should submit them in advance or during the public comment segment. Comments submitted up to 30 days after the meeting will be included in the public record and may be considered at the next meeting. Comments submitted in advance must be identified by Docket ID FEMA–2008–0010 and may be submitted by *one* of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Electronic Delivery:* Email Deborah Gartrell-Kemp at *Deborah.GartrellKemp@fema.dhs.gov* no later than November 25, 2022, for consideration at the December 6, 2022, meeting.

*Instructions:* All submissions received must include the words ''Federal Emergency Management Agency'' and the Docket ID for this action. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided. You may wish to view the Privacy and Security Notice via a link on the homepage of *www.regulations.gov.*

*Docket:* For access to the docket and to read background documents or comments received by the National Fire Academy Board of Visitors, go to *http://www.regulations.gov,* click on ''Advanced Search,'' then enter ''FEMA–2008–0010'' in the ''By Docket ID'' box, then select ''FEMA'' under ''By Agency,'' and then click ''Search.''

**FOR FURTHER INFORMATION CONTACT:**

*Designated Federal Officer:* Eriks Gabliks, (301) 447–1117, *Eriks.Gabliks@fema.dhs.gov.*

*Logistical Information:* Deborah Gartrell-Kemp, (301) 447–7230, *Deborah.Gartrell-Kemp@fema.dhs.gov.*

**SUPPLEMENTARY INFORMATION:** The Board will meet virtually on Tuesday, December 6, 2022. The meeting will be open to the public. Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. appendix.

## Purpose of the Board

The purpose of the Board is to review annually the programs of the National Fire Academy (Academy) and advise the Administrator of the Federal Emergency Management Agency (FEMA), through the United States Fire Administrator, on the operation of the Academy and any improvements therein that the Board deems appropriate. In carrying out its responsibilities, the Board examines Academy programs to determine whether these programs further the basic missions that are approved by the FEMA Administrator, examines the physical plant of the Academy to determine the adequacy of the Academy's facilities, and examines the funding levels for Academy programs. The Board submits a written annual report through the United States Fire Administrator to the FEMA Administrator. The report provides detailed comments and recommendations regarding the operation of the Academy.

## Agenda

On Tuesday, December 6, 2022, there will be four sessions, with deliberations and voting at the end of each session as necessary:

1. The Board will discuss United States Fire Administration Data, Research, Prevention and Response.

2. The Board will discuss deferred maintenance and capital improvements on the National Emergency Training Center campus and Fiscal Year 2023 and beyond Budget Request/Budget Planning.

3. The Board will deliberate and vote on recommendations on Academy program activities to include developments, deliveries, staffing, admissions, and strategic plan.

4. There will also be an update on the Board of Visitors Subcommittee Groups for the Professional Development Initiative Update and the National Fire Incident Report System.

There will be a 10-minute comment period after each agenda item and each speaker will be given no more than 2 minutes to speak. Please note that the public comment period may end before the time indicated following the last call for comments. Contact Deborah Gartrell-Kemp to register as a speaker. Meeting materials will be posted by November 10, 2022, at *https://www.usfa.fema.gov/training/nfa/about/bov.html.*

**Eriks J. Gabliks,**

*Superintendent, National Fire Academy, United States Fire Administration, Federal Emergency Management Agency.*

[FR Doc. 2022–23547 Filed 10–27–22; 8:45 am]

**BILLING CODE 9111–74–P**

# DEPARTMENT OF HOMELAND SECURITY

## Federal Emergency Management Agency

**[Docket ID FEMA–2022–0002]**

## Final Flood Hazard Determinations

**AGENCY:** Federal Emergency Management Agency, Department of Homeland Security.

**ACTION:** Notice.

**SUMMARY:** Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below. The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP).

**DATES:** The date of April 5, 2023 has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

**ADDRESSES:** The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *https://msc.fema.gov* by the date indicated above.

**FOR FURTHER INFORMATION CONTACT:** Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

**SUPPLEMENTARY INFORMATION:** The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in

newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at *https://msc.fema.gov.*

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

**Nicholas A. Shufro,**

*Assistant Administrator for Risk Management (Acting), Federal Emergency Management Agency, Department of Homeland Security.*

| Community | Community map repository address |
|---|---|
| **City of Fredericksburg, Virginia (Independent City) Docket No.: FEMA–B–2057** | |
| City of Fredericksburg | Community Planning and Building Office, 601 Caroline Street, Suite 400, Fredericksburg, VA 22401. |

[FR Doc. 2022–23546 Filed 10–27–22; 8:45 am]

**BILLING CODE 9110–12–P**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–7050–N–55; OMB Control No. 2502–0005]**

## 30-Day Notice of Proposed Information Collection: FHA Lender Approval, Annual Renewal, Periodic Updates and Required Reports by FHA Approved Lenders

**AGENCY:** Office of Policy Development and Research, Chief Data Officer, HUD.

**ACTION:** Notice.

**SUMMARY:** HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for an additional 30 days of public comment.

**DATES:** *Comments Due Date:* November 28, 2022.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_submission@omb.eop.gov* or *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit: *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.* Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

**SUPPLEMENTARY INFORMATION:** This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on August 29, 2022 at 87 FR 52804.

### A. Overview of Information Collection

*Title of Information Collection:* FHA Lender Approval, Annual Renewal, Periodic Updates and Required Reports by FHA-Approved Lenders.

*OMB Approval Number:* 2502–0005.

*OMB Expiration Date:* October 31, 2022.

*Type of Request:* Revision.

*Form Number:* Online form, with no corresponding number.

*Description of the need for the information and proposed use:* This revision incorporates the requirements of 2 CFR 25, and 2 CFR 170, requiring all entities currently conducting or seeking to do business with the federal government must have a Unique Entity Identifier (UEI) registered in GSA's System of Award Management. Collection of the UEI is vital to HUD's compliance with the Federal Funding Accountability and Transparency Act of 2006 (FFATA) and Digital Accountability and Transparency Act of 2014.

*Respondents:*

*Estimated Number of Respondents:* 2,421.

*Estimated Number of Responses:* 2,430.

*Frequency of Response:* Annual/Periodic.

*Average Hours per Response:* 1 hour.

*Total Estimated Burden:* 2,421.[1]

### B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

[1] Each year of the 2,421 respondents approximately 9 respondents are expected to not meet all eligibility requirements. These respondents must also submit an ''unable to certify'' report which requires further review before they may proceed. The result is 2,430 total responses from 2,421 respondents.

HUD encourages interested parties to submit comment in response to these questions.

**C. Authority**

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507.

**Colette Pollard,**

*Department Reports Management Officer, Office of Policy Development and Research, Chief Data Officer.*

[FR Doc. 2022–23509 Filed 10–27–22; 8:45 am]

**BILLING CODE 4210–67–P**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–7050–N–56]**

### 30-Day Notice of Proposed Information Collection: Previous Participation Certification; OMB Control No.: 2502–0118

**AGENCY:** Office of Policy Development and Research, Chief Data Officer, HUD.

**ACTION:** Notice.

**SUMMARY:** HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for an additional 30 days of public comment.

**DATES:** *Comments Due Date:* November 28, 2022.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_submission@omb.eop.gov* or *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

**SUPPLEMENTARY INFORMATION:** This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on July 12, 2022, at 87 FR 41346.

**A. Overview of Information Collection**

*Title of Information Collection:* Previous Participation Certification.

*OMB Approval Number:* 2502–0118.

*OMB Expiration Date:* November 30, 2022.

*Type of Request:* Extension of a currently approved collection.

*Form Number:* HUD Form 2530.

*Description of the need for the information and proposed use:* The HUD–2530 process provides review and clearance for participants in HUD's multifamily insured and non-insured projects. The information collected (participants' previous participation record) is reviewed to determine if they have carried out their past financial, legal, and administrative obligations in a satisfactory and timely manner. The HUD–2530 process requires a principal to certify to their prior participation in multifamily projects, and to disclose other information which could affect the approval for the proposed participation.

*Respondents:* Multifamily project participants such as owners, managers, developers, consultants, general contractors, and nursing home owners and operators.

*Estimated Number of Respondents:* 9,000.

*Estimated Number of Responses:* 9,000.

*Frequency of Response:* 1.

*Average Hours per Response:* Three hours for paper 2530 and 1 hour for electronic 2530.

*Total Estimated Burden:* 12,000.

**B. Solicitation of Public Comment**

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

(5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

HUD encourages interested parties to submit comment in response to these questions.

**C. Authority**

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

**Colette Pollard,**

*Department Reports Management Officer, Office of Policy Development and Research, Chief Data Officer.*

[FR Doc. 2022–23520 Filed 10–27–22; 8:45 am]

**BILLING CODE 4210–67–P**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–7056–N–43]**

### 60-Day Notice of Proposed Information Collection: Multifamily Financial Management Template, OMB Control No.: 2502–0551

**AGENCY:** Office of the Assistant Secretary for Housing- Federal Housing Commissioner, HUD.

**ACTION:** Notice.

**SUMMARY:** HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

**DATES:** *Comments Due Date:* December 27, 2022.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email

at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

**FOR FURTHER INFORMATION CONTACT:** Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

**SUPPLEMENTARY INFORMATION:** This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

**A. Overview of Information Collection**

*Title of Information Collection:* Multifamily Financial Management Template.

*OMB Approval Number:* 2502–0551.

*Type of Request:* Reinstatement, with change, of previously approved collection for which approval has expired.

*Form Number:* None.

*Description of the need for the information and proposed use:* Owners of certain HUD-insured and HUD-assisted properties, which includes most owners of multifamily housing properties are required to submit annual financial statements to HUD via the internet in the HUD-prescribed format and chart of accounts, and in accordance with the generally accepted accounting principles (GAAP). In accordance with the Department's Uniform Financial Reporting Standards (UFRS) regulation, 24 CFR part 5, owners of certain HUD-insured and HUD-assisted properties are required to submit annual financial statements electronically to HUD via the internet in the HUD-prescribed format and chart of accounts, and in accordance with the generally accepted accounting principles (GAAP). The Department uses this information to monitor the owner's compliance with regulatory requirements and to assess fiscal performance.

*Respondents:* Business or other for profit.

*Estimated Number of Respondents:* 26,995.

*Estimated Number of Responses:* 26,995.

*Frequency of Response:* Annually.

*Average Hours per Response:* 14.

*Total Estimated Burden:* 377,930.

**B. Solicitation of Public Comment**

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

**C. Authority**

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

**Jeffrey D. Little,**

*General Deputy Assistant Secretary, Office of Housing.*

[FR Doc. 2022–23516 Filed 10–27–22; 8:45 am]

**BILLING CODE 4210–67–P**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. FR–7056–N–32]**

## 60-Day Notice of Proposed Information Collection: Multifamily Project Applications and Construction Prior to Initial Endorsement, OMB Control No.: 2502–0029

**AGENCY:** Office of the Assistant Secretary for Housing- Federal Housing Commissioner, HUD.

**ACTION:** Notice.

**SUMMARY:** HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

**DATES:** *Comments Due Date:* December 27, 2022.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

**FOR FURTHER INFORMATION CONTACT:** Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

**SUPPLEMENTARY INFORMATION:** This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

**A. Overview of Information Collection**

*Title of Information Collection:* Multifamily Project Applications and Construction Prior to Initial Endorsement.

*OMB Approval Number:* 2502–0029.

*OMB Expiration Date:* 4/30/20.

*Type of Request:* Reinstatement, with change, of previously approved collection for which approval has expired.

*Form Number (s):* HUD–92013, HUD–92013–SUPP, HUD–92013–A, HUD–92013–B, HUD–92013–C, HUD–92013–D, HUD–92264, HUD–92264–A, HUD–92273, HUD–92274, HUD–92326, HUD–92329, HUD–92331, HUD–92415, HUD–92447, HUD–92452, HUD–92485, HUD–91708, HUD–92010, FM–1006, HUD–2880, HUD–92466, (Rider Forms—HUD–92466–R1, –92466–R2, –92466–R3, –92466–R4, –92466–R5), HUD–92466M, HUD–92408 HUD–95379 and HUD–2.

*Description of the need for the information and proposed use:* The information collection is utilized during the processing of an application for FHA insured mortgage. The respondents are owners/sponsors, general contractors, lenders, and others involved in multifamily housing projects/rehabs. One of the options used in processing an application for FHA insured mortgage is Multifamily Application Processing (MAP). Third party contractors for mortgage insurance perform MAP. Mortgagors submit application for Multifamily Projects to an approved lender for a project to be insured by HUD. The lender's underwriters will complete all processing forms and submit them to HUD. The contractors involved are architects, cost analysts, appraisers, and mortgage credit analysts. An environmental review is also conducted, as well as a market analysis.The information collection allows the multifamily staff to determine the appropriate mortgage insurance premium to apply in the underwriting of the loan for an FHA insured mortgage.

*Respondents;* Individuals participating in HUD Multifamily mortgage insurance programs as principals of sponsors, mortgagors, and general contractors.

*Estimated Number of Respondents:* 23,588.

*Estimated Number of Responses:* Varies.

*Frequency of Response:* Varies.

*Average Hours per Response:* Varies.

*Total Estimated Burden:* 383,056.

**B. Solicitation of Public Comment**

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

**C. Authority**

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

**Jeffrey D. Little,**

*General Deputy Assistant Secretary, Office of Housing.*

[FR Doc. 2022–23512 Filed 10–27–22; 8:45 am]

**BILLING CODE 4210–67–P**

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

**[Docket No. FWS–HQ–MB–2022–0056; FF09M21200–223–FXMB1231099BPP0; OMB Control Number 1018–0022]**

### Agency Information Collection Activities; Federal Fish and Wildlife Permit Applications and Reports—Migratory Birds

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of information collection; revision of proposed changes; comment period reopening.

**SUMMARY:** In accordance with the Paperwork Reduction Act, on May 17, 2022, we, the U.S. Fish and Wildlife Service, published a notice announcing that we are proposing to renew an existing information collection with revisions. The notice opened a public comment period, which closed on July 18, 2022. Because we have additional proposed changes, we are now republishing the notice and reopening the comment period.

**DATES:** Interested persons are invited to submit comments on or before December 27, 2022.

**ADDRESSES:** Send your comments on the information collection request (ICR) by one of the following methods (please reference OMB Control Number ''1018–0022'' in the subject line of your comment):

- *Internet (preferred): https://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–HQ–MB–2022–0056.
- *Email: Info_Coll@fws.gov.*
- *U.S. mail:* Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, Docket No. FWS–HQ–MB–2022–0056, 5275 Leesburg Pike, MS: PRB (JAO/3W), Falls Church, VA 22041–3803.

**FOR FURTHER INFORMATION CONTACT:** Madonna L. Baucum, Service Information Collection Clearance Officer, by email at *Info_Coll@fws.gov,* or by telephone at (703) 358–2503. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

**SUPPLEMENTARY INFORMATION:** In accordance with the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501 *et seq.*) and its implementing regulations in the Code of Federal Regulations (CFR) at 5 CFR 1320, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

On May 17, 2022, we published a notice announcing that we are proposing to renew an existing information collection with revisions (87 FR 29872). The notice opened a public comment period, which closed on July 18, 2022. Because we have additional proposed changes, we are now republishing the notice in full and reopening the comment period. Our final determination will take into consideration all written comments and any additional information we receive during both comment periods.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper

performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

*Abstract:* The U.S. Fish and Wildlife Service's regional migratory bird permit offices use information that we collect on permit applications to determine the eligibility of applicants for permits requested in accordance with the criteria in various Federal wildlife conservation laws and international treaties, including:

(1) Migratory Bird Treaty Act (16 U.S.C. 703 *et seq.*).

(2) Lacey Act (18 U.S.C. 42; 16 U.S.C. 3371 *et seq.*).

(3) Bald and Golden Eagle Protection Act (16 U.S.C. 668 *et seq.*).

Service regulations implementing these statutes and treaties are in chapter I, subchapter B of title 50 of the Code of Federal Regulations (CFR), parts 10, 13, 20, and 21. These regulations stipulate general and specific requirements that, when met, allow us to issue permits to authorize activities that are otherwise prohibited.

Generally, with the exception of forms 3–186 and 3–186a, all Service migratory bird permit application and report forms are in the 3–200 and 3–202 series of forms, each tailored to a specific activity based on the requirements for specific types of permits. We collect standard identifier information for all permits. The information that we collect on applications and reports is the minimum necessary for us to determine if the applicant meets/continues to meet issuance requirements for the particular activity.

In accordance with Federal regulations at 50 CFR 13.12, we collect standard identifier information for all permit applications, such as:

- Applicant's full name and address (street address, city, county, State, and zip code; and mailing address if different from street address); home and work telephone numbers; and a fax number and email address (if available), and

—If the applicant resides or is located outside the United States, an address in the United States, and, if the applicant is applying for permission to conduct commercial activities, the name and address of his or her agent that is located in the United States; and

—If the applicant is an individual, the date of birth, occupation, and any business, agency, organizational, or institutional affiliation associated with the wildlife or plants to be covered by the license or permit; or

—If the applicant is a business, corporation, public agency, or institution, the tax identification number; description of the business type, corporation, agency, or institution; and the name and title of the person responsible for the permit (such as president, principal officer, or director);

- Location where the requested permitted activity is to occur or be conducted;

- Certification containing the following language:

—''I hereby certify that I have read and am familiar with the regulations contained in title 50, part 13, of the Code of Federal Regulations and the other applicable parts in subchapter B of chapter I of title 50, Code of Federal Regulations, and I further certify that the information submitted in this application for a permit is complete and accurate to the best of my knowledge and belief. I understand that any false statement herein may subject me to suspension or revocation of this permit and to the criminal penalties of 18 U.S.C. 1001.''

- Requested effective date of permit (except where issuance date is fixed by the part under which the permit is issued);

- Current date;

- Signature of the applicant;

- Such other information as the Director determines relevant to the processing of the application, including but not limited to

—Information on the environmental effects of the activity consistent with 40 CFR 1506.5 and Departmental procedures at 516 DM 6, appendix 1.3A; and

—Additional information required on applications for other types of permits may be found by referring to table 1 to paragraph (b) in 50 CFR 13.12.

Standardization of general information common to the application forms makes the filing of applications easier for the public, as well as expediting our review of applications. The information that we collect on applications and reports is the minimum necessary for us to determine whether the applicant meets/continues to meet issuance requirements for the particular activity.

**Proposed Revisions to This Information Collection**

With this submission, we are proposing the following revisions to the existing information collection:

*Revisions to Section E in Permit Applications*

In 2020, the Service implemented a new automated permit application called ePermits. The ePermits system allowed the Service to move towards a streamlined permitting process to reduce the information collection burden on the public, particularly small businesses. Public burden reduction is a priority for the Service; the Assistant Secretary for Fish and Wildlife and Parks; and senior leadership at the Department of the Interior. The ePermits system will fully automate the permitting process to improve the customer experience and to reduce time burden on respondents. This system enhances the user experience by allowing users to enter data from any device that has internet access, including personal computers, tablets, and smartphones. It also links the permit applicant to the *Pay.gov* system for payment of the associated permit application fee.

A user of the ePermits system registers for and uses an account which will then automatically populate the forms they complete with the required identification information. The system eliminates the need for the applicant to enter their information multiple times when they apply for multiple permits, thereby reducing burden on the applicant. The account registration process will also provide private sector users an opportunity to self-identify as a small business, which will enable the Service to more accurately report burden associated with information collection requirements placed on them.

At this time, the ePermits system is unable to fully automate Section E of the permit application process. Section E of each permit application is customized based on the permit type. We anticipate being able to begin digitizing Section E on our forms in calendar year 2022. As a result of challenges with the development of forms within the ePermits system, we do not have a timeline for full automation of Section E. We anticipate beginning the digitization of the report forms contained in this collection by 2023 and believe the digitization of Section E on application forms should be finalized by fiscal year 2024, as funding and resources become available.

We propose the following changes to certain permit application forms contained in this collection via the ePermits system, to include the following:

- Applicants will be able to select the type of business they manage (for-profit, small business, farm, not-for-profit, or government entity).
- Requesting businesses using ePermits will be asked to provide email addresses for both the principal officer and the business.
- The signature block will be replaced by with electronic submission of the online applications.

The updates to the ePermits system will also:

- Allow users to apply on behalf of another individual or business as a new way to identify if a consultant is applying for a client.
- Ask for the name of the authorized individual to include on the permit.
- Allow a business to nickname their applications.
- Ask the applicant to identify the location where the majority of the authorized activities will occur.
- Ask the applicant to identify the physical address of the preparer of application.
- Ask the applicants to identify if they are tax exempt.
- Prompt applicants to provide their preferred contact method.
- Prompt the applicant to describe changes associated with amendments or renewals (with changes) of their permit.
- Prompt applicants to opt in or out of releasing their information for all applications except migratory bird rehabilitation permits (businesses are automatically opted in).
- Prompt the applicant to provide a parent permit number, which allows the ePermits System to direct the user to the correct version of their permit for renewals or amendments to a permit.

In addition to the ePermits changes listed above, we propose the below listed changes to the questions within Section E of four application forms in this collection:

*3–200–10b: Migratory Bird Rehabilitation*

- Question 1:

—Update the species group list to a previous version of this list that better aligns with the terminology the Service uses to group species: eagles, raptors, songbirds, seabirds, waterbirds, waterfowl.
—Add levels of care to the species request (restricted, limited, and unlimited).

- General:

—Clarify that the permit will authorize species groups (eagles, raptors, songbirds, seabirds, waterbirds, waterfowl) and level of care (restricted, limited, and unlimited), and that the questions must be answered sufficiently to make determinations for each of the species/care levels requested.
—Add clarifying language for subpermittees, in particular, falconers. as subpermittees.

*3–200–7: Migratory Bird and Eagle Scientific Collecting*

- Add a question regarding whether institutional animal care and use committee (IACUC) approval is required. If Yes, provide your approval or copy of your application.

*3–200–8: Migratory Bird Taxidermy*

- Add a yes/no check box to indicate whether there are any subpermittees.
- Rephrase question 4 to clarify subpermittee names.

*3–200–13: Migratory Bird Depredation*

- Question 8:

—Modify the questions to clarify that this applies if you are applying on behalf of an airport. Request the dates of the Hazard Management Plan (WHMP) or Bird Air Strike Hazard (BASH) plan; request the FAA and USDA–WS review dates of the plan; and state that the applicant may be required to submit a copy of the plan(s).

- General: Add a new question as follows: Is the applicant operating under an existing NEPA document? If yes, include the title of document, status (draft/final), and date(s) published. The applicant may be required to submit a copy of the document.

In addition to the form-specific updates listed above, we propose to update Section E on all of the application forms to indicate which questions are required for renewal.

We also propose the following changes to the below listed report forms in this collection:

*3–202–9: Migratory Bird Depredation*

- In the reporting table header, the following changes are being proposed:

—Remove the words ''(required)'' from the header ''County.''
—Update ''Month Taken'' to ''Date''.
—Update ''Birds Relocated'' to ''Birds Captured''.
—Add directions for reporting birds captured to be consistent with the 2004 Policy Memo.

*3–202–17: USFWS Bird and Bat Injury and Mortality Reporting System (Excel Sheet) and the Injury and Mortality Reporting System*

The Service is revising Form 3–202–17 as a result of a close review and enhancement of the Injury and Mortality Reporting (IMR) system, which bases the information it collects on the fields and information collected in Form 3–202–17. The changes are expected to result in an overall burden reduction to the public and an overall improved user experience as a result of the net reduction in fields and the streamlining and update of both the Excel form and IMR user interface. Creation of a project record prior to logging injury/mortality records will now be optional, which should reduce the burden for some users.

We propose the following changes to the form and system, including fields being removed, overall system improvements, and field additions:

- Removal of 26 fields from the form:

—Primary Contact Name (required).
—Primary Contact Title (required).
—Event Observed? (required).
—Other Species or Species Type (required if other two species options weren't populated).
—FWS Project Consultation Number.
—How Aged.
—Other Aging Method.
—Nearby Features.
—Other How Identified.
—Other Location Accuracy.
—Probable Cause.
—Probable Cause Details.
—Suspected Cause.
—Suspected Cause Details.
—Other Disposition.
—Wing Chord.
—Hallux.
—Culmen.
—Tarsus.
—Footpad.
—Weather Conditions.
—Temperature.
—Wind Speed.
—Barometric Pressure.

—Humidity.
—Wind Direction.

• System modifications to streamlining actions and added efficiency for IMR system users:

—More intuitive user interface—The new IMR interface will be more user-friendly and instructive.
—Improved bulk record uploading capabilities—The IMR bulk upload graphic user interface will be simplified to reflect the changes taking place on the IMR form. The bulk upload process itself will also be made more streamlined, efficient, and user-friendly.
—Improvements to ability of users to give others access to records—Users will be able share records with other IMR users, as they currently do. However, a new ''view-only'' role will be added so that users can allow individuals to see their records, but not modify them.
—Consolidation of ID fields—USGS Band Number, FWS Toe Tag ID, Local Specimen Number, and Has Telemetry Tag? fields will be consolidated into one field that allows users to ''Add an ID Type'', which will allow users to associate multiple ID types and information about those ID types (*e.g.,* the ID number) with a single record.
—Ability to take certain actions on multiple records (*e.g.,* bulk associate records with a particular project or permit). This new feature will enable this functionality and make managing records and information much easier and more efficient for users.
—Ability to bulk upload documents—Currently, IMR users cannot bulk upload documents. This feature will be a time saver for users that have a large number of documents they would like to associate with a project or record.

• Adding 14 fields to the form:

—Project Location (conditionally required)—This field will be added to the Project record form and only required if a user chooses to create a Project record with which to associate their injury/mortality records.
—Record Type (required)—Users will indicate whether the record is associated with an Injury, Mortality, Nest Removal, or Nest Relocation. The answer to this question will refine the subsequent form questions so the user answers only the questions relevant to the selection made.
—Reporting an Eagle Record? (required)—If the answer is ''Yes'', the user workflow is simplified to be eagle-specific.
—Number of Nests (required)—This field will be revealed only if Nest Removal or Nest Relocation is chosen for ''Record Type'' field.
—Species Known? (required)—If the answer is ''No'', the user workflow is simplified to only allow species categories rather than individual species names.
—Company—If new contacts are added, users will have the option of specifying the company with which they are associated.
—Species Notes.
—Date Relocated or Removed—This field is revealed only if ''Nest Removal'' or ''Nest Relocation'' is chosen for the ''Record Type'' field.
—Possible Cause.
—Possible Cause Details.
—In Search Plot?
—Hazard Azimuth.
—Hazard Distance.
—Nearest Turbine ID.

*Falconry Program*

We propose to modify Form 3–186A to update the field ''USFWS Band Number'' to say ''USFWS/State/Tribe/Territory band number'' and ''USFWS Permit Number'' to say ''USFWS/State/Tribe/Territory permit number.''

*Migratory Bird Permit Program Service Manual Chapters*

With this submission, we will seek OMB approval of the *Migratory Bird Permit Program Handbook* (Handbook) and associated Service Manual chapters at 724 FW 1 (''Migratory Bird Permits'') and 724 FW 2 (''Migratory Bird Management''), all of which contain references to information collections. The Handbook provides detailed procedures and other operational information to implement the Service Manual chapters in part 724 and more generally in part 720.

New and existing information collections contained in the Handbook requiring OMB approval include the following:

• Renewal procedures associated with the reauthorization of an existing permit (with or without changes to the conditions);

• Reinstatement procedures associated with the reauthorization of an existing permit (with or without changes to the conditions);

• Discontinuance procedures at the permittee's request to discontinue a valid permit;

• Solicitation of appropriate documentation from entities authorized to act on behalf of State, local, Tribal, and Federal government agencies to verify their exempt status for fee-exemption purposes;

• Fee waiver request process as outlined in 50 CFR 13.11(d)(3)(iii);

• Requests for reconsideration of a denial, partial denial, suspension, or revocation of a permit (requiring submission of a written request with the required information in 50 CFR 13.29(b) within 45 days after the permit decision); and

• Appeals of reconsideration request decisions (requiring the permittee submit a written request to the Regional Director (see 50 CFR 13.29(e)) within 45 days of the reconsideration decision).

*Consolidation of Information Collections Contained in OMB Control No. 1018–0175, ''Federal Fish and Wildlife Permit Applications and Reports—Special Double-Crested Cormorants; 50 CFR 21'' Into OMB Control No. 1018–0022*

With this submission, we will request OMB approval to consolidate the following information collections currently approved under OMB Control No. 1018–0175 (expires 1/31/2024, viewable at *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202010-1018-003*) into information collection 1018–0022:

• *FWS Form 3–200–90, Special Double-Crested Cormorant Permit Application (and amendments, as appropriate)*—This permit is available only to State or Tribal fish and wildlife agencies responsible for migratory bird management on lands and in waters managed by those agencies within their jurisdictions. Under this permit, the Service authorizes State and Tribal fish and wildlife agencies to conduct lethal take to reduce conflicts involving depredation at State- and Tribal-owned or operated aquaculture facilities (including hatcheries); impacts to health and human safety; impacts to threatened and endangered species (as listed under the ESA and listed species identified in State- or Tribal-specific legislation as threatened or endangered) or those listed as species of greatest conservation need in State wildlife action plans; damage to State- or Tribal-owned property and assets; and depredations of wild and publicly stocked fish managed by State fish and wildlife agencies or federally recognized Tribes and accessible to the public or all Tribal members. Take activities to prevent depredation on aquatic species of greatest conservation need may occur only in natural or public waters.

Any State or Tribal fish and wildlife agency wishing to obtain a permit must submit to the appropriate Regional Director Form 3–200–90, containing the general information and certification required by 50 CFR 13.12(a). These annual permits, managed by calendar year, allow for alignment with permit

processing cycles and the need to evaluate allocation at the beginning of a calendar year. Section E of each application collects information specific to the activity the applicant wishes to conduct, as well as information concerning:

(1) A brief description of the State's or Tribe's double-crested cormorant conflicts, including physical location(s) and type of conflict;

(2) A detailed description of the nonlethal methods (*i.e.,* active hazing, passive hazing, habitat management, and changes in management practices) that the applicant has and/or will implement, and how activities will address one or more of the issues;

(3) The requested annual take of double-crested cormorants by life-stage, including eggs and nests;

(4) A description of long-term plans to eliminate or significantly reduce continued need to take double-crested cormorants;

(5) A statement indicating that the State or Tribe will inform and brief all employees and subpermittees of the requirements of these regulations and permit conditions;

(6) A list of all subpermittees who may conduct activities under the special double-crested cormorant permit, including their names, addresses, and telephone numbers; and

(7) The name and telephone number of the individual in your agency who will oversee the double-crested cormorant management activities authorized under the permit.

• *FWS Form 3–202–56, Annual Report—Special Double-Crested Cormorant*—In conjunction with issuance of the special double-crested cormorant permit, the Service requires that the permittee submit Form 3–202–56 detailing activities, including the date, numbers, and locations and life stages of birds, eggs, and nests taken and nonlethal techniques utilized, by January 31 for activities conducted during the preceding calendar year. We collect the following information via Form 3–202–56 to ensure that the applicant remains in compliance with the terms of their permit:

(1) Permittee contact information, permit number, permit calendar year, and permit report due date;

(2) Description of non-lethal techniques utilized;

(3) Month and location of activity;

(4) Purpose;

(5) Numbers of birds killed, nests oiled, and/or nests destroyed;

(6) Final Disposition (what they did with the birds, eggs, carcasses [*e.g.,* buried; incinerated; euthanized and donated]); and

(7) Take of non-target bird species, including numbers of birds.

• *Recordkeeping*—Any State or Tribal agency, when exercising the privileges of this permit, must keep records of all activities, including those of subpermittees, carried out under the authority of the special permit.

• *Landowner Notifications*—If a State or Tribe must enter private property to access State and Tribal lands or waters where take is approved in their permit, the State or Tribe must obtain authorization from the private property owner.

The public may request copies of any form or document contained in this information collection by sending a request to the Service Information Collection Clearance Officer in **ADDRESSES**, above.

*Title of Collection:* Federal Fish and Wildlife Permit Applications and Reports—Migratory Birds; 50 CFR 10, 13, 20, and 21.

*OMB Control Number:* 1018–0022.

*Form Numbers:* FWS Forms 3–186, 3–186A, 3–200–6 through 3–200–9, 3–200–10a through 3–200–10c, 3–200–10e, 3–200–10f, 3–200–12 through 3–200–13, 3–200–67, 3–200–79, 3–200–81, 3–202–1 through 3–202–10, 3–202–12, 3–202–17, 3–200–90, and 3–202–56.

*Type of Review:* Revision of an existing information collection.

*Respondents/Affected Public:* Individuals; private sector (including zoological parks, museums, universities, scientists, taxidermists, businesses, and utilities); and State, local, Tribal, and Federal governments.

*Respondent's Obligation:* Required to obtain or retain a benefit.

*Frequency of Collection:* On occasion for applications; annually or on occasion for reports.

*Total Estimated Annual Nonhour Burden Cost:* $491,050 (primarily associated with application processing fees in OMB Control No. 1018–0022).

| OMB control No. | Average number of annual respondents | Average number of annual responses | Average completion time per response | Estimated annual burden hours |
|---|---|---|---|---|
| 1018–0022 | 27,980 | 53,510 | Varies from 15 minutes to 260 hours | 394,967 |
| 1018–0175 | 711 | 711 | Varies from 1 minute to 17 hours | 4,598 |
| Totals | 28,691 | 54,221 | | 399,565 |

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

**Madonna Baucum,**

*Information Collection Clearance Officer, U.S. Fish and Wildlife Service.*

[FR Doc. 2022–23491 Filed 10–27–22; 8:45 am]

**BILLING CODE 4333–15–P**

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

**[Docket No. FWS–HQ–IA–2022–0054; FXIA16710900000–223–FF09A30000]**

### Marine Mammal Protection Act; Receipt of Permit Applications

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of receipt of permit applications; request for comments.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), invite the public to comment on applications to conduct certain activities with foreign species that the Service has jurisdiction under the Marine Mammal Protection Act (MMPA). With some exceptions, the MMPA prohibits activities with listed species unless Federal authorization is issued that allows such activities. The MMPA also requires that we invite public comment before issuing permits for any activity otherwise prohibited by the MMPA with respect to any endangered species or marine mammals.

**DATES:** We must receive comments by November 28, 2022.

**ADDRESSES:**

*Obtaining Documents:* The application, application supporting materials, and any comments and other

materials that we receive will be available for public inspection at *https://www.regulations.gov* in Docket No. FWS–HQ–IA–2022–0054.

*Submitting Comments:* When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. You may submit comments by one of the following methods:

- *Internet: https://www.regulations.gov.* Search for and submit comments on Docket No. FWS–HQ–IA–2022–0054.
- *U.S. Mail:* Public Comments Processing, Attn: Docket No. FWS–HQ–IA–2022–0054; U.S. Fish and Wildlife Service Headquarters, MS: PRB/3W; 5275 Leesburg Pike, Falls Church, VA 22041–3803.

For more information, see Public Comment Procedures under **SUPPLEMENTARY INFORMATION.**

**FOR FURTHER INFORMATION CONTACT:** Brenda Tapia, by phone at 703–358–2185, or via email at *DMAFR@fws.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

**SUPPLEMENTARY INFORMATION:**

## I. Public Comment Procedures

*A. How do I comment on submitted applications?*

We invite the public and local, State, Tribal, and Federal agencies to comment on applications. Before issuing any requested permits, we take into consideration any information that we receive during the public comment period.

You may submit your comments and materials by one of the methods in **ADDRESSES**. We will not consider comments sent by email or fax, or to an address not in **ADDRESSES**. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**).

When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. Provide sufficient information to allow us to authenticate any scientific or commercial data you include. The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) those that include citations to, and analyses of, the applicable laws and regulations.

*B. May I review comments submitted by others?*

You may view and comment on others' public comments at *https://www.regulations.gov* unless our allowing so would violate the Privacy Act (5 U.S.C. 552a) or Freedom of Information Act (5 U.S.C. 552).

*C. Who will see my comments?*

If you submit a comment at *https://www.regulations.gov,* your entire comment, including any personal identifying information, will be posted on the website. If you submit a hardcopy comment that includes personal identifying information, such as your address, phone number, or email address, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. Moreover, all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

## II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 104(c) of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), we invite public comments on permit applications before final action is taken. With some exceptions, MMPA prohibits certain activities with listed species unless Federal authorization is issued that allows such activities. Service regulations regarding prohibited activities with endangered species, captive-bred wildlife registrations, and permits for any activity otherwise prohibited by the ESA with respect to any endangered species are available in title 50 of the Code of Federal Regulations in part 17. Service regulations regarding permits for any activity otherwise prohibited by the MMPA with respect to any marine mammals are available in title 50 of the Code of Federal Regulations in part 18. Concurrent with publishing this notice in the **Federal Register**, we are forwarding copies of the marine mammal applications to the Marine Mammal Commission and the Committee of Scientific Advisors for their review.

## III. Permit Applications

We invite comments on the following applications.

*Applicant: USGS Alaska Science Center, Anchorage, AK; Permit No. 067925*

The applicant requests a permit to capture/recapture, transport, immobilize, hold, administer drugs to, flipper tag, surgically implant transmitters inside, measure, collect biological samples from, and release northern sea otter (*Enhydra lutris kenyoni*) in the wild for the purpose of scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

*Applicant: BBC Studios Productions Ltd, Bristol, UK; Permit No. PER0036892*

The applicant requests a permit to photograph (video and photos) Pacific walrus (*Odobenus rosmarus*) in the wild at Round Island, AK, for the purpose of commercial photography. This notification covers activities to be conducted by the applicant over a 5-year period.

## IV. Next Steps

After the comment period closes, we will make decisions regarding permit issuance. If we issue permits to the applicants listed in this notice, we will publish a notice in the **Federal Register**. You may locate the notice announcing the permit issuance by searching *https://www.regulations.gov* for the permit number listed above in this document. For example, to find information about the potential issuance of Permit No. 12345A, you would go to *regulations.gov* and search for ''12345A''.

## V. Authority

We issue this notice under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), and its implementing regulations.

**Brenda Tapia,**

*Supervisory Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.*

[FR Doc. 2022–23508 Filed 10–27–22; 8:45 am]

**BILLING CODE 4333–15–P**

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

**[FWS–R4–OSA–2022–N054; FF04S00000 223 FXSC14200400000; OMB Control Number 1018-New]**

### Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Southeast Conservation Adaptation Strategy (SECAS) Social Network Analysis Survey

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of information collection; request for comment.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service (Service), are proposing a new information collection.

**DATES:** Interested persons are invited to submit comments on or before November 28, 2022.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. Please provide a copy of your comments to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS: PRB (JAO/3W), 5275 Leesburg Pike, Falls Church, VA 22041–3803 (mail); or by email to *Info_Coll@fws.gov.* Please reference ''1018–SECAS'' in the subject line of your comments.

**FOR FURTHER INFORMATION CONTACT:** Madonna L. Baucum, Service Information Collection Clearance Officer, by email at *Info_Coll@fws.gov,* or by telephone at (703) 358–2503. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

**SUPPLEMENTARY INFORMATION:** In accordance with the Paperwork Reduction Act (PRA, 44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR 1320.8(d)(1), all information collections require approval under the PRA. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

On July 6, 2022, we published a **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information (87 FR 40261). In that notice, we solicited comments for 60 days, ending on September 6, 2022. In an effort to increase public awareness of, and participation in, our public commenting processes associated with information collection requests, the Service also published the **Federal Register** notice on *https://www.regulations.gov* [Docket No. FWS–R4–OSA–2022–0086]. We received one comment in response to that notice which did not address the information collection requirements; therefore, no response was required.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

*Abstract:* The Fish and Wildlife Act of 1956 (16 U.S.C. 742d) designates the Department of the Interior as a key agency responsible for the conservation and protection of wildlife and fisheries resources in the United States. This responsibility requires the Service to gather accurate data on conservation efforts through means such as research to improve the development, management, and advancement of efforts. The Service's Science Applications and Migratory Bird Program in the Service's Southeast Region is seeking to conduct a social network analysis to collect information regarding regional conservation efforts, conservation partnership goals, structure, and focal geography, and the connectedness of these efforts and partnerships. The proposed survey collects information necessary to address this gap in understanding and will serve to advance the Southeast Conservation Adaptation Strategy's (SECAS) leadership role as a regional forum and decision-support hub.

The proposed survey collects the following information:

- Familiarity and engagement with SECAS, including satisfaction with SECAS aspects and importance of SECAS indicators (section 2);
- Organizational conservation priorities, including level of importance and usefulness of and reliance on SECAS resources (section 3);
- Conservation partnerships, including identification of partner organizations and collaboration types (section 4); and
- Organizational information, including type of organization and scope of work (section 5).

The information collected in this effort will be used to develop multiple products aimed at translating the data into information that can strengthen partnerships, identify gaps, and inform conservation decisions.

The public may request a copy of the proposed survey instrument by sending a request to the Service Information Collection Clearance Officer (see **ADDRESSES**, above).

*Title of Collection:* Southeast Conservation Adaptation Strategy (SECAS) Social Network Analysis.

*OMB Control Number:* 1018-New.

*Form Number:* None.

*Type of Review:* New.

*Respondents/Affected Public:* Leaders and executives in the private sector and

State, local, and Tribal governments in the Service's Southeast Region.

*Total Estimated Number of Annual Respondents:* 200 (100 private sector entities and 100 State/local/Tribal governments).

*Total Estimated Number of Annual Responses:* 200.

*Estimated Completion Time per Response:* 15 minutes.

*Total Estimated Number of Annual Burden Hours:* 50.

*Respondent's Obligation:* Voluntary.

*Frequency of Collection:* One time.

*Total Estimated Annual Nonhour Burden Cost:* There is no cost associated with the survey.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

**Madonna Baucum,**

*Information Collection Clearance Officer, U.S. Fish and Wildlife Service.*

[FR Doc. 2022–23488 Filed 10–27–22; 8:45 am]

**BILLING CODE 4333–15–P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Indian Affairs

**[2231A2100DD/AAKC001030/A0A501010.999900; OMB Control Number 1076–0180]**

### Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Leasing of Osage Reservation Lands for Oil and Gas Mining

**AGENCY:** Bureau of Indian Affairs, Interior.

**ACTION:** Notice of information collection; request for comment.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, we, the Bureau of Indian Affairs (BIA) are proposing to renew an information collection.

**DATES:** Interested persons are invited to submit comments on or before November 28, 2022.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. Please provide a copy of your comments to Steven Mullen, Information Collection Clearance Officer, Office of Regulatory Affairs and Collaborative Action—Indian Affairs, U.S. Department of the Interior, 1001 Indian School Road NW, Suite 229, Albuquerque, New Mexico 87104; or by email to *comments@bia.gov.* Please reference OMB Control Number 1076–0180 in the subject line of your comments.

**FOR FURTHER INFORMATION CONTACT:** To request additional information about this ICR, please contact Steven Mullen, Information Collection Clearance Officer, *comments@bia.gov,* (202) 924–2650. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

**SUPPLEMENTARY INFORMATION:** In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on July 22, 2022 (87 FR 43889). No comments were received.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed ICR that is described below. We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

*Abstract:* Congress passed legislation specifically addressing oil and gas leasing on Osage lands and requiring Secretarial approval of leases. *See* 34 Stat. 543, section 3, as amended. The regulations at 25 CFR 226 implement that statute by specifying what information a lessee must provide related to drilling, development, and production of oil and gas on Osage reservation land. The oil, gas, and land are assets that the United States holds in trust or restricted status for Indian beneficiaries. The information collections in 25 CFR 226 are necessary to ensure that the beneficial owners of the mineral rights are provided the royalties due them, ensure that the oil and gas trust assets are protected, and to ensure that the surface estate assets are protected.

*Title of Collection:* Leasing of Osage Reservation lands for Oil and Gas Mining.

*OMB Control Number:* 1076–0180.

*Form Number:* Form A, Form B, Form C, Form D, Form F, Form H, Form G, Form 101, Form 101A, Form 133, Form 139, Form 157, Form 208, Form 229, Form 300.

*Type of Review:* Extension of a currently approved collection.

*Respondents/Affected Public:* Individual Indians, businesses, and Tribal authorities.

*Total Estimated Number of Annual Respondents:* 1,001.

*Total Estimated Number of Annual Responses:* 48,539.

*Estimated Completion Time per Response:* Varies from 15 minutes to eight hours.

*Total Estimated Number of Annual Burden Hours:* 22,731.

*Respondent's Obligation:* Required to Obtain or Retain a Benefit.

*Frequency of Collection:* Varies from yearly to monthly.

*Total Estimated Annual Nonhour Burden Cost:* 4,535.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

**Steven Mullen,**

*Information Collection Clearance Officer, Office of Regulatory Affairs and Collaborative Action—Indian Affairs.*

[FR Doc. 2022–23451 Filed 10–27–22; 8:45 am]

**BILLING CODE 4337–15–P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Indian Affairs

**[223A2100DD/AAKC001030/A0A501010.999900]**

### Self-Governance PROGRESS Act Negotiated Rulemaking Committee; Notice of Meeting

**AGENCY:** Bureau of Indian Affairs, Interior.

**ACTION:** Notice of virtual public meetings.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, the Self-Governance PROGRESS Act Negotiated Rulemaking Committee (Committee), will hold their third (November 2022) and fourth (December 2022) virtual public meeting to negotiate and advise the Secretary of the Interior (Secretary) on a proposed rule to implement the Practical Reforms and Other Goals to Reinforce the Effectiveness of Self-Governance and Self-Determination for Indian Tribes Act of 2019 (PROGRESS Act).

**DATES:** Please see **ADDRESSES** below for details on how to submit written comments. Please see **SUPPLEMENTARY INFORMATION** below for details on how to participate.

- *November 2022 Meeting:* The meeting will be open to the public and held virtually on Monday, November 14, 2022; from 1:00 to 5:00 p.m. Eastern Time. Interested persons are invited to submit comments on or before December 15, 2022.
- *December 2022 Meeting:* The meeting will be open to the public and held virtually on Friday, December 16, 2022; from 1:00 to 5:00 p.m. Eastern Time. Interested persons are invited to submit comments on or before January 17, 2022.

**ADDRESSES:** Send your comments to the Designated Federal Officer, Vickie Hanvey, by any of the following methods:

- *Preferred method:* Email to *comments@bia.gov.*
- *Alternate method:* Mail, hand-carry or use an overnight courier service to the Designated Federal Officer, Ms. Vickie Hanvey, Office of Self-Governance, Office of the Assistant Secretary—Indian Affairs, 1849 C Street NW, Mail Stop 3624, Washington, DC 20240.

**FOR FURTHER INFORMATION CONTACT:** Vickie Hanvey, Designated Federal Officer, *comments@bia.gov,* (918) 931–0745. Individuals in the United States who are deaf, blind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

**SUPPLEMENTARY INFORMATION:** This meeting is being held under the PROGRESS Act (Pub. L. 116–180), the Negotiated Rulemaking Act (5 U.S.C. 561 *et seq.*), and the Federal Advisory Committee Act (5 U.S.C. Appendix 2). The Committee is to negotiate and reach consensus on recommendations for a proposed rule that will replace the existing regulations at 25 CFR part 1000. The Committee will be charged with developing proposed regulations for the Secretary's implementation of the PROGRESS Act's provisions regarding the Department of the Interior's (DOI) Self-Governance Program.

The PROGRESS Act amends subchapter I of the Indian Self-Determination and Education Assistance Act (ISDEAA), 25 U.S.C. 5301 *et seq.,* which addresses Indian Self-Determination, and subchapter IV of the ISDEAA which addresses DOI's Tribal Self-Governance Program. The PROGRESS Act also authorizes the Secretary to adapt negotiated rulemaking procedures to the unique context of self-governance and the government-to-government relationship between the United States and Indian Tribes. The **Federal Register** (87 FR 30256) notice published on May 18, 2022, discussed the issues to be negotiated and the members of the Committee.

#### Meeting Agenda

These meetings are open to the public. Detailed information about the Committee, including meeting agendas can be accessed at *https://www.bia.gov/service/progress-act.* Topics for these meetings may include Committee operating protocols, negotiated rulemaking process, schedule and agenda setting for future meetings, Committee caucus, and public comment.

The third Plenary Committee meeting will begin at 1:00 p.m. Eastern Time on Monday, November 14, 2022. Members of the public wishing to attend the meeting should visit *https://teams.microsoft.com/l/meetup-join/19%3ameeting_ODZkOWE3NzItOWE5ZC00MzcwLTlhMzgtODQ0ZDAxMGY0Y2E4%40thread.v2/0?context=%7b%22Tid%22%3a%220693b5ba-4b18-4d7b-9341-f32f400a5494%22%2c%22Oid%22%3a%2213321130-a12b-4290-8bcf-30387057bd7b%22%2c%22IsBroadcastMeeting%22%3atrue%7d&btype=a&role=a* for virtual access.

The fourth Plenary Committee meeting will begin at 1:00 p.m. Eastern Time on Friday, December 16, 2022. Members of the public wishing to attend the meeting should visit *https://teams.microsoft.com/l/meetup-join/19%3ameeting_YjM2ZTVjNTAtZTlmOS00MmE5LWFkNGQtNzIxYjJjNmY5YTIy%40thread.v2/0?context=%7b%22Tid%22%3a%220693b5ba-4b18-4d7b-9341-f32f400a5494%22%2c%22Oid%22%3a%2213321130-a12b-4290-8bcf-30387057bd7b%22%2c%22IsBroadcastMeeting%22%3atrue%7d&btype=a&role=a* for virtual access.

#### Meeting Accessibility/Special Accommodations

Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. We ask that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice at least seven (7) business days prior to the meeting to give the Department of the Interior sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

#### Public Comments

Depending on the number of people who want to comment and the time available, the amount of time for individual oral comments may be limited. Requests to address the Committee during the meeting will be accommodated in the order the requests are received. Individuals who wish to expand upon their oral statements, or those who had wished to speak but could not be accommodated on the agenda, may submit written comments to the Designated Federal Officer up to 30 days following the meeting. Written

comments may be sent to Vickie Hanvey listed in the **ADDRESSES** section above.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

*Authority:* 5 U.S.C. Appendix 2.

**Bryan Newland,**

*Assistant Secretary—Indian Affairs.*

[FR Doc. 2022–23472 Filed 10–27–22; 8:45 am]

**BILLING CODE 4337–15–P**

## DEPARTMENT OF THE INTERIOR

### National Park Service

**[NPS–WASO–CR–HPS–NPS0034375; PPWOCRADP1, PRN00HP12.CS0000, XXXP104214; OMB Control Number 1024–0009]**

### Agency Information Collection Activities; Historic Preservation Certification Application

**AGENCY:** National Park Service, Interior.

**ACTION:** Notice of information collection; request for comment.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, we, the National Park Service (NPS) are proposing to revise an information collection.

**DATES:** Interested persons are invited to submit comments on or before December 27, 2022.

**ADDRESSES:** Please provide a copy of your comments to the NPS Information Collection Clearance Officer (ADIR–ICCO), 12201 Sunrise Valley Drive, (MS–242) Reston, VA 20191 (mail); or *phadrea_ponds@nps.gov* (email). Please reference OMB Control Number 1024–0009 in the subject line of your comments.

**FOR FURTHER INFORMATION CONTACT:** To request additional information about this ICR by mail, contact Brian Goeken, Chief, Technical Preservation Services, 1849 C St. NW, Mail Stop 7243, Washington, DC 20240; or by email at *brian_goeken@nps.gov;* or by telephone at 202–354–2033. Please reference OMB Control Number 1024–0009 in the subject line of your comments. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

**SUPPLEMENTARY INFORMATION:** In accordance with the Paperwork Reduction Act of 1995, (PRA, 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), all information collections require approval under the PRA.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility.

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used.

(3) Ways to enhance the quality, utility, and clarity of the information to be collected.

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

*Abstract:* The Federal Historic Preservation Tax Incentives Program encourages private-sector investment in the rehabilitation and re-use of historic buildings. Through this program, underutilized or vacant buildings throughout the country of every period, size, style, and type have been rehabilitated and reused in a manner that maintains their historic character. To be eligible for tax incentives for historic buildings, a building must be listed individually on the National Register of Historic Places (NRHP); or located in a registered historic district and certified by the NPS as contributing to the historic significance of that district. A registered historic district is any district listed on the NRHP; or a state or local district if the district and the enabling statute have also been certified by the NPS. The NRHP is the official list of the Nation's historic places worthy of preservation.

Section 47 of the Internal Revenue Code requires that the Secretary of the Interior certify to the Secretary of the Treasury upon application by owners of historic properties for Federal tax benefits: (a) the historic significance of the property and (b) that the rehabilitation work is consistent with its historic character. The NPS administers the program with the Internal Revenue Service in partnership with the State Historic Preservation Offices (SHPOs). The NPS uses the information collected in the Historic Preservation Certification Application (Forms 10–168, 10–168a, 10–168b, and 10–168c) to evaluate the condition and historic significance of buildings undergoing rehabilitation and to evaluate whether or not the rehabilitation work meets the Secretary of the Interior's Standards for Rehabilitation. The program is moving towards an electronic system (SharePoint site) for the submission and review process of the application within the next fiscal year, 2023.

Regulations codified in 36 CFR part 67 contain a requirement for completion of an application form. The NPS uses the information collected on the application form to allow the authorized officer to determine if the project is qualified to obtain historic preservation certifications from the Secretary of the Interior. These certifications are necessary for an applicant to receive substantial federal tax incentives authorized by section 47 of the Internal Revenue Code. These incentives include a 20% federal income tax credit for the rehabilitation of income-producing historic buildings and an income tax deduction for the charitable donation of easements on historic properties. The Internal Revenue Code also provided a 10% federal income tax credit for the rehabilitation of non-historic,

nonresidential buildings built before 1936. An owner of a non-historic building in a historic district must also use the application to obtain a certification from the Secretary of the Interior that his or her building does not contribute to the significance of the historic district before claiming this lesser tax credit for rehabilitation. The 10% credit was repealed as part of the 2017 tax reform legislation but may remain in effect under certain transition rules.

SHPOs are the first point of contact for property owners wishing to use the rehabilitation tax credits. They help applicants determine if a historic building is eligible for Federal or State historic preservation tax incentives, provide guidance on an application before or after the project begins, and provide advice on appropriate preservation work. SHPOs use Forms 10–168d and 10–168e to make recommendations to NPS.

In accordance with 36 CFR 67, we also collect information for:

(1) certifications of State and local statutes (§ 67.8),

(2) certifications of State or local historic districts (§ 67.9), and

(3) appeals (§ 67.10).

*Title of Collection:* Historic Preservation Certification Application.

*OMB Control Number:* 1024–0009.

*Form Number:* NPS Forms 10–168, 10–168a, 10–168b, 10–168c, 10–168d, 10–168e.

*Type of Review:* Revision of a currently approved collection.

*Respondents/Affected Public:* Individuals, organizations, companies and businesses, and State or tribal governments.

*Total Estimated Number of Annual Respondents:* 11,874.

*Total Estimated Number of Annual Responses:* 11,874.

*Estimated Completion Time per Response:* Estimates vary from 3 to 51 hours depending on activity.

*Total Estimated Number of Annual Burden Hours:* 126,577.

*Respondent's Obligation:* Required to obtain or retain a benefit.

*Frequency of Collection:* On occasion.

*Total Estimated Annual Nonhour Burden Cost:* $3,973,359 based primarily on application fees and other costs (includes: printing photographs and architectural drawings).

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

**Phadrea Ponds,**

*Information Collection Clearance Officer, National Park Service.*

[FR Doc. 2022–23514 Filed 10–27–22; 8:45 am]

**BILLING CODE 4312–52–P**

## DEPARTMENT OF THE INTERIOR

### National Park Service

**[NPS–WASO–NRNHL–DTS#–34750; PPWOCRADI0, PCU00RP14.R50000]**

### National Register of Historic Places; Notification of Pending Nominations and Related Actions

**AGENCY:** National Park Service, Interior.

**ACTION:** Notice.

**SUMMARY:** The National Park Service is soliciting electronic comments on the significance of properties nominated before October 15, 2022, for listing or related actions in the National Register of Historic Places.

**DATES:** Comments should be submitted electronically by November 14, 2022.

**ADDRESSES:** Comments are encouraged to be submitted electronically to *National_Register_Submissions@nps.gov* with the subject line ''Public Comment on <property or proposed district name, (County) State>.'' If you have no access to email, you may send them via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C Street NW, MS 7228, Washington, DC 20240.

**FOR FURTHER INFORMATION CONTACT:** Sherry A. Frear, Chief, National Register of Historic Places/National Historic Landmarks Program, 1849 C Street NW, MS 7228, Washington, DC 20240, *sherry_frear@nps.gov,* 202–913–3763.

**SUPPLEMENTARY INFORMATION:** The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before October 15, 2022. Pursuant to section 60.13 of 36 CFR part 60, comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Nominations submitted by State or Tribal Historic Preservation Officers.

*Key:* State, County, Property Name, Multiple Name (if applicable), Address/Boundary, City, Vicinity, Reference Number.

**ALABAMA**

**Jefferson County**

Mountain Brook Office Park Historic District, 2900 Cahaba Rd., 1–17 Office Park Cir., 100–510 Office Park Dr., Mountain Brook, SG100008399

**COLORADO**

**Denver County**

Emily Griffith Opportunity School, 1250 Welton St., Denver, SG100008396

**Mineral County**

Zang's Hotel and Annex, 120 North Main St., Creede, SG100008397

**INDIANA**

**Adams County**

Decatur Homesteads, Each side of Homestead Dr. and the west side of High St., Decatur, SG100008407

**Allen County**

Becker House, 425 West Williams St., Fort Wayne, SG100008406

**Brown County**

Nashville Historic District, Roughly bounded by Old School Way, Johnson, Mound, and Franklin Sts. including blk. south of Franklin St. between Van Buren and Jefferson Sts., Nashville, SG100008408

**Cass County**

Riverside Historic District, Roughly bounded by Erie Ave., High, and Market Sts., Logansport, SG100008409

**Fayette County**

Trinity Episcopal Church & Parish House, 518 North Eastern Ave. and 215 East 6th St., Connersville, SG100008410

**Gibson County**

Patoka Church of God in Christ-Patoka Colored School, 309 South Wood St., Patoka, SG100008411

**LaGrange County**

Bloomfield Township Graded School (Indiana's Public Common and High Schools MPS), 3020 East US 20, LaGrange vicinity, MP100008412

**Wabash County**

Josiah White's Manual Labor Institute, Each side of Cty. Rd. 50 East/Bailey Rd. extending south approx. ½ mi. from W 500 S., Wabash vicinity, SG100008413

**NEW YORK**

**Albany County**

Turner Farmhouse (Colonie Town MRA), 475 Loudon Rd., Loudonville, MP100008395
Beattie Machine Works, 24 Amity St., Cohoes, SG100008404

**Erie County**

J.W. Ruger & Deck Bros. Building, 220–222 Chicago St., Buffalo, SG100008402
Brisbane Building, 395 Main St., Buffalo, SG100008403
Aldrich & Ray Manufacturing Company Building, 1491 Niagara St., Buffalo, SG100008405

**OHIO**

**Cuyahoga County**

Rauch & Lang Carriage Company Building, 2168 West 25th St., Cleveland, SG100008415

A request for removal has been made for the following resource:

**INDIANA**

**Pulaski County**

Monterey Bandstand, Walnut St., Monterey, OT12000339

A documentation has been received for the following resource:

**RHODE ISLAND**

**Newport County**

Newport Historic District (Additional Documentation), Bounded roughly by Van Zandt and Bellevue Aves., Broadway, Newport Harbor, Thames, Pope, William, Bull, and Kingston Sts., Newport, AD68000001

Nomination submitted by Federal Preservation Officer:

The State Historic Preservation Officer reviewed the following nomination and responded to the Federal Preservation Officer within 45 days of receipt of the nomination and supports listing the property in the National Register of Historic Places.

**PUERTO RICO**

**Rio Grande Municipality**

Jimenez Petroglyph Site (Prehistoric Rock Art of Puerto Rico MPS), Address Restricted, Rio Grande vicinity, MP100008398

*Authority:* Section 60.13 of 36 CFR part 60.

Dated: October 19, 2022.

**Sherry A. Frear,**

*Chief, National Register of Historic Places/National Historic Landmarks Program.*

[FR Doc. 2022–23490 Filed 10–27–22; 8:45 am]

**BILLING CODE 4312–52–P**

## DEPARTMENT OF THE INTERIOR

### National Park Service

**[NPS–WASO–BSD–FEES–NPS0033965; PX.XBSAD0113.00.1 (211); OMB Control Number 1024–0252]**

### Agency Information Collection Activities; The Interagency Access Pass and Senior Pass Application Processes

**AGENCY:** National Park Service, Interior.

**ACTION:** Notice of information collection; request for comment.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, we, the National Park Service (NPS) are proposing to revise an information collection.

**DATES:** Interested persons are invited to submit comments on or before December 27, 2022.

**ADDRESSES:** Please provide a copy of your comments to the NPS Information Collection Clearance Officer (ADIR–ICCO), 12201 Sunrise Valley Drive, (MS–242) Reston, VA 20191 (mail); or *phadrea_ponds@nps.gov* (email). Please reference OMB Control Number 1024–0252 in the subject line of your comments.

**FOR FURTHER INFORMATION CONTACT:** To request additional information about this ICR, contact Linda Thurn, Interagency Pass Program Manager, National Park Service by email at *linda_thurn@nps.gov;* or by telephone at 202 513–7095. Please reference OMB Control Number 1024–0252 in the subject line of your comments. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

**SUPPLEMENTARY INFORMATION:** In accordance with the Paperwork Reduction Act of 1995, (PRA, 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), all information collections require approval under the PRA.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility.

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used.

(3) Ways to enhance the quality, utility, and clarity of the information to be collected.

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

*Abstract:* Authorized by the Federal Lands Recreation Enhancement Act (FLREA; 16 U.S.C. 6801–6814), the America the Beautiful—National Parks and Federal Recreation Lands Pass Program provides recreation opportunities on public lands managed by four Department of the Interior agencies: the National Park Service, U.S. Fish and Wildlife Service, Bureau of Land Management, and the Bureau of Reclamation in addition to the Department of Agriculture's U.S. Forest Service and the U.S. Army Corps of Engineers. This program manages the application process and distribution of passes to provide visitors with an affordable and convenient way to access Federal recreation lands. The pass program's proceeds are used to improve and enhance visitor recreation services.

NPS Form 10–596, ''Interagency Access Pass'' is a free, lifetime pass issued to citizens or residents who are

domiciled in the United States, regardless of age, who have a medical determination and documentation of permanent disability. Ordering an Access Pass requires a complete application, proof of residency, documentation that proves permanent disability, and payment of the $5 processing fee, plus actual shipping costs. Passes can be obtained in person from a participating Federal recreation site or office, through the mail, or online via the U.S. Geological Survey (USGS) store at *https://store.usgs.gov/access-pass.*

If a person arrives at a recreation site and claims eligibility for the Interagency Access Pass, but cannot produce any documentation, that person must read, sign, and date NPS Form 10–597, ''Statement of Disability'' in the presence of the agency officer issuing the Interagency Access Pass. If the applicant cannot read and/or sign the form, someone else may read, date, and sign the statement on his/her behalf in the applicant's presence and in the presence of the agency officer issuing the Interagency Access Pass.

NPS Form 10–595, ''Interagency Senior Pass'' is a pass issued to U.S. citizens or permanent residents who are 62 years or older. Senior Passes may be issued on a lifetime or annual basis. Both types of the Senior Pass can be purchased at any federal recreation site, including national parks, that charges an entrance or standard amenity (day-use) fee; online or through the mail from USGS. Ordering a Senior Pass requires a complete application, proof of residency, payment ($20 for Annual Senior or $80 for Lifetime Senior Pass, plus $5 processing fee, and shipping costs. Passes can be obtained in person from a participating Federal recreation site or office, through the mail, via the U.S. Geological Survey (USGS) store at *https://store.usgs.gov/senior-pass.*

Agency websites provide information on the passes and acceptable documentation. All documentation submitted in person or through the mail is returned to the applicant or destroyed after the form is processed.

*Title of Collection:* The Interagency Access Pass and Senior Pass Application Processes.

*OMB Control Number:* 1024–0252.

*Form Number:* NPS Forms 10–595, 10–596, and 10–597.

*Type of Review:* Extension of a currently approved collection.

*Respondents/Affected Public:* Individuals, organizations, businesses, and State, local, or tribal governments.

*Total Estimated Number of Annual Respondents:* 212,000.

*Total Estimated Number of Annual Responses:* 212,000.

*Estimated Completion Time per Response:* Varies from 5 minutes to 10 minutes, depending on activity.

*Total Estimated Number of Annual Burden Hours:* 22,667.

*Respondent's Obligation:* Required to obtain or retain a benefit.

*Frequency of Collection:* On occasion.

*Total Estimated Annual Nonhour Burden Cost:* $666,000 (mail-in applicants—application fee, mailing and processing).

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

**Phadrea Ponds,**

*Information Collection Clearance Officer, National Park Service.*

[FR Doc. 2022–23511 Filed 10–27–22; 8:45 am]

**BILLING CODE 4312–52–P**

## DEPARTMENT OF THE INTERIOR

### National Park Service

**[NPS–WASO–NRSS–BRD–NPS0034550; PWONRADB0 PPMRSNR1Y.NM00000 (222); OMB Control Number 1024–0265]**

### Agency Information Collection Activities; NPS Institutional Animal Care and Use Committee (IACUC) General Submission, Field Study, Concurrence, Annual Review, and Amendment Forms

**AGENCY:** National Park Service, Interior.

**ACTION:** Notice of information collection; request for comment; re-opening of the comment period.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, we, the National Park Service (NPS) propose to renew an information collection with revisions. We are re-opening the comment period, which originally ended on June 21, 2022, as announced in the **Federal Register** on April 22, 2022 (87 FR 24196). This document includes information regarding the proposed utilization of a new platform, Key Solutions eProtocol IACUC Software Module for Animal Subjects, that was not described in the original notice. If you have already submitted comments, you are not required to resubmit them.

**DATES:** Interested persons are invited to submit comments on or before December 27, 2022.

**ADDRESSES:** Please provide a copy of your comments to the NPS Information Collection Clearance Officer (ADIR–ICCO), 12201 Sunrise Valley Drive, (MS–242) Reston, VA 20191 (mail); or *phadrea_ponds@nps.gov* (email). Please include ''1024–0265'' in the subject line of your comments.

**FOR FURTHER INFORMATION CONTACT:** To request additional information about this ICR by mail, contact Allie Petersen, NPS IACUC Administrator by mail at Biological Resource Division, 1201 Oakridge Drive, Suite 200, Fort Collins, CO 80525; or *npsiacuc@nps.gov* (email). You may also contact Dr. Laurie Baeten at *laurie_baeten@nps.gov* (email) or telephone at (970) 966–0756. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

**SUPPLEMENTARY INFORMATION:** In accordance with the Paperwork Reduction Act of 1995, (PRA, 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), all information collections require approval under the PRA.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility.

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used.

(3) Ways to enhance the quality, utility, and clarity of the information to be collected.

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic,

mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

*Abstract:* Pursuant to the Animal Welfare Act (AWA), its Regulations (AWAR), and the Interagency Research Animal Committee (IRAC), any entity or institution that uses vertebrate animals for research, testing, or training purposes must have an oversight committee to evaluate all aspects of that institution's animal care and use. To be in compliance, the NPS is responsible for managing and maintaining an Institutional Animal Care and Use Committee (IACUC) that has the experience and expertise necessary to assess and approve all research, testing, or training activities involving vertebrate animals on NPS managed lands and territories. All research, testing, or training projects involving animals taking place on NPS territories must be approved by the NPS IACUC prior to their commencement.

*Additional Issue for Comment:* In coordination with the U.S. Fish and Wildlife Service (FWS) the NPS proposes to utilize a new platform, Key Solutions eProtocol IACUC Software Module for Animal Subjects, to support the IACUC review and approval process. The eProtocol IACUC will help ensure that NPS staff and anyone else in any activities on NPS-managed lands and territories employ field methods that are consistent with current best practices that minimize discomfort, distress, and pain by facilitating effective and efficient communication between the IACUC and submitters and assisting with committee administration management. The NPS will jointly use the eProtocol IACUC platform to facilitate collaboration and coordination with the FWS AUC. The shared, but compartmentalized, FWS/NPS platform will allow the two bureaus to maintain separate committees and protocol submissions but share data and move protocols and technical experts between the committees, as necessary.

The eProtocol IACUC will collect the following information in the current forms from submitters for consideration by the committee:

- IACUC General Submission (GS) Form (NPS Form 10–1301)
- IACUC Amendment Form (NPS Form 10–1301A)
- IACUC Annual Review Form (NPS Form 10–1302)
- IACUC Concurrence Form (NPS Form 10–1303)
- IACUC Field Study Form (NPS Form 10–1304)

As directed by the AWA, NPS IACUC is a self-regulating entity that currently consists of a Chair, NPS Regional members, and two additional members (a veterinarian serving as the ''Attending Veterinarian'' and another individual serving as the ''Unaffiliated Member at-Large'').

*Title of Collection:* NPS Institutional Animal Care and Use Committee (IACUC) General Submission, Annual Review, Concurrence, Field Study, and Amendment Forms.

*OMB Control Number:* 1024–0265.

*Form Numbers:* NPS Forms 10–1301, 10–1301A, 10–1302, 10–1303 and 10–1304.

*Type of Review:* Revision of a currently approved collection.

*Respondents/Affected Public:* State and local governments; nonprofit organizations and private businesses.

*Respondent's Obligation:* Mandatory.

*Total Estimated Annual Number of Responses:* 223.

*Estimated Completion Time per Response:* 10 min to 3 hours (times vary depending upon the activity).

*Total Estimated Annual Burden Hours:* 141 Hours.

*Frequency of Collection:* On occasion.

*Total Estimated Annual Nonhour Burden Cost:* None.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

**Phadrea Ponds,**

*Information Collection Clearance Officer, National Park Service.*

[FR Doc. 2022–23515 Filed 10–27–22; 8:45 am]

**BILLING CODE 4312–52–P**

## DEPARTMENT OF THE INTERIOR

### National Park Service

**[NPS–WASO–VRP–REGS–NPS0034238; PPWOVPADU0, POPFR2021.XZ0000 (222); OMB Control Number 1024–0026]**

### Agency Information Collection Activities; Special Park Use Applications.

**AGENCY:** National Park Service, Interior.

**ACTION:** Notice of information collection; request for comment.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, we, the National Park Service (NPS) are proposing to renew an information collection.

**DATES:** Interested persons are invited to submit comments on or before December 27, 2022.

**ADDRESSES:** Send your comments on this information collection request (ICR) by mail to the NPS Information Collection Clearance Officer (ADIR–ICCO), 12201 Sunrise Valley Drive, (MS –242) Reston, VA 20191 (mail); or by email at *phadrea_ponds@nps.gov* (email). Please reference OMB Control Number 1024–0026 in the subject line of your comments.

**FOR FURTHER INFORMATION CONTACT:** To request additional information about this ICR by mail, contact Maggie Tyler, Special Park Uses Program Manager, 1849 C Street NW, Main Interior Building—Rm 2474, Washington DC 20240; or by email at *Maggie_tyler@nps.gov* (email); or by telephone at 202–513–7092. Please reference OMB Control Number 1024–0026 in the subject line of your comments. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point of contact in the United States.

**SUPPLEMENTARY INFORMATION:** In accordance with the Paperwork Reduction Act of 1995, (PRA, 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), all information collections require approval under the PRA.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize

the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility.

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used.

(3) Ways to enhance the quality, utility, and clarity of the information to be collected.

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

*Abstract:* Authorized by the National Park Service Act Organic Act, 54 U.S.C. 100101, we must preserve America's natural wonders unimpaired for future generations, while also making them available for the enjoyment of the visitor. Meeting this mandate requires that we balance preservation with use. Maintaining a good balance requires both information and limits. In accordance with regulations at 36 CFR, we issue permits for special park uses.

Special park uses cover a wide range of activities including, but not limited to special events, First Amendment activities, grazing and agricultural use, filming, still photography, construction, and vehicle access. Permits are issued for varying amounts of time based on the requested use, but generally do not exceed 5 years. A new application must be submitted in order to request the renewal of an existing permit.

The information we collect in the special use applications allows park managers to determine if the requested use is consistent with the laws and NPS regulations referenced above and with the public interest. The park manager must also determine that the requested activity will not cause unacceptable impacts to park resources and values. The information is collected using the following NPS forms:

- 10–930—Application for Special Use Permit
- 10–930c—Application for Special Use Permit—Climbing
- 10–930s—Application for Special Use Permit (short form)
- 10–931—Application for Special Use Permit—Still Photography Permit (short)
- 10–932—Application for Special Use Permit—Still Photography Permit (long)
- 10–933—Application for Special Use Permit—Vehicle/Watercraft Use

The information collected on the forms is used to evaluate requests for Special Use Permits and facilitate the permitting process. If the requested use is consistent with park regulations, the information collected is used to issue a permit.

*Title of Collection:* Special Park Use Applications.

*OMB Control Number:* 1024–0026.

*Form Number:* NPS Forms 10–930, 10–930c, 10–930s, 10–931, 10–932, and 10–933.

*Type of Review:* Extension of a currently approved collection.

*Respondents/Affected Public:* Individuals or households; businesses or other for-profit entities; and Federal, State, local and tribal governments.

*Total Estimated Number of Annual Respondents:* 96,062.

*Total Estimated Number of Annual Responses:* 96,062.

*Estimated Completion Time per Response:* Estimates vary from 15–30 minutes depending on activity.

*Total Estimated Number of Annual* Burden Hours: 26,843.

*Respondent's Obligation:* Required to obtain or retain a benefit.

*Frequency of Collection:* On *occasion.*

*Total Estimated Annual Nonhour Burden Cost:* $9,660,200 for application fees.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

**Phadrea Ponds,**

*Information Collection Clearance Officer, National Park Service.*

[FR Doc. 2022–23517 Filed 10–27–22; 8:45 am]

**BILLING CODE 4312–52–P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Ocean Energy Management

**[Docket No. BOEM–2020–0018]**

### Final Environmental Impact Statement on the Cook Inlet Lease Sale 258

**AGENCY:** Bureau of Ocean Energy Management (BOEM), Interior.

**ACTION:** Notice of Availability (NOA) of a final environmental impact statement.

**SUMMARY:** BOEM announces the availability of a final environmental impact statement (Final EIS) for the Cook Inlet Outer Continental Shelf Oil and Gas Lease Sale 258 (Lease Sale 258). The Final EIS provides an analysis of potential environmental impacts of the Proposed Action and identifies BOEM's Preferred Alternative.

**DATES:** BOEM will issue a final record of decision no sooner than November 28, 2022.

**ADDRESSES:** The Final EIS with appendices are available for review on BOEM's website at *https://www.boem.gov/ak258.*

**FOR FURTHER INFORMATION CONTACT:** For more information on the Cook Inlet Lease Sale 258 Final EIS, you may contact Casey Rowe, Bureau of Ocean Energy Management, Alaska Regional Office, 3801 Centerpoint Drive, Suite 500, Anchorage, Alaska 99503–5823, or at telephone number (907) 334–5200.

**SUPPLEMENTARY INFORMATION:** The Final EIS will inform the lease sale process for Lease Sale 258, which BOEM is required to hold by the end of December 2022, as directed in the Inflation Reduction Act of 2022 (Pub. L. 117–169, enacted Aug. 16, 2022). While BOEM has no discretion on whether to hold the sale, BOEM has prepared this final EIS to follow its normal leasing process to the fullest extent possible.

On October 29, 2021, the Notice of Availability of the Draft EIS was published in the **Federal Register** (86 FR 60068), beginning a 45-day public comment period that ended December 13, 2021. During that time, BOEM also held three public hearings. BOEM received a total of 92,907 public comments through the Federal e-Rulemaking Portal (*http://*

*www.regulations.gov,* docket BOEM–2020–0018). Following the close of the public comment period, BOEM assessed and considered all comments received and responded by making revisions to the EIS as appropriate. Detailed responses to comments received are provided in Appendix B to the Final EIS.

This Final EIS contains analyses of the potential environmental impacts that could result from a Cook Inlet lease sale. Additionally, BOEM's Preferred Alternative is identified. The Preferred Alternative would offer for lease 193 unleased blocks in the lease sale area, and combines the two critical habitat exclusion alternatives and three mitigation alternatives: Alternative 3A (Beluga Whale Critical Habitat Exclusion), Alternative 3C (Beluga Whale Nearshore Feeding Areas Mitigation), Alternative 4A (Northern Sea Otter Critical Habitat Exclusion), Alternative 4B (Northern Sea Otter Critical Habitat Mitigation), and Alternative 5 (Gillnet Fishery Mitigation). BOEM's announcement of Cook Inlet Lease Sale 258 will be made in a final notice of sale and record of decision.

*Authority:* The National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*) and 43 CFR 46.415.

**Amanda Lefton,**

*Director, Bureau of Ocean Energy Management.*

[FR Doc. 2022–23496 Filed 10–27–22; 8:45 am]

**BILLING CODE 4340–98–P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Ocean Energy Management

### Notice on Outer Continental Shelf Oil and Gas Lease Sales

**AGENCY:** Bureau of Ocean Energy Management (BOEM), Interior.

**ACTION:** List of restricted joint bidders.

**SUMMARY:** Pursuant to the Energy Policy and Conservation Act of 1975 and BOEM's regulatory restrictions on joint bidding, BOEM is publishing this list of restricted joint bidders. Each entity within one of the following groups is restricted from bidding with any entity in any of the other groups listed below at Outer Continental Shelf oil and gas lease sales held during the bidding period of November 1, 2022, through April 30, 2023.

**DATES:** This list of restricted joint bidders covers the bidding period of November 1, 2022, through April 30, 2023, and succeeds all prior published lists.

**SUPPLEMENTARY INFORMATION:**

*Group I*
BP America Production Company
BP Exploration & Production Inc.
*Group II*
Chevron Corporation
Chevron U.S.A. Inc.
Chevron Midcontinent, L.P.
Unocal Corporation
Union Oil Company of California
Pure Partners, L.P.
*Group III*
Eni Petroleum Co. Inc.
Eni Petroleum US LLC
Eni Oil US LLC
Eni Marketing Inc.
Eni BB Petroleum Inc.
Eni US Operating Co. Inc.
Eni BB Pipeline LLC
*Group IV*
Equinor ASA
Equinor Gulf of Mexico LLC
Equinor USA E&P Inc.
*Group V*
Exxon Mobil Corporation
ExxonMobil Exploration Company
*Group VI*
Shell Oil Company
Shell Offshore Inc.
SWEPI LP
Shell Frontier Oil & Gas Inc.
SOI Finance Inc.
Shell Gulf of Mexico Inc.
*Group VII*
Total E&P USA, Inc.

Even if an entity does not appear on the above list, BOEM may disqualify and reject certain joint or single bids submitted by an entity if that entity is chargeable for the prior production period with an average daily production in excess of 1.6 million barrels of crude oil, natural gas, and natural gas liquids. *See* 30 CFR 556.512.

*Authority:* 42 U.S.C. 6213; and 30 CFR 556.511–556.515.

**Amanda Lefton,**

*Director, Bureau of Ocean Energy Management.*

[FR Doc. 2022–23494 Filed 10–27–22; 8:45 am]

**BILLING CODE 4340–98–P**

## INTERNATIONAL TRADE COMMISSION

**[Investigation No. 731–TA–860 (Final)]**

### Tin- and Chromium-Coated Steel Sheet From Japan; Request for Comments Regarding the Institution of a Section 751(b) Review Concerning the Commission's Affirmative Determination

**AGENCY:** United States International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** The Commission invites comments from the public on whether changed circumstances exist sufficient to warrant the institution of a review pursuant to section 751(b) of the Tariff Act of 1930 regarding the Commission's affirmative determination in investigation No. 731–TA–860 (Final). The purpose of the proposed review would be to determine whether revocation of the existing antidumping duty order on imports of tin- and chromium-coated steel sheet from Japan would be likely to lead to continuation or recurrence of material injury.

**DATES:** October 21, 2022.

**FOR FURTHER INFORMATION CONTACT:** Alejandro Orozco (202–205–3177), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov).* The public record for this matter may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

**SUPPLEMENTARY INFORMATION:**

*Background.*—In August 2000, the Commission determined that an industry in the United States was materially injured by reason of imports of tin- and chromium-coated steel sheet from Japan found by the U.S. Department of Commerce (Commerce) to be sold in the United States at less than fair value (65 FR 50005, August 16, 2000). Effective August 28, 2000, Commerce issued an antidumping duty order (65 FR 52067).

Following the first five-year reviews by Commerce and the Commission, effective July 21, 2006, Commerce issued a continuation of the antidumping duty order on imports of tin- and chromium-coated steel sheet from Japan (71 FR 41422). Following the second five-year reviews by Commerce and the Commission, effective June 12, 2012, Commerce issued a continuation of the antidumping duty order on imports of tin- and chromium-coated steel sheet from Japan (77 FR 34938). Following the third five-year reviews by Commerce and the Commission, effective July 11, 2018, Commerce issued a continuation of the

antidumping duty order on imports of tin- and chromium-coated steel sheet from Japan (83 FR 32074).

On August 5, 2022, the Commission received a request to review its affirmative determination in investigation No. 731–TA–860 (Final) pursuant to section 751(b) of the Act (19 U.S.C. 1675(b)). The request was filed by the Can Manufacturers Institute, Silgan Containers LLC, Sonoco Product Company, Trivium Packaging USA Inc., Crown Holdings Inc., and Nippon Steel Corporation (collectively, the ''Requestors''). The Requestors argue that there have been recent and significant changes in the tin- and chromium-coated steel sheet industries in the United States and Japan that warrant a changed circumstance review. The Requestors allege that a reduction in domestic production capacity of tin- and chromium-coated steel sheet has resulted in supply shortages, which they argue ''will only worsen as more domestic supply is taken off line by the end of 2023'' with the complete closure of USS–POSCO Industries, a major source of tin- and chromium-coated steel sheet to West Coast companies which supply the agricultural industry in California. In addition, the Requestors allege that the largest producers of tin- and chromium-coated steel sheet in Japan have reduced their capacity and currently have only limited ability to increase their exports.

*Written comments requested.*—Pursuant to section 207.45(b) of the Commission's Rules of Practice and Procedure, the Commission requests comments concerning whether the alleged changed circumstances, brought about by the aforementioned changes in the tin- and chromium-coated steel sheet industries in the United States and Japan, are sufficient to warrant institution of a review.

*Written submissions.*—Comments must be filed with the Secretary to the Commission by December 15, 2022. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain business proprietary information must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission has not included a process for access to business proprietary information pursuant to an administrative protective order during the pre-institution comment period in this proceeding (See 56 FR 11918, 11922 (March 21, 1991)). In the event that the Commission finds sufficient changed circumstances to warrant institution of a review investigation following the comment period, access to business proprietary information under an administrative protective order will be available at that time. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

Please note the Secretary's Office will accept only electronic filings at this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

*Authority:* This notice is published pursuant to section 207.45 of the Commission's rules.

By order of the Commission.
Issued: October 21, 2022.

**Katherine Hiner,**

*Acting Secretary to the Commission.*

[FR Doc. 2022–23468 Filed 10–27–22; 8:45 am]

**BILLING CODE 7020–02–P**

## INTERNATIONAL TRADE COMMISSION

**[Investigation No. 337–TA–1278]**

### Certain Radio Frequency Transmission Devices and Components Thereof; Notice of Request for Submissions on the Public Interest

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that on September 16, 2022, the presiding Chief Administrative Law Judge (''Chief ALJ'') issued an Initial Determination on Violation of Section 337. The Chief ALJ also issued a Recommended Determination on remedy and bonding should a violation be found in the above-captioned investigation. The Commission is soliciting submissions on public interest issues raised by the recommended relief should the Commission find a violation. This notice is soliciting comments from the public only.

**FOR FURTHER INFORMATION CONTACT:** Houda Morad, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708–4716. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

**SUPPLEMENTARY INFORMATION:** Section 337 of the Tariff Act of 1930 provides that, if the Commission finds a violation, it shall exclude the articles concerned from the United States:

unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry.

19 U.S.C. 1337(d)(1). A similar provision applies to cease and desist orders. 19 U.S.C. 1337(f)(1).

The Commission is soliciting submissions on public interest issues raised by the recommended relief should the Commission find a violation, specifically: a limited exclusion order directed to certain radio frequency transmission devices and components thereof imported, sold for importation, and/or sold after importation by respondent OnAsset Intelligence, Inc. (''OnAsset'') of Irving, Texas; and a cease and desist order directed to OnAsset. Parties are to file public interest submissions pursuant to 19 CFR 210.50(a)(4).

The Commission is interested in further development of the record on the public interest in this investigation. Accordingly, members of the public are invited to file submissions of no more than five (5) pages, inclusive of attachments, concerning the public interest in light of the Chief ALJ's Recommended Determination on Remedy and Bonding issued in this investigation on September 16, 2022. Comments should address whether issuance of the recommended remedial orders in this investigation, should the Commission find a violation, would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) explain how the articles potentially subject to the recommended remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the recommended orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third-party suppliers have the capacity to replace the volume of articles potentially subject to the recommended orders within a commercially reasonable time; and

(v) explain how the recommended orders would impact consumers in the United States.

Written submissions must be filed no later than by close of business on November 22, 2022.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (Mar. 19, 2020). Submissions should refer to the investigation number (''Inv. No. 337–TA–1278'') in a prominent place on the cover page and/or the first page. (*See Handbook for Electronic Filing Procedures, https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. Any non-party wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing and must be served in accordance with Commission Rule 210.4(f)(7)(ii)(A) (19 CFR 210.4(f)(7)(ii)(A)). All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: October 24, 2022.

**Katherine Hiner,**

*Acting Secretary to the Commission.*

[FR Doc. 2022–23463 Filed 10–27–22; 8:45 am]

**BILLING CODE 7020–02–P**

## INTERNATIONAL TRADE COMMISSION

### Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Video Processing Devices and Components Thereof, DN 3651;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

**FOR FURTHER INFORMATION CONTACT:** Katherine M. Hiner, Acting Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

**SUPPLEMENTARY INFORMATION:** The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of DivX, LLC on October 24, 2022. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of regarding certain video processing devices and components thereof. The complainant names as respondents: Amazon.com, Inc of Seattle, WA and VIZIO, Inc. of Irvine, CA. The complainant requests that the Commission issue a limited exclusion order and a cease and desist order, and impose a bond upon respondent's alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3651'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [1]). Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*.) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: October 25, 2022.

**Katherine M. Hiner,**

*Acting Secretary to the Commission.*

[FR Doc. 2022–23542 Filed 10–27–22; 8:45 am]

**BILLING CODE 7020–02–P**

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

## INTERNATIONAL TRADE COMMISSION

**[USITC SE–22–045]**

### Sunshine Act Meetings

**AGENCY HOLDING THE MEETING:** United States International Trade Commission.

**TIME AND DATE:** November 4, 2022 at 11:00 a.m.

**PLACE:** Room 101, 500 E Street SW, Washington, DC 20436, Telephone: (202) 205–2000.

**STATUS:** Open to the public.

**MATTERS TO BE CONSIDERED:**

1. Agendas for future meetings: none.
2. Minutes.
3. Ratification List.
4. Commission vote on Inv. No. 731–TA–1313 (Review) (Ferrovanadium from South Korea). The Commission currently is scheduled to complete and file its determination and views on November 15, 2022.
5. Commission vote on Inv. Nos. 701–TA–563 and 731–TA–1331–1333 (Review) (Finished Carbon Steel Flanges from India, Italy, and Spain). The Commission currently is scheduled to complete and file its determinations and views of the Commission on November 15, 2022.
6. Outstanding action jackets: none.

**CONTACT PERSON FOR MORE INFORMATION:** William Bishop, Supervisory Hearings and Information Officer, 202–205–2595.

The Commission is holding the meeting under the Government in the Sunshine Act, 5 U.S.C. 552(b). In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: October 25, 2022.

**William Bishop,**

*Supervisory Hearings and Information Officer.*

[FR Doc. 2022–23590 Filed 10–26–22; 11:15 am]

**BILLING CODE 7020–02–P**

## DEPARTMENT OF JUSTICE

### Bureau of Alcohol, Tobacco, Firearms and Explosives

**[OMB Number 1140–0010]**

### Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Currently Approved Collection; Application To Transport Interstate or Temporarily Export Certain National Firearms Act (NFA) Firearms—ATF F 5320.20

**AGENCY:** Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

**ACTION:** 30-Day notice.

**SUMMARY:** The Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), Department of Justice (DOJ), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

**DATES:** The proposed information collection was previously published in the **Federal Register**, on August 23, 2022, allowing for a 60-day comment period. Comments are encouraged and will be accepted for an additional 30 days until November 28, 2022.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

**SUPPLEMENTARY INFORMATION:** Written comments and suggestions from the

public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

• Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

• Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

• Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

**Overview of This Information Collection**

1. *Type of Information Collection:* Revision of a Currently Approved Collection.

2. *The Title of the Form/Collection:* Application to Transport Interstate or Temporarily Export Certain National Firearms Act (NFA) Firearms.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

*Form number:* ATF F 5320.20.

*Component sponsor:* Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

*Primary:* Individuals or households.

*Other:* Business or other for-profit, Federal Government, State Local or Tribal Government.

*Abstract:* The Application to Transport Interstate or Temporarily Export Certain National Firearms Act (NFA)—ATF Form 5320.20 is used by persons other than a qualified Federal firearms licensee, to request approval to transport interstate or temporarily export certain NFA firearms.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 20,000 respondents will respond to this collection once annually, and it will take each respondent approximately 20 minutes to complete their responses.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 6,667 hours, which is equal to 20,000 (total respondents) * 1 (# of responses per respondent) * .333333 (20 minutes or the time taken to prepare each response).

7. *An Explanation of the Change in Estimates:* Due to more filings of this application, both the total respondents and responses to this collection have increased from 17,000 in 2019 to 20,000 in 2022. Consequently, the total burden hours have also increased from 5,610 to 6,667 hours since the last renewal.

*If additional information is required contact:* Robert Houser, Department Clearance Officer, Policy and Planning Staff, Office of the Chief Information Officer, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, Mail Stop 3.E–206, Washington, DC 20530.

Dated: October 18, 2022

**Robert J. Houser,**

*Department Clearance Officer, Policy and Planning Staff, Office of the Chief Information Officer, U.S. Department of Justice.*

[FR Doc. 2022–23474 Filed 10–27–22; 8:45 am]

**BILLING CODE 4410–FY–P**

## DEPARTMENT OF JUSTICE

### Federal Bureau of Investigation

**[OMB Number 1110–0001]**

### Agency Information Collection Activities; Proposed eCollection; eComments Requested; Revision of a Currently Approved Collection; Return A—Monthly Return of Offenses Known to Police and Supplement to Return A—Monthly Return of Offenses Known to Police

**AGENCY:** Federal Bureau of Investigation, Department of Justice.

**ACTION:** 30-Day notice.

**SUMMARY:** The Criminal Justice Information Services (CJIS) Division, Federal Bureau of Investigation (FBI), Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. This proposed information collection was previously published in the **Federal Register** on August 1, 2022, allowing for a 60-day comment period.

**DATES:** Comments are encouraged and will be accepted for an additional 30 days until November 28, 2022.

**FOR FURTHER INFORMATION CONTACT:** Written comments and/or suggestions regarding the items contained in this notice, especially the estimated burden and associated response time, should be directed to Mr. Edward Abraham, Unit Chief, Federal Bureau of Investigation, Criminal Justice Information Services Division, Module D–1, 1000 Custer Hollow Road, Clarksburg, West Virginia 26306, telephone 304–625–4830. Written comments and/or suggestions can also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC 20503 or send to *OIRA_submissions@omb.eop.gov.*

**SUPPLEMENTARY INFORMATION:** Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

• Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

• Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

• Evaluate the quality, utility, and clarity of the information to be collected; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

**Overview of This Information Collection**

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *Title of the Form/Collection:* Return A—Monthly Return of Offenses Known to Police and Supplement to Return A—Monthly Return of Offenses Known to Police and Supplement of Return A—Monthly Return of Offenses Known to Police.

3. *Agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form Number: 1–720 and 1–706. Sponsor: Criminal Justice Information Services Division, Federal Bureau of Investigation, Department of Justice.

4. *Affected public will be asked or required to respond, and a brief abstract:* Federal, state, county, city, and tribal law enforcement agencies. Abstract: This collection requests Part I offense and clearance data, and stolen and recovered monetary values of stolen property throughout the United States from federal, state, county, city, and tribal law enforcement agencies in order for the FBI's Uniform Crime Reporting (UCR) Program to serve as the national clearinghouse for the collection and dissemination of crime data and to publish these statistics in *Crime in the United States.*

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* There are approximately 18,600 law enforcement agencies within the universe of potential respondents. Due to the recent National Incident-Based Reporting System (NIBRS) transition, the UCR Program is no longer accepting new monthly submissions from *Return A* and *Supplement to Return A* data using this clearance. This clearance is being maintained to allow the submission of updates to past Summary Reporting System (SRS) submissions that were provided by agencies prior to the 2021 NIBRS transition. The submission of updates to past data is strictly voluntary and at the discretion of the contributing agency. Based on existing reporting patterns, the UCR Program has received 87,059 *Return A* and *Supplement to Return A* update submissions from 5,580 responding agencies in 2021 with an estimated response time of 10 minutes per response for *Return A* and 11 minutes for Supplement to Return A on this form. This number has changed from the 60-day notice due to a recalculation of the data available to the program. In order to provide a singular calculation of the estimated burden, the approximate minutes per response calculation is averaged between the *Return A* and *Supplement to Return A* forms. This results in a calculation of 10.5 minutes per response for the entire 1110–0001 clearance. The total burden for this clearance is determined by taking the 87,059 total responses received multiplied by the average minutes per response of 10.5 minutes per response. This provides a total minute of burden of 914,119.5 minutes. Converted to hours, the total number of burden hours for this collection is 15,235 hours. As the UCR Program moves further from the NIBRS transition, it is expected the total number of updates will steadily decline, mainly due to the updates being done through NIBRS on a more frequent basis. However, due to the need for these updates, the burden hour estimate is based on the most recent submission volumes to achieve the highest possible burden estimate.

6. *An estimate of the total public burden (in hours) associated with the collection:* There are approximately 15,235 hours, annual burden, associated with this information collection.

*If additional information is required contact:* Robert Houser, Department Clearance Officer, Policy and Planning Staff, Office of the Chief Information Officer, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 3.E–206, Washington, DC 20530.

Dated: October 25, 2022.

**Robert Houser,**

*Assistant Director, Policy and Planning Staff, Office of the Chief Information Officer, U.S. Department of Justice.*

[FR Doc. 2022–23487 Filed 10–27–22; 8:45 am]

**BILLING CODE 4410–02–P**

## DEPARTMENT OF JUSTICE

### Notice of Lodging of Proposed Consent Decree

In accordance with Department of Justice Policy, 28 CFR 50.7, notice is hereby given that a proposed Consent Decree in *United States* v. *Petroff Trucking Company, Inc.,* Civil Action No. 20–cv–930–DWD, was lodged with the United States District Court for the Southern District of Illinois on October 24, 2022.

The proposed Consent Decree concerns a complaint filed by the United States against Defendant Petroff Trucking Company, Inc., pursuant to sections 301 and 304 of the Clean Water Act, 33 U.S.C. 1311 and 1344, to obtain from Defendant injunctive relief for violating the Clean Water Act by discharging pollutants from point sources into waters of the United States without a permit. The proposed Consent Decree resolves these allegations by requiring the Defendant to perform compensatory mitigation.

The Department of Justice will accept written comments relating to the proposed Consent Decree for thirty (30) days from the date of publication of this Notice. Please address comments to Benjamin Grillot, United States Department of Justice, Environment and Natural Resources Division, Post Office Box 7611, Washington, DC 20044, *pubcomment_eds.enrd@usdoj.gov,* and refer to *United States* v. *Petroff Trucking Company, Inc.,* DJ # 90–5–1–1–21662.

The proposed Consent Decree may be examined at the Clerk's Office, United States District Court for the Southern District of Illinois, located at 750 Missouri Avenue, East St. Louis, IL 62201. In addition, the proposed Consent Decree may be examined electronically at *https://www.justice.gov/enrd/consent-decrees.*

**Cherie Rogers,**

*Assistant Section Chief, Environmental Defense Section, Environment and Natural Resources Division.*

[FR Doc. 2022–23499 Filed 10–27–22; 8:45 am]

**BILLING CODE 4410–CW–P**

## DEPARTMENT OF JUSTICE

### Notice of Proposed Settlement Agreement

In accordance with Departmental Policy and 42 U.S.C. 9622(i), notice is hereby given of a proposed Settlement Agreement reached by the United States, Chevron U.S.A., Inc. (''Chevron''), and Crowley Marine Services, Inc. (''Crowley''), concerning costs of responding to environmental contamination at the West Nome Tank Farm Site in Nome, Alaska.

This proposed Settlement Agreement resolves potential claims that the United States, Chevron, and/or Crowley could have brought against each other pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9601 *et seq.,* as amended; Alaska Statutes Title 46 and Alaska Administrative Code Title 18; the Resource Conservation and Recovery Act, 42 U.S.C. 6901 *et seq.,* as amended; and the Clean Water Act, 33 U.S.C. 1251 *et seq.,* as amended; and/or other law for past or future costs of responding to existing petroleum contamination by the United States, Chevron, and/or Crowley, or injunctive relief related to or in connection with such contamination at the West Nome Tank Farm Site. The proposed Settlement Agreement provides for Chevron and Crowley to pay the United States for response costs as soon as reasonably practicable after the Effective Date of the Settlement Agreement. It also provides that the United States Air Force will implement and maintain the remedy at the West Nome Tank Farm Site, and Chevron and Crowley will reimburse the United States at fixed percentages for potential response costs that might be incurred in the future.

The Department of Justice will accept written comments relating to this proposed Settlement Agreement for thirty (30) days from the date of

publication of this Notice. Please address comments to Sonya J. Shea, United States Department of Justice, Environment and Natural Resources Division, Environmental Defense Section, 999 18th Street, South Terrace, Suite 370, Denver, CO 80202, or this email address: *pubcomment_eds.enrd@usdoj.gov,* and refer to *In re: West Nome Tank Farm Site,* DJ # 90–11–6–17656/1.

The proposed Settlement Agreement may be examined electronically at *https://www.justice.gov/enrd/public-comments.*

**Cherie Rogers,**

*Assistant Section Chief, Environmental Defense Section, Environment and Natural Resources Division.*

[FR Doc. 2022–23498 Filed 10–27–22; 8:45 am]

**BILLING CODE 4410–CW–P**

## DEPARTMENT OF LABOR

### Secretary's Order 03–2022—Delegation of Authorities and Assignment of Responsibilities to the Chief Information Officer

1. *Purpose.* This Secretary's Order (Order) updates the delegation of authority and assignment of responsibilities to the Chief Information Officer (CIO) for implementation of the Federal Information Technology Acquisition Reform Act of 2014 (FITARA), the Federal Information Security Modernization Act of 2014 (FISMA), the Modernizing Government Technology (MGT) Act, the E-Government Act of 2002, the Clinger-Cohen Act of 1996 (also known as the Information Technology (IT) Management Reform Act of 1996), and the Paperwork Reduction Act of 1995 (PRA).

2. *Authority and Directives Affected.*

A. *Authorities.* This Order is established pursuant to the following authorities.

1. Public Law 85–67, Title I, 71 Stat. 210 (June 29, 1957), as amended.

2. Public Law 99–619, Reorganization Plan Number 6.

3. Public Law 104–13, the Paperwork Reduction Act (PRA).

4. Public Law 104–106, The Clinger-Cohen Act.

5. Public Law 104–231, The Electronic Freedom of Information Act Amendments (E–FOIA).

6. Public Law 106–554, Consolidated Appropriations Act, 2001, Section 1(a) (incorporating Section 515 of H.R. 5658, the Treasury and General Government Appropriations Act).

7. Public Law 107–347, The E-Government Act of 2002 [Sections 101, 202–204, 206–212, 214, 301, 302 & 305].

8. Public Law 113–235, FITARA of 2014; and Public Law 115–88, the FITARA Enhancement Act of 2017.

9. Public Law 113–283, the FISMA of 2014.

10. Public Law 115–91, the MGT Act, 131 Stat. 1332.

11. 5 U.S.C. 301, 552(g), 3701–3707 & 5315 (2018).

12. 29 U.S.C. 551 & 563 (2018).

13. 40 U.S.C. 11312–11319 & 11331.

14. 41 U.S.C. 266a.

15. 44 U.S.C. 3505–3506, 3553–3554, 3603 & 3606.

16. OMB Circular A–130, Managing Information as a Strategic Resource (2016).

17. OMB Memorandum M–15–14, Management and Oversight of Federal Information Technology (2015).

B. *Directives Affected.*

1. This Order does not affect the authorities and responsibilities assigned by any other Secretary's Order, unless otherwise expressly provided in this or another Order.

2. This Secretary's Order replaces the previous Secretary's Order 06–2020 regarding CIO responsibilities, and as such, Secretary's Order 06–2020 is cancelled.

3. *Background.* This Order replaces Secretary's Order 06–2020, which delegated authority and assigned responsibility for implementation of FITARA, FISMA, MGT Act, PRA, Clinger-Cohen Act, and E-Government Act. This Order further implements guidance provided by OMB in Memorandum M–15–14 that, in situations where ''the CIO and other management officials report to a COO, Undersecretary for Management, Assistant Secretary for Administration, or similar management executive, the CIO shall have direct access to the agency head (*i.e.,* the Secretary, or Deputy Secretary serving on the Secretary's behalf) regarding programs that include information technology''.

4. *Reporting Authority.* The CIO has direct access to, and authority for direct contact with, the Secretary for any matters the CIO deems necessary to carry out the responsibilities of this Secretary's Order.

5. *Assignment of Responsibilities to the CIO.*

A. The Clinger-Cohen Act established the position of the CIO with information resource management duties as their primary duty. The CIO performs the responsibilities set forth below.

1. Ensure compliance by all DOL agencies with the prompt, efficient, and effective implementation of IRM responsibilities and reduction of information collection burdens on the public.

2. Provide advice and assistance to the Secretary and other DOL senior management personnel to ensure IT is acquired, and information resources are managed, effectively and efficiently.

3. Perform strategic planning for all IT management functions including developing, updating, and maintaining the DOL IT strategic plan.

4. Establish, implement, and ensure compliance with the DOL information security program.

5. Develop, facilitate, and maintain the implementation of the enterprise architecture for DOL.

6. Promote the effective and efficient design and operation of all major IRM processes for DOL, including improvements to work processes of the Department.

7. Monitor and evaluate the performance of IT programs of DOL based on applicable performance measurements, and advise the Secretary of Labor and other senior management personnel regarding whether to continue, modify, or terminate a program or project.

8. Annually, in consultation with DOL agencies and as part of the strategic planning and performance evaluation process, assess the requirements established for DOL personnel regarding knowledge and skill in IRM, develop plans for hiring and training aimed at meeting those requirements, and report to the Secretary on the progress made in improving IRM capability.

9. Serve as a member of the executive branch Chief Information Officers Council, participate in its functions, and monitor the Department's implementation of IT standards.

10. Perform any additional duties which are assigned to the CIO by applicable law, including OMB regulations and circulars.

B. FITARA, the FITARA Enhancement Act of 2017, and the MGT Act further enhanced the responsibilities of the CIO in the following areas as defined below.

1. Resources, Planning and Portfolio Management. It is the responsibility of the CIO to:

a. Have a significant role in the decision processes for all annual and multiyear planning, programming, budgeting, and execution decisions, related reporting requirements, and reports related to IT;

b. Have a significant role in the management, governance, and oversight processes related to IT;

c. Review and approve the IT budget request;

d. Certify IT investments are adequately implementing incremental development, as defined in capital

planning guidance issued by the Office of Management and Budget (OMB);

e. Review and approve any contract or other agreement for IT or IT services. Governance process can be used to approve contracts or other agreements as long as the CIO is a full participant in the governance processes; and

f. Review and approve the reprogramming of funds for IT.

2. Agency Risk Management Information. It is the responsibility of the CIO to:

a. Provide the Director of OMB with a list of each major IT investment on at least a semiannual basis, using existing data systems and processes;

b. Categorize each major IT investment according to risk, in consultation with other appropriate agency officials; and

c. Conduct a review of the investment to identify the root causes of the high level of risk, the extent to which these causes have been addressed, and the probability of future success for each major IT investment receiving a high risk rating.

3. Information Technology Portfolio, Program and Resource Reviews. It is the responsibility of the CIO to:

a. Identify or develop ways to increase the efficiency and effectiveness of the IT investments;

b. Identify or develop opportunities to consolidate the acquisition and management of IT services, and increase the use of shared-service delivery models;

c. Identify potential duplication, waste, and cost savings, and develop plans for actions to optimize the IT portfolio, programs, and resources;

d. Develop ways to better align the IT portfolio, programs, and financial resources to any multi-year funding requirements or strategic plans required by law; and

e. Conduct an annual review of the IT portfolio.

4. Government-wide Data Center Consolidation and Optimization Metrics. It is the responsibility of the CIO to:

a. Assist the Secretary in the submission to the Federal CIO in the Office of the Federal Chief Information Officer (formerly the Administrator of the Office of Electronic Government and Information Technology), and OMB, a comprehensive inventory of the data centers owned, operated, or maintained by or on behalf of the agency and a multi-year strategy to achieve the consolidation and optimization of the data centers inventoried;

b. Submit a statement to the Federal CIO stating whether the agency has complied with the requirements and make the statement publicly available. If the agency has not complied with the requirements, the CIO must submit a statement to the Federal CIO explaining the reasons for not complying with such requirements; and

c. Provide updates to the Federal CIO on a quarterly basis regarding the completion of activities by the agency; all progress of the agency towards meeting the Government-wide data center consolidation and optimization metrics; and the actual cost savings and other improvements realized through the implementation of the strategy of the agency.

5. Technology Modernization Fund. It is the responsibility of the CIO to evaluate applications for funding from the Technology Modernization Fund including a strong business case, technical design, consideration of commercial off-the-shelf products and services, procurement strategy (including adequate use of rapid, iterative software development practices), and program management.

6. *Delegation of Authorities and Assignment of Responsibilities.*

A. Subject to the Reservation of Authority in section VII of this Order, the following duties assigned by the PRA, E–FOIA, and related legislation, and OMB guidance to the Secretary are hereby delegated to the CIO.

1. Establish a process, sufficiently independent of DOL program agencies, to evaluate whether proposed collections of information should be approved under the PRA.

2. Coordinate with DOL agencies to ensure proposed collections of information covered by the PRA are published in the **Federal Register**.

3. Coordinate with DOL agencies to ensure they provide notice and an opportunity to comment on any collections of information contained within notices of proposed rulemaking published in the **Federal Register**.

4. Certify for each collection of information submitted to OMB for review the DOL program agency has fully complied with all PRA provisions.

5. Coordinate with DOL agencies to prepare and maintain an annual inventory of the DOL's major information systems.

6. Maintain a leadership role in overseeing the implementation of DOL's guidelines on information quality matters consistent with the Department's Information Quality Guidelines, and be responsible for the annual Data Quality report to the Director of OMB.

B. Subject to the Reservation of Authority in section VII of this Order, the following duties assigned by the Clinger-Cohen Act and related OMB guidance to the Secretary are hereby delegated to the CIO.

1. Design, implement, and maintain DOL's process for maximizing the value and assessing and managing the risks of IT acquisitions to:

a. Provide for the selection of IT investments to be made by DOL, the management of such investments, and the evaluation of the results of such investments;

b. Be integrated with the processes for making budget, financial, and program management decisions within DOL;

c. Include minimum criteria to be applied in considering whether to undertake a particular investment in information systems;

d. Provide for identifying information systems investments resulting in shared benefits or costs for other Federal agencies or State or local governments;

e. Provide for identifying quantifiable measurements for determining the net benefits and risks for a proposed investment; and

f. Provide the means for DOL senior management personnel to obtain timely information regarding the progress of an investment in an information system.

2. Institutionalize performance-based and results-based management for IT in coordination with the Office of the Chief Financial Officer, the Office of the Assistant Secretary for Administration and Management (OASAM), other DOL agencies, and other DOL governance structures (*e.g.,* Working Capital Fund).

3. Review and approve the acquisition of IT for DOL and, in accordance with guidance issued by OMB, the award of contracts that provide for multi-agency acquisitions of information technology.

4. Monitor the Department's compliance with the policies, procedures, and guidance in OMB Circular A–130 (or equivalent guidance), recommend or take appropriate corrective action in instances of failures to comply and, as required by Circular A–130, report to the OMB Director.

C. Subject to the Reservation of Authority in section VII of this Order, the following duties assigned by the MGT Act to the Secretary are hereby delegated to the CIO.

1. Establish an information technology system modernization and working capital fund for necessary expenses as described in paragraph 3 of the MGT Act.

2. Prioritize funds within the IT working capital fund to be used initially for cost savings activities.

3. Reprogram and transfer any amounts saved as a direct result of the cost savings activities for deposit into

the IT working capital fund, consistent with paragraph (2)(A) of the MGT Act.

D. Subject to the Reservation of Authority in section VII of this Order, the following duties assigned by the E-Government Act of 2002 to the Secretary are hereby delegated to the CIO.

1. Consider the impact of Departmental E-Government policies and programs on persons without access to the internet and work with all DOL agencies to ensure, to the extent practicable, the availability of government information and services is not diminished for individuals who lack access to the internet.

2. Submit annually to the OMB Director of the E-Government Status Report required by Section 202 of the E-Government Act.

3. Ensure the Department's methods for use and acceptance of electronic signatures are compatible with the relevant policies and procedures issued by the OMB Director.

4. Work with the Office of Public Affairs and the Office of the Solicitor to ensure a publicly accessible DOL website includes all required information.

5. Coordinate with the Office of the Assistant Secretary for Policy to ensure the Department implements electronic rulemaking submissions and electronic dockets.

6. Oversee the Department's preparation of privacy impact assessments; ensure privacy impact assessments are provided to OMB for each information system for which funding is requested; and ensure, if practicable and appropriate, DOL privacy impact assessments are made available to the public.

7. Establish and operate IT training programs and encourage DOL employee participation in such programs.

8. Establish a system for appropriately sharing OMB and DOL policies, guidance, standards and other communications relating to IT and IRM.

9. Ensure the Department develops performance measures demonstrating how electronic government enables progress toward DOL objectives, strategic goals, and statutory mandates.

10. Ensure the Department is in compliance with Section 508 of the Rehabilitation Act of 1974 (29 U.S.C. 794d).

11. Ensure the Department complies with all OMB policies relating to the categorization of information.

12. Ensure that privacy notices posted on DOL websites comply with OMB guidance (see Section 208(c) of the E-Government Act).

13. Ensure the Department, consistent with guidance developed by the National Archivist, adopts policies and procedures to effectively and comprehensively fulfill its records management responsibilities with respect to DOL information on the internet and other electronic records.

E. Subject to the Reservation of Authority in section VII of this Order, the following duties assigned by FISMA to the Secretary are hereby delegated to the CIO.

1. Designate a senior Department official who will report to the CIO and have responsibility for Department-wide information security as their primary duty.

2. Ensure the Department has trained personnel sufficient to assist in complying with the requirements of FISMA and related policies, procedures, standards, and guidelines.

3. Ensure the Department's information security management processes are integrated into its strategic and operational planning processes.

4. Prepare the Department's annual report to the Congress and Comptroller General on compliance with FISMA, as required by Section 3544(c) of the E-Government Act.

5. Ensure the adequacy and effectiveness of information security policies, procedures, and practices are addressed in plans and reports relating to the Department's annual budget; information resources management; IT management; program performance under the Government Performance Results Act; financial management and financial management systems; and internal accounting and administrative controls.

6. Ensure any significant deficiency in information security policies, practices or procedures is reported as a material weakness under Section 3512 of Title 31 of the U.S. Code and, if related to financial management systems, as an instance of a lack of substantial compliance under the Federal Financial Management Improvement Act.

7. Ensure the Department's annual performance plan includes a description of the time periods, budget resources, staffing and training necessary to implement the Department's information security program.

8. Ensure the public receives timely notice and opportunity for comment on proposed information security policies and procedures affecting communication with the public.

9. Cooperate with the Office of Inspector General on the annual independent evaluation of the Department's information security program and practices, and ensure the evaluation is submitted to OMB.

10. Provide information security protections commensurate with the risk and magnitude of the harm resulting from unauthorized access, use, disclosure, disruption, modification, or destruction of information and information systems.

11. Comply with the requirements of FISMA and related OMB policies and NIST procedures, standards, and guidelines.

12. Report annually to the OMB Director, the Comptroller General of the United States, and selected congressional committees on the adequacy and effectiveness of agency information security policies and procedures.

F. In addition to the above duties specifically assigned by the PRA, the Clinger-Cohen Act, and the E-Government Act, the CIO is delegated the following authority and assigned the following responsibilities, subject to the Reservation of Authority in section VII.

1. The CIO will act as the Department's spokesperson on all matters relating to Departmental IRM and IT management.

2. The CIO will ensure the DOL is responsive to the needs of employees who require adaptive technologies and will represent the Department on GSA's Section 508 Committee.

3. The CIO will ensure continuous modernization of Departmental communications and processes through adoption of new technologies, and ensure maximum appropriate use of web technologies and electronic mail.

4. The CIO will perform any other related duties which are assigned by the Secretary.

G. The Solicitor of Labor. The Solicitor of Labor is delegated authority and assigned responsibility for providing legal advice and counsel to the Department and agencies relating to the administration and implementation of this Order and the statutory provisions, regulations, and Executive Orders listed above, including without limitation, providing counsel to the Secretary, ASAM, CIO, Agency Heads, managers, and supervisors. The Solicitor of Labor shall have responsibility for legal advice and assistance through opinions and interpretations of applicable laws and regulations. The bringing of, and defense against, legal proceedings under the authorities cited herein, the representation of the Department, the Secretary, and other officials of the Department, and determinations of whether such proceedings or representations are appropriate in a given case, are delegated exclusively to the Solicitor.

7. *Reservations of Authority.*

A. The submission of reports and recommendations to the President and Congress concerning the administration of the statutory provisions and Executive Orders listed above is reserved to the Secretary.

B. No delegation of authority or assignment of responsibility under this Order will be deemed to affect the Secretary's authority to continue to exercise or further delegate such authority or responsibility.

8. *Effective Date.* This Order is effective immediately.

**Martin J. Walsh,**

*Secretary of Labor.*

[FR Doc. 2022–23503 Filed 10–27–22; 8:45 am]

**BILLING CODE 4510–04–P**

## NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

**[NARA–22–0022; NARA–2023–002]**

### Records Schedules; Availability and Request for Comments; Correction

**AGENCY:** National Archives and Records Administration (NARA).

**ACTION:** Notice; correction.

**SUMMARY:** On October 12, 2022, the National Archives and Records Administration (NARA) published a **Federal Register** notice that made record schedules available for comment. The docket number on the notice is incorrect.

**DATES:** The document published at 87 FR 61631 on October 12, 2022. The original comment due date of 11/28/2022 remains the same.

**FOR FURTHER INFORMATION CONTACT:** Kimberly Richardson, Strategy and Performance Division, by email at *regulation_comments@nara.gov* or at 301–837–2902. For information about records schedules, contact Records Management Operations by email at *request.schedule@nara.gov* or by phone at 301–837–1799.

**SUPPLEMENTARY INFORMATION:**

#### Correction

In the **Federal Register** of October 12, 2022, in 87 FR 61631, FR Doc #2022–22136, on page 61631, in the second column, correct the docket number in the header to read: [NARA–22–0022; NARA–2023–002].

**Laurence Brewer,**

*Chief Records Officer for the U.S. Government.*

[FR Doc. 2022–23024 Filed 10–27–22; 8:45 am]

**BILLING CODE 7515–01–P**

## NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

**[NARA–2023–004]**

### Chief Freedom of Information Act (FOIA) Officers Council Meeting

**AGENCY:** Office of Government Information Services (OGIS), National Archives and Records Administration (NARA) and Office of Information Policy (OIP), U.S. Department of Justice (DOJ).

**ACTION:** Notice of meeting.

**SUMMARY:** We are announcing a meeting of the Chief Freedom of Information Act (FOIA) Officers Council, co-chaired by the Director of OGIS and the Director of OIP.

**DATES:** The meeting will be on Thursday, November 3, 2022, from 10 a.m. to 12:30 p.m. EDT. Please register for the meeting no later than 11:59 p.m. EDT on Tuesday, November 1, 2022 (registration information is detailed below).

**ADDRESSES:** The November 3, 2022, meeting will be a virtual meeting. We will send access instructions to those who register according to the instructions below.

**FOR FURTHER INFORMATION CONTACT:** Martha Murphy, by email at *ogis@nara.gov* with the subject line ''Chief FOIA Officers Council,'' or by telephone at 202–741–5770.

**SUPPLEMENTARY INFORMATION:** This meeting is open to the public in accordance with the Freedom of Information Act (5 U.S.C. 552(k)). Additional details about the meeting, including the agenda, will be available on OGIS's website at *https://www.archives.gov/ogis/about-ogis/chief-foia-officers-council* and OIP's website at *https://www.justice.gov/oip/chief-foia-officers-council.*

*Procedures:* The virtual meeting is open to the public. If you wish to offer oral public statements during the public comment period, you must register in advance through Eventbrite at *https://chief-foia-officers-council-11-3-2022.eventbrite.com.* You must provide an email address so that we can provide you with information to access the meeting online. Public comments will be limited to three minutes per individual. We will also live-stream the meeting on the National Archives YouTube channel, *https://youtu.be/ITVHhu1f3jU,* and include a captioning option. To request additional accommodations (*e.g.,* a transcript), email *ogis@nara.gov* or call 202–741–5770. Members of the media who wish to register, those who are unable to register online, and those who require special accommodations, should contact OGIS Deputy Director Martha Murphy (contact information listed above).

Dated: October 18, 2022.

**Alina M. Semo,**

*Director, Office of Government Information Services.*

[FR Doc. 2022–23030 Filed 10–27–22; 8:45 am]

**BILLING CODE 7515–01–P**

## NATIONAL LABOR RELATIONS BOARD

### Notice of Appointments of Individuals To Serve as Members of Performance Review Boards

**AGENCY:** National Labor Relations Board.

**ACTION:** Notice; appointment to serve as members of performance review boards.

**SUMMARY:** The National Labor Relations Board is issuing this notice that the individuals whose names and position titles appear below have been appointed to serve as members of performance review boards in the National Labor Relations Board for the rating year beginning October 1, 2021 and ending September 30, 2022.

**FOR FURTHER INFORMATION CONTACT:** Roxanne L. Rothschild, Executive Secretary, National Labor Relations Board, 1015 Half Street SE, Washington, DC 20570, (202) 273–1940 (this is not a toll-free number), 1–866–315–6572 (TTY/TDD).

**SUPPLEMENTARY INFORMATION:**

#### Name and Title

Peter Sung Ohr—Deputy General Counsel, Office of the General Counsel

Joan A. Sullivan—Associate General Counsel, Division of Operations Management

Nancy Kessler Platt—Associate General Counsel, Division of Legal Counsel

Ruth Burdick—(Alternate)—Deputy Associate General Counsel, Division of Enforcement Litigation, Appellate and Supreme Court Litigation Branch

Andrew Krafts—Executive Assistant to the Chairman (Chief of Staff), the Board

Terence G. Schoone-Jongen—Director of the Office of Representation Appeals

*Authority:* 5 U.S.C. 4314(c)(4).

Dated: October 25, 2022.

By Direction of the Board

**Roxanne L. Rothschild,**

*Executive Secretary.*

[FR Doc. 2022–23492 Filed 10–27–22; 8:45 am]

**BILLING CODE 7545–01–P**

## NATIONAL SCIENCE FOUNDATION

### Sunshine Act Meetings

The National Science Board's Awards and Facilities Committee hereby gives notice of the scheduling of a teleconference for the transaction of National Science Board business pursuant to the National Science Foundation Act and the Government in the Sunshine Act.

**TIME AND DATE:** Friday, November 4, 2022, from 2:00–3:00 p.m. EDT.

**PLACE:** This meeting will be held by videoconference through the National Science Foundation.

**STATUS:** Closed.

**MATTERS TO BE CONSIDERED:** The agenda of the teleconference is: Committee Chair's Opening Remarks; Antarctic research infrastructure strategy, including long-range budget, personnel, safety, and communications matters.

**CONTACT PERSON FOR MORE INFORMATION:** Point of contact for this meeting is: Amanda Vernon, *avernon@nsf.gov,* (703) 292–7000. Meeting information and updates may be found at *www.nsf.gov/nsb.*

**Chris Blair,**

*Executive Assistant to the National Science Board Office.*

[FR Doc. 2022–23577 Filed 10–26–22; 11:15 am]

**BILLING CODE 7555–01–P**

## OFFICE OF PERSONNEL MANAGEMENT

### Federal Prevailing Rate Advisory Committee; Virtual Public Meeting

**AGENCY:** Office of Personnel Management.

**ACTION:** Notice.

**SUMMARY:** According to the provisions of section 10 of the Federal Advisory Committee Act, notice is hereby given that a virtual meeting of the Federal Prevailing Rate Advisory Committee will be held on Thursday, November 17, 2022. There will be no in-person gathering for this meeting. The Federal Prevailing Rate Advisory Committee is composed of a Chair, five representatives from labor unions holding exclusive bargaining rights for Federal prevailing rate employees, and five representatives from Federal agencies.

**DATES:** The virtual meeting will be held on November 17, 2022, beginning at 10:00 a.m. (ET).

**ADDRESSES:** The meeting will convene virtually.

**FOR FURTHER INFORMATION CONTACT:** Ana Paunoiu, 202–606–2858, or email *pay-leave-policy@opm.gov.*

**SUPPLEMENTARY INFORMATION:** The Committee's primary responsibility is to review the Prevailing Rate System and other matters pertinent to establishing prevailing rates under subchapter IV, chapter 53, 5 U.S.C., as amended, and from time to time advise the Office of Personnel Management. Entitlement to membership on the Committee is provided for in 5 U.S.C. 5347.

Annually, the Chair compiles a report of pay issues discussed and concluded recommendations. These reports are available to the public. Reports for calendar years 2008 to 2020 are posted at *http://www.opm.gov/fprac.* Previous reports are also available, upon written request to the Committee.

The public is invited to submit material in writing to the Chair on Federal Wage System pay matters felt to be deserving of the Committee's attention. Additional information on these meetings may be obtained by contacting the Committee at Office of Personnel Management, Federal Prevailing Rate Advisory Committee, Room 7H31, 1900 E Street NW, Washington, DC 20415, (202) 606–2858.

This meeting is open to the public, with an audio option for listening. This notice sets forth the agenda for the meeting and the participation guidelines.

*Meeting Agenda.* The tentative agenda for this meeting includes the following Federal Wage System items:

- The definition of Monroe County, PA
- The definition of San Joaquin County, CA
- The definition of the Salinas-Monterey, CA, wage area
- The definition of the Puerto Rico wage area

*Public Participation:* The November 17, 2022, meeting of the Federal Prevailing Rate Advisory Committee is open to the public through advance registration. Public participation is available for the meeting. All individuals who plan to attend the virtual public meeting to listen must register by sending an email to *pay-leave-policy@opm.gov* with the subject line ''November 17 FPRAC Meeting'' no later than Tuesday, November 15, 2022.

The following information must be provided when registering:

- Name.
- Agency and duty station.
- Email address.
- Your topic of interest.

Members of the press, in addition to registering for this event, must also RSVP to *media@opm.gov* by November 15, 2022.

A confirmation email will be sent upon receipt of the registration. Audio teleconference information for participation will be sent to registrants the morning of the virtual meeting.

Office of Personnel Management.

**Stephen Hickman,**

*Federal Register Liaison.*

[FR Doc. 2022–23469 Filed 10–27–22; 8:45 am]

**BILLING CODE P**

## POSTAL REGULATORY COMMISSION

**[Docket Nos. MC2023–25 and CP2023–24]**

### New Postal Products

**AGENCY:** Postal Regulatory Commission.

**ACTION:** Notice.

**SUMMARY:** The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

**DATES:** *Comments are due:* October 31, 2022.

**ADDRESSES:** Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

**FOR FURTHER INFORMATION CONTACT:** David A. Trissell, General Counsel, at 202–789–6820.

**SUPPLEMENTARY INFORMATION:**

### Table of Contents



### I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an

officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

**II. Docketed Proceeding(s)**

1. *Docket No(s).:* MC2023–25 and CP2023–24; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 73 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* October 21, 2022; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Jethro Dely; *Comments Due:* October 31, 2022.

This Notice will be published in the **Federal Register**.

**Erica A. Barker,**

*Secretary.*

[FR Doc. 2022–23450 Filed 10–27–22; 8:45 am]

**BILLING CODE 7710–FW–P**

## PRIVACY AND CIVIL LIBERTIES OVERSIGHT BOARD

**[Notice-PCLOB–2022–02; Docket No. 2022–0009; Sequence No. 2]**

### Notice of Public Forum; Extension of Comment Period

**AGENCY:** Privacy and Civil Liberties Oversight Board (PCLOB).

**ACTION:** Notice; Extension of comment period.

**SUMMARY:** The PCLOB, or Board, is extending the comment period for the notice announcing a request for comments on the Board's Oversight Project examining Section 702 of the Foreign Intelligence Surveillance Act (FISA) that appeared in the **Federal Register** of September 26, 2022.

**DATES:** The Board is extending the comment period announced in the notice and request for comments published on September 26, 2022 (87 FR 58393) to Friday, November 4, 2022.

**FOR FURTHER INFORMATION CONTACT:** Alan Silverleib, Public and Legislative Affairs Officer at 202–997–7719; *pao@pclob.gov.*

**Lois D. Mandell,**

*Director, Regulatory Secretariat Division, Office of Government-Wide Policy, General Services Administration.*

[FR Doc. 2022–23530 Filed 10–27–22; 8:45 am]

**BILLING CODE 6820–B5–P**

## OFFICE SCIENCE AND TECHNOLOGY POLICY

### Request for Information on Data Collection for Emergency Clinical Trials and Interoperability Pilot

**AGENCY:** Office of Science and Technology Policy (OSTP).

**ACTION:** Notice of Request for Information (RFI) on Data Collection for Emergency Clinical Trials and Interoperability Pilot.

**SUMMARY:** As described in the recent RFI on Clinical Research Infrastructure and Emergency Clinical Trials, the White House Office of Science and Technology Policy (OSTP), in partnership with the National Security Council (NSC), is leading efforts to ensure that coordinated and large-scale clinical trials can be efficiently carried out across a range of institutions and sites as needed to address outbreaks of disease and other emergencies. In this RFI on Data Collection for Emergency Clinical Trials and Interoperability Pilot, issued in partnership with the Office of the National Coordinator for Health Information Technology (ONC), OSTP and ONC seek input on viable technical strategies to distribute clinical trial protocols and capture clinical trial data using common application programming interfaces (APIs), in the pre-emergency phase as well as in emergency settings. One specific objective for this RFI is to gather information about whether there is value in a pilot or demonstration project to operationalize data capture in the near term, for example within 6–12 months of the close of comments on this RFI.

**DATES:** Interested persons and organizations are invited to submit comments on or before 5:00 p.m. ET on December 27, 2022.

**ADDRESSES:** Interested individuals and organizations should submit comments electronically to *datacollectionforclinicaltrials@ostp.eop.gov* and include ''Data Collection for Clinical Trials RFI'' in the subject line of the email. Due to time constraints, mailed paper submissions will not be accepted, and electronic submissions received after the deadline cannot be ensured to be incorporated or taken into consideration.

**Instructions**

Response to this RFI is voluntary. Each responding entity (individual or organization) is requested to submit only one response. Please feel free to respond to one or as many prompts as you choose.

Please be concise with your submissions, which must not exceed 10 pages in 12-point or larger font, with a page number on each page. Responses should include the name of the person(s) or organization(s) filing the comment.

OSTP invites input from all stakeholders including members of the public, representing all backgrounds and perspectives. In particular, OSTP is interested in input from health information technology (health IT) companies, app developers, clinical trial designers, and users of health IT products. *Please indicate which of these stakeholder types, or what other description, best fits you as a respondent.* If a comment is submitted on behalf of an organization, the individual respondent's role in the organization may also be provided on a voluntary basis.

Comments containing references, studies, research, and other empirical data that are not widely published should include copies or electronic links of the referenced materials. No business proprietary information, copyrighted information, or personally identifiable information should be submitted in response to this RFI. Please be aware that comments submitted in response to this RFI may be posted on OSTP's website or otherwise released publicly.

In accordance with FAR 15.202(3), responses to this notice are not offers and cannot be accepted by the Federal

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

Government to form a binding contract. Additionally, those submitting responses are solely responsible for all expenses associated with response preparation.

**FOR FURTHER INFORMATION CONTACT:** For additional information, please direct questions to Grail Sipes at 202–456–4444 or *datacollectionforclinicaltrials@ostp.eop.gov.*

**SUPPLEMENTARY INFORMATION:**

*Background on emergency clinical trial research:* OSTP (in partnership with the NSC and other Executive Office of the President components) is leading an initiative to enhance U.S. capacity to carry out clinical trials in emergency situations. This initiative is undertaken in accordance with the 2022 National Biodefense Strategy for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security [1] and aligns with the goals of the American Pandemic Preparedness Plan (AP3).[2]

In the recent RFI on Clinical Research Infrastructure and Emergency Clinical Trials, OSTP is seeking input on the emergency clinical trials effort generally, including U.S.-level governance models to support the emergency clinical trials effort. Governance functions might include determining when coordinated, large-scale clinical research is needed, including research on countermeasures, to address outbreaks of disease or other biological incidents. A further governance function might be to develop clinical trial protocols (in coordination with external stakeholders), which could range from relatively simple studies to more complex ones involving the evaluation of investigational agents. OSTP also seeks comment in the RFI on Emergency Clinical Trials on how emergency clinical trial data should be managed to facilitate researchers' access and analysis of results. One potential model would be the use of a centralized data repository and biorepository for specimens collected during trials.

In this RFI on Data Collection for Emergency Clinical Trials and Interoperability Pilot, to further prepare the U.S. clinical trials enterprise to carry out coordinated, potentially large-scale research protocols in an emergency setting, OSTP is seeking input on how best to operationalize protocol distribution and data capture from a technical perspective. Specifically, in this RFI we seek input on viable technical strategies to distribute clinical trial protocols and capture clinical trial data using common Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR®)-based APIs, in the pre-emergency phase as well as in an emergency setting. We seek comment on how to build towards both of these goals in a data capture pilot or demonstration project. This pilot, if implemented, could provide training for sites in underserved communities, thereby enlarging and strengthening the overall clinical trials infrastructure.

*Desired use case:* OSTP is still in the process of collecting information on governance models and other aspects of the emergency clinical trials initiative. For purposes of responding to this RFI, however, we would like responders to consider the following multi-step use case.

1. A U.S.-level governing entity would oversee development of a clinical trial protocol for broad distribution across clinical trial networks and sites.

2. Study sites would enroll participants in the trial (potentially using software mechanisms that can alert sites to potential subjects for a specific protocol in a manner that increases the diversity of trial populations). Sites would obtain appropriate e-consents and authorizations from participants.

3. Clinical trial data is typically sent to the trial sponsor though an electronic case report form (eCRF), which is the record of data that is required under the protocol to be captured for each trial participant. A data element in an eCRF is the smallest unit of observation for a particular subject.

4. The eCRFs would be transmitted electronically via common APIs to the sponsor.

5. The study site's health IT system would present the eCRF content to clinicians in a manner that expedites data collection and (ideally) fits within clinician workflows.

6. As the clinician obtains data elements to complete the eCRF, that data would be captured in the patient's electronic health record.

7. The clinical trial data would also be sent to a central data repository or small set of data repositories for researchers to analyze. It would be sent via common APIs so that researchers can easily interpret the eCRF data elements. Commercial cloud solutions are likely to house the data repository or repositories. Nonetheless, we would like a solution that would work across multiple cloud vendors.

For the purposes of this RFI, we are interested in the feasibility of all steps in the above hypothetical use case; we would also like input on how much of the use case could be operationalized in a pilot or demonstration project that might move forward in a timeframe of 6–12 months from the close of comments on this RFI.

*ONC standards for interoperability:* We believe that a pilot or demonstration project such as described above would be well supported by the regulatory and governance structure for interoperability of electronic health records (EHRs) that has been put in place by the Office of the National Coordinator for Health Information Technology (ONC). Among other initiatives, ONC is currently supporting development of the United States Core Data for Interoperability (USCDI) standard; the FHIR application programming interfaces (APIs); and Substitutable Medical Applications and Reusable Technologies (SMART) platform technologies that are compatible with FHIR interfaces and have given rise to a category of ''SMART on FHIR'' APIs. Certified health IT developers seeking certification on their Health IT Modules are currently working to meet various ONC certification criteria intended to improve data interoperability. For example, certified developers are required to implement certified API technology capable of patient and population services based on FHIR Release 4, the FHIR US Core Implementation Guide, and based on the HL7 FHIR® Bulk Data Access (Flat FHIR®) (v1.0.0: STU 1), August 22, 2019 Implementation Guide, by December 31, 2022.

In addition, ONC published the Trusted Exchange Framework, Common Agreement—Version 1, and QHIN Technical Framework—Version 1 on January 19, 2022. The overall goal of the Trusted Exchange Framework and Common Agreement (TEFCA) is to establish a universal floor for interoperability across the country. The Common Agreement will establish the infrastructure model and governing approach for users in different networks to securely share basic clinical information with each other—all under commonly agreed-to expectations and rules, and regardless of which network they happen to be in. Entities seeking to be designated as Qualified Health Information Networks (QHINs),[3] per the

[1] 2022 National Biodefense Strategy for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security (October 2022), section 4.1.4.

[2] First Annual Report on Progress Towards Implementation of the American Pandemic Preparedness Plan (September 2022), at 22–23.

[3] The Common Agreement defines a QHIN as ''to the extent permitted by applicable Standard Operating Procedure(s) (SOP(s)), a Health Information Network that is a U.S. Entity that has been Designated by the RCE and is a party to the Common Agreement countersigned by the RCE.''

Common Agreement, can apply for that designation on a voluntary basis. A QHIN is a network of organizations that work together to share health information. The goal of TEFCA is for QHINs to connect directly to each other to ensure interoperability between the networks they represent and to serve a wide range of end users.

The Common Agreement defines Exchange Purpose(s) [4] as ''the reason, as authorized by this Common Agreement including the Exchange Purposes SOP [5], for a Request, Use, Disclosure, or Response transmitted via QHIN-to-QHIN exchange as one step in the transmission.'' Although research is not an authorized Exchange Purpose under the current version of the Common Agreement, it is a planned future Exchange Purpose, and responses to this RFI could inform how TEFCA might best support research in the future.

The implementation SOPs for Public Health and some other current Exchange Purposes, including Payment, Health Care Operations, and Government Benefits Determination, have not yet been developed. These SOPs will need to specify constraints, and at least some of the to-be-defined constraints are likely to be applicable to a future research-focused Exchange Purpose. Therefore, this RFI also seeks input on how TEFCA's Public Health Exchange Purpose Implementation SOP might be designed to enable public health authorities to answer questions that align with the activities described in this RFI.

More information on ONC data interoperability initiatives is available at *https://www.healthIT.gov,* and more specific information about TEFCA at *https://www.healthit.gov/TEFCA* and *https://rce.sequoiaproject.org/.*

*Information Requested:* OSTP invites input from all interested parties as outlined in the instructions. Respondents may provide information for *one or as many topics* below as they choose.

Our goal for this RFI is to support optimized data collection for clinical trials carried out across a range of institutions and sites, both in emergency settings and in the pre-emergency phase, under the use case described above. We also seek input specifically on the value of designing a pilot or demonstration project to operationalize data capture in the near term, for example within 6–12 months of the close of comments on this RFI. With those goals in mind, we request input on the following topics:

*1. United States Core Data for Interoperability (USCDI).* We seek input on how U.S. Government and external stakeholders might leverage USCDI and future extensions of USCDI standards (such as USCDI+, an extension that supports federal partner program-specific requirements) to support emergency clinical trial research. It would also be helpful to receive comment on areas in which additional extensions might be necessary.

*2. HL7 FHIR APIs.* We seek comment on how U.S. Government and external stakeholders might leverage FHIR APIs to support research in emergency settings as well as in the pre-emergency phase, and in what areas further advances might be needed. Specific topics in this connection include:

a. Use of an API that supports FHIR Bulk Data Access to support clinical research; whether bulk data exports from EHR systems can be used to support certain clinical trial protocols.

b. Use of the FHIR Questionnaire and QuestionnaireResponse resources to support clinical research.

*3. SMART on FHIR APIs:* We seek input on how U.S. Government and external stakeholders might leverage SMART on FHIR APIs, and in what areas further extensions might be needed. It would be helpful to receive comments on:

a. The most promising ways to create SMART on FHIR technologies that are portable across different institutions and EHR systems, but also provide adequate functionality to support emergency clinical trial research.

b. Whether the portability of SMART on FHIR tools provides a way to reach institutions and sites that have limited information technology resources; any promising ways to use SMART on FHIR to expand clinical research into underserved settings.

*4. Clinical Decision Support (CDS) Hooks:* We seek comments on how the HL7 CDS Hooks specification might be used to support clinical research, for example by creating prompts within the practitioner workflow during interaction with patients; and any advances that might be needed to support the use case described above.

*5. Operationalizing protocols of varying complexity.* As noted above, emergency clinical trial designs could range from relatively simple protocols to more complex studies involving the evaluation of investigational agents. We would appreciate comments on the following topics:

a. Whether any of the tools described above might be particularly well suited for certain types of studies.

b. For example,

i. Whether a bulk FHIR API export could be used to gather data for a simple trial protocol that is relatively close to the standard of care for a particular condition.

ii. Whether a FHIR Questionnaire/QuestionnaireResponse or a SMART on FHIR form would be useful in capturing data for a more complex protocol, such as one that involves an investigational agent.

c. Any technical limitations that we should be aware of regarding use of the above tools to operationalize clinical trial protocols.

*6. Consent, deidentification, return of results.* The use case in this RFI contemplates that data would be managed through a central repository or repositories and made available to researchers beyond a patient's home institution.

a. In light of this, we seek comment on how the tools described above can be used to obtain, collect and/or manage any required informed consents and/or authorizations from patients or individuals in accordance with applicable regulations.

b. We also seek input on what additional capabilities would be required to deidentify or otherwise manage protected health information. It would be helpful to receive comments on which deidentification and protection approaches are sufficiently mature to support a pilot effort in the near term.

c. Ideally, patient authorization would allow clinical trial data to be used for additional research beyond the original study. We would appreciate input on how the content collected for consent and authorization as well as the interfaces with deidentification technologies should be designed to enable flexible and responsible reuse of clinical trial data.

d. We seek comment on any technical capabilities that could support return of results to study sites or participants, where appropriate.

e. We seek comment on any regulatory or ethical guidelines that are relevant to patients' consents and authorizations under the use case described in this RFI, and on ways in

*See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 10, 6 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-.*

[4] *See* Common Agreement for Nationwide Health Information Interoperability Version 1, at 6 (Jan. 2022), *https://www.healthit.gov/sites/default/files/page/2022-.*

[5] The current version of the TEFCA ''Standard Operating Procedure: Exchange Purposes'' specifies that authorized Exchange Purposes under the Common Agreement and that SOP are: Treatment, Payment, Health Care Operations, Public Health, Government Benefits Determination, and Individual Access Services.

which technical solutions might help ensure adherence to applicable regulatory or ethical guidelines.

*7. User interface and experience.* With all of the above technologies, we seek input on:

a. The best way to optimize the experience of health care providers, administrators, and other users, so as to maximize the utility and uptake of the product.

b. To the extent a particular form, app or other tool requires input from a health care provider or other user, the best ways to increase the likelihood that users will actually provide that input. It would be helpful to receive comments on methods that are available for completing empty fields after the fact, or otherwise managing any missing data.

c. For clinicians and health IT users: what existing tools, apps, or processes you have found most usable and why.

8. *Capturing data elements required for clinical trial protocols.*

a. We seek comment on the most promising technical approaches that would leverage common APIs to translate a particular clinical trial's data elements into data elements captured by user-facing tools (*e.g.,* FHIR Questionnaire feeding into a SMART on FHIR form or application).

b. If a tool such as a FHIR Questionnaire, FHIR QuestionnaireResponse, or SMART form or app is used to capture required data elements in this way, we seek comment on whether that creates an effective method for ''pushing out'' a research protocol to investigators and sites.

c. It would be helpful to receive comments on how best to ensure compliance with regulatory requirements for eCRFs when designing interfaces for data capture.

*9. TEFCA and QHINs.* As noted above, TEFCA is in the implementation phase at this time. In the future, the TEFCA QHINs are expected to support implementation of the FHIR APIs (see the ONC Recognized Coordinating Entity's January 2022 FHIR Roadmap for TEFCA Exchange [6]). We would appreciate comment on the opportunities and challenges regarding development of API implementations toward the use case described above, particularly given the current status of TEFCA and QHIN participation. Specific topics in this connection include the following:

a. Certain policy and/or technical constraints will need to be specified for currently authorized Exchange Purposes under the Common Agreement (*e.g.,* Public Health). We seek comment on which of these constraints will also be applicable to a future research-focused Exchange Purpose.

b. Opportunities that may exist for using the initially authorized Exchange Purposes to accomplish the use case described in this RFI.

c. How the Public Health Exchange Purpose could be used to advance the goals of this RFI; what aspects of the use case described above might fall within the scope of the Public Health Exchange Purpose.

d. How a future research-focused Exchange Purpose could be structured to advance the goals of this RFI.

e. Other opportunities or constraints related to TEFCA that should be considered with regard to this RFI.

*10. Emerging technologies.* We welcome comments on any future technological developments we should anticipate. Relevant technical developments include but are not limited to differential privacy; federated machine learning; other technologies referenced in the recent OSTP RFI related to privacy-enhancing technologies (PET) (*see* **Federal Register:** Request for Information on Advancing Privacy-Enhancing Technologies); and technologies outside of the PET space. Specific topics in this area include:

a. How future technologies might affect the use case and underlying assumptions laid out in this RFI.

b. How future technologies might change the nature of the software architecture, data architecture, or potential data collection solutions for clinical trials.

*11. Pilot or demonstration project.* We seek comment on how the U.S. Government can best work with external stakeholders and developers to develop a pilot or demonstration project that will operationalize clinical trial data capture and serve as a basis and model for data collection in the event of an emergency. This pilot or demonstration project could also potentially support clinical research in the pre-emergency phase. Specific topics include:

a. Whether data can be managed through a central repository or small set of central data repositories; options for cloud-based data storage.

b. Technical options that might hold promise in the short term to enable researchers from diverse locations to analyze the data collected from multiple clinical trial sites. We also seek comment on any additional options that should be considered in the long term.

c. Whether any parts of the pilot would be appropriately supported as

i. A demonstration project with commercial partnership.

ii. A public-private partnership.

iii. An agency-funded program.

*12. Specific commercial capabilities.* Commenters who are developing a technology or product that might be relevant to any of the topics set forth above are welcome to include a description of that product. Comments about a specific technology or product should be limited to three pages or less.

Dated: October 25, 2022.

**Stacy Murphy,**

*Operations Manager.*

[FR Doc. 2022–23489 Filed 10–27–22; 8:45 am]

**BILLING CODE 3270–F1–P**

[6] *https://rce.sequoiaproject.org/three-year-fhir-roadmap-for-tefca/.*

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–96134; File No. SR–ICEEU–2022–010]**

## Self-Regulatory Organizations; ICE Clear Europe Limited; Order Approving Proposed Rule Change Relating to Amendments to the ICE Clear Europe Clearing Membership Procedures

October 24, 2022.

### I. Introduction

On August 30, 2022, ICE Clear Europe Limited (''ICE Clear Europe'') filed with the Securities and Exchange Commission (''Commission''), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend its Clearing Membership Procedures (the ''Procedures''). The proposed rule change was published for comment in the **Federal Register** on September 13, 2022.[3] The Commission did not receive comments regarding the proposed rule change. For the reasons discussed below, the Commission is approving the proposed rule change.

### II. Description of the Proposed Rule Change

The Procedures describe how ICE Clear Europe applies its policies for reviewing applications for clearing membership, variations of permissions for Clearing Members, ongoing monitoring of Clearing Members, and termination of clearing membership.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing of Proposed Rule Change Relating to Amendments to the ICE Clear Europe Clearing Membership Procedures, Exchange Act Release No. 95683 (Sep. 7, 2022); 87 FR 56110 (Sep. 13, 2022) (SR–ICEEU–2022–010) (''Notice'').

The proposed rule change would amend the Procedures to: (i) correct a typographical error and establish a new defined term; (ii) update the names of responsible ICE Clear Europe departments and committees; (iii) correct or remove references to material found in other ICE Clear Europe policies or the ICE Clear Europe Clearing Rules (the ''Rules''); and (iv) clarify certain aspects of ICE Clear Europe's process for approving and reviewing Clearing Members.[4]

*i. Typographical Correction and New Defined Term*

The proposed rule change would first make minor updates to Section 1, which describes the purpose of the Procedures. First, it would make a typographical correction, changing ''these'' to ''the'' at the beginning of the first sentence of the section.

Section 1 of the Procedures also states that terms used in the document are defined in the document or in ICE Clear Europe's Clearing Rules. The proposed rule change would retain this statement but would add a defined term for ''the Rules'' at the end of the sentence. Throughout the Procedures, the proposed rule change would use this new defined term and replace references to the ''Clearing Rules'' with references to the ''Rules.''

*ii. Names of ICE Clear Europe Departments and Committees*

Next, the proposed rule change would update the names of responsible ICE Clear Europe departments and committees. Currently, the Procedures provide that all applications for clearing membership will be subject to due diligence from relevant ICE Clear Europe departments, including, among others, Operations, Risk, and Treasury. The proposed rule change would change the reference to the ''Risk'' department to the ''Credit and Clearing Risk'' department, to encompass both the Credit Risk Department and the Clearing Risk Department.

Similarly, the Procedures currently provide that all applications are submitted to the ''Committee'' for approval. The proposed rule change would correct this reference to the ''Executive Risk Committee,'' which is the current and correct name of that Committee. Throughout the Procedures, the proposed rule change also would change references to the ''Committee'' to the ''Executive Risk Committee'' or ''ERC.''

*iii. Material Found in Other ICE Clear Europe Policies or Rules*

The proposed rule change also would make a number of amendments to correct or remove references to material found in other ICE Clear Europe policies or in the Rules. For example, Section 2.2.1 of the Procedures, which describes the process to approve an application for clearing membership, provides that the Clearing Risk department will conduct a review based on financial and qualitative information of prospective clearing members. The proposed rule change would remove this statement because this review is described in, and governed by, ICE Clear Europe's Counterparty Credit Risk Policy and Counterparty Credit Risk Procedures.[5]

Section 2.4 describes how ICE Clear Europe may terminate the membership of a Clearing Member. Section 2.4.2 states that ICE Clear Europe may terminate Clearing Membership in accordance with ICE Clear Europe Rule 209 and that the ICE Clear Europe Board is required to approve the issuance of a Termination Notice against a Clearing Member. The proposed rule change would delete the requirement that the ICE Clear Europe Board approve the issuance of a Termination Notice. The proposed rule change would remove this requirement because it is not part of Rule 209, and ICE Clear Europe would instead rely on the general delegation of authority provided by ICE Clear Europe Rule 114.[6]

Section 3.1.1 of the Procedures describes the minimum capital requirements for Clearing Members. Section 3.1.1 states that the data sources used to determine a Clearing Member's capital are found in the Counterparty Credit Policy. The proposed rule change would remove this statement because this information is described in, and governed by, ICE Clear Europe's Counterparty Credit Risk Policy and Counterparty Credit Risk Procedures.[7]

Section 3.1.1 also states that in relation to the minimum capital requirement, ICE Clear Europe may, among other things, establish additional risk-based requirements for Clearing Members which are FCM/BD Clearing Members (meaning Clearing Members that are registered as futures commission merchants and/or broker-dealers) and that wish to provide client clearing services. The proposed rule change would clarify that ICE Clear Europe could only establish these additional requirements for CDS Clearing Members, which are Clearing Members that are authorized to clear CDS Contracts. The proposed rule change would add this statement because this provision is actually referring to Section 2 of the ICE Clear Europe CDS Procedures, which specify additional membership requirements for CDS Clearing Members.

Section 3.1.2 of the Procedures describes, in general, the contributions that Clearing Members must make to ICE Clear Europe's CDS and Futures and Options (''F&O'') Guaranty Funds. The proposed rule change would add to this description references to the F&O Guaranty Fund Policy and the CDS Risk Policy because these are the correct ICE Clear Europe policies that describe these requirements.

Section 3.1.3 of the Procedures briefly describes ICE Clear Europe's margin-to-capital ratio, which helps to ensure that a Clearing Member's maximum margin requirement does not exceed a specified multiple of its balance sheet capital. The proposed rule change would delete this section as unnecessary because this information is described in, and governed by, ICE Clear Europe's Counterparty Credit Risk Policy and Counterparty Credit Risk Procedures.[8]

Section 4 of the Procedures describes in general how ICE Clear Europe monitors Clearing Members on an ongoing basis. Section 4 currently contains a general statement that further

[4] This description is substantially excerpted from the Notice, 87 FR at 56110. Capitalized terms not otherwise defined herein have the meanings assigned to them in the Rules or the Procedures, as applicable.

[5] For a description of the Counterparty Credit Risk Policy and Counterparty Credit Risk Procedures, *see* Self-Regulatory Organizations; ICE Clear Europe Limited; Order Approving Proposed Rule Change Relating to Adoption of the Counterparty Credit Risk Policy and Counterparty Credit Risk Procedures, Exchange Act Release No. 93880 (Dec. 30, 2021), 87 FR 513 (Jan. 5, 2022) (SR–ICEEU–2021–015).

[6] Rule 114(a) provides that ''any action permitted or required to be taken by the Clearing House may be taken by the Board, the Chairman, the President, any other Director or any other employee, officer or committee (or any individual committee member) to whom or which authority has been delegated by the Clearing House, the Board, the Chairman, the President or any committee.'' Although ICE Clear Europe has not issued a specific delegation of authority with respect to the issuance of a termination notice, ICE Clear Europe believes its existing general Delegation of Authority to its President implemented pursuant to Rule 114(a) could potentially apply to issuance of a Termination Notice in certain emergency scenarios. Notice, 87 FR at 56111.

[7] *See* Self-Regulatory Organizations; ICE Clear Europe Limited; Order Approving Proposed Rule Change Relating to Adoption of the Counterparty Credit Risk Policy and Counterparty Credit Risk Procedures, Exchange Act Release No. 93880 (Dec. 30, 2021), 87 FR 513 (Jan. 5, 2022) (SR–ICEEU–2021–015).

[8] *See* Self-Regulatory Organizations; ICE Clear Europe Limited; Order Approving Proposed Rule Change Relating to Adoption of the Counterparty Credit Risk Policy and Counterparty Credit Risk Procedures, Exchange Act Release No. 93880 (Dec. 30, 2021), 87 FR 513 (Jan. 5, 2022) (SR–ICEEU–2021–015).

information on the ongoing monitoring of Clearing Members can be found in the Counterparty Credit Risk Policy. The proposed rule change would delete this reference as unnecessary because this information is described in, and governed by, ICE Clear Europe's Counterparty Credit Risk Policy and Counterparty Credit Risk Procedures.[9]

Section 4.3 describes in general ICE Clear Europe's Quarterly Counterparty Rating System Report. Section 4.3 currently states that ICE Clear Europe's counterparty rating system aggregates risk factors covering credit, market price, liquidity and operational risk for each Clearing Member and is updated at least once per quarter. The proposed rule change would delete this reference as unnecessary because this information is described in, and governed by, ICE Clear Europe's Counterparty Credit Risk Policy and Counterparty Credit Risk Procedures.[10]

*iv. Clarifying Other Aspects of the Clearing Membership Process*

Finally, the proposed rule change would clarify certain aspects of the clearing membership process.

Section 2.2.1 of the Procedures provides that ICE Clear Europe's list of Approved Jurisdiction for applicants for clearing membership (meaning those jurisdictions for which additional legal and regulatory analysis is not required) is maintained in ICE Clear Europe's Clearing Membership Parameters. The proposed rule change would delete this statement because ICE Clear Europe's legal department maintains this list, and ICE Clear Europe does not keep this list in the Clearing Membership Parameters.

Section 4.1 of the Procedures describes ICE Clear Europe's periodic reviews of its Clearing Members. Section 4.1 currently states that ICE Clear Europe conducts periodic reviews of the financial position and compliance with the membership requirements of each Clearing Member to provide a baseline measurement of each Clearing Member's reported financial position and a measure of relative performance. The proposed rule change would retain this description, but would add that ICE Clear Europe's periodic reviews include know-your-customer and anti-money laundering assessments. ICE Clear Europe is adding this to memorialize a review that it already performs in practice.[11]

Section 4.5 of the Procedures describes ICE Clear Europe's Annual Member Return. The Annual Member Return is an annual process through which ICE Clear Europe requests that Clearing Members provide and confirm information related to their membership. ICE Clear Europe uses the Annual Member Return to update information about its Clearing Members. Section 4.5 currently states that the Annual Member Return includes information on, among other things, key contacts, authorized signatories, and compliance with ICE Clear Europe rules. The proposed rule change would retain this description and add to it ''updated Clearing Member information.'' ICE Clear Europe would be making this change to require that Clearing Members provide, as part of the Annual Member Return, updated information about the legal entity that is the Clearing Member, such as its address and legal name.

## III. Discussion and Commission Findings

Section 19(b)(2)(C) of the Act directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to such organization.[12] For the reasons discussed below, the Commission finds that the proposed rule change is consistent with section 17A(b)(3)(F) of the Act[13] and Rules 17Ad–22(e)(2)(i) and 17Ad–22(e)(18) thereunder.[14]

*i. Consistency With Section 17A(b)(3)(F) of the Act*

Section 17A(b)(3)(F) of the Act requires, among other things, that the rules of ICE Clear Europe be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions.[15] Based on its review of the record, and for the reasons discussed below, the Commission believes the proposed changes to the Procedures are consistent with the promotion of the prompt and accurate clearance and settlement of securities transactions.

The Commission believes that a number of the changes discussed above would improve the overall operation and application of the Procedures. For example, the Commission believes that correcting the errors and introducing the defined term discussed in Part II.i above would help to ensure that ICE Clear Europe personnel apply the Procedures in a consistent manner and free from error. The Commission further believes that correcting the names of responsible ICE Clear Europe departments and committees discussed Part II.ii above would help to ensure that the correct ICE Clear Europe personnel complete the processes and responsibilities specified in the Procedures. Finally, the Commission believes that correcting and removing references to material found in other ICE Clear Europe policies or in the Rules would help to reduce the possibility of conflict between the Procedures and other ICE Clear Europe policies or the Rules. The Commission believes these changes would help to ensure that ICE Clear Europe personnel apply the Procedures in a manner consistent with other ICE Clear Europe policies or Rules.

The Commission further believes that the changes discussed in Part II.iv above would help to improve the overall operation and application of the Procedures by clarifying certain aspects of ICE Clear Europe's process for review and approving clearing membership. Specifically, the changes to Section 2.2.1 and 4.1 would make the Procedures consistent with ICE Clear Europe's current practices in maintaining the list of Approved Jurisdictions and reviewing know-your-customer and anti-money laundering compliance. Memorializing these practices in the Procedures should help to ensure that ICE Clear Europe continues to perform these practices consistently in the future. Similarly, the amendment to Section 4.5 should help to ensure that Clearing Members provide to ICE Clear Europe updated legal entity information, as needed, as part of the Annual Member Return.

The Commission believes that the Procedures help to ensure that ICE Clear Europe effectively manages the potential risks posed by its Clearing Members in the clearance and settlement of securities transactions. The Commission further believes that these potential membership risks, if not properly managed, could threaten ICE Clear Europe's ability to operate and thereby clear and settle transactions. The Commission therefore believes that the proposed rule change, in improving the Procedures, would help to ensure that that ICE Clear Europe effectively manages the potential risks posed by its Clearing Members and thereby should help to ensure ICE Clear Europe's ability to promptly and accurately clear and settle securities transactions, consistent with Section 17A(b)(3)(F) of the Act.[16]

[9] *Id.*

[10] *Id.*

[11] Notice, 87 FR at 56111.

[12] 15 U.S.C. 78s(b)(2)(C).

[13] 15 U.S.C. 78q–1(b)(3)(F).

[14] 17 CFR 240.17Ad–22(e)(2)(i) and (e)(18).

[15] 15 U.S.C. 78q–1(b)(3)(F).

[16] 15 U.S.C. 78q–1(b)(3)(F).

*ii. Consistency With Rule 17Ad–22(e)(2)(i)*

Rule 17Ad–22(e)(2)(i) requires that ICE Clear Europe establish, implement, maintain and enforce written policies and procedures reasonably designed to provide for governance arrangements that are clear and transparent.[17] The Commission believes that deleting the requirement that the ICE Clear Europe Board approve the issuance of a Termination Notice from Section 2.4.2., as discussed in Part II.iii above, would help to clarify the process for issuing such a Termination Notice. Because Board approval is not a requirement of Rule 209, and because Board approval could potentially conflict with a delegation issued under ICE Clear Europe Rule 114, the Commission believes this proposed change would reduce the possibility for conflict and thereby clarify the governance arrangement for issuing a Termination Notice.

Therefore, the Commission finds that the proposed rule change is consistent with Rule 17Ad–22(e)(2)(i).[18]

*iii. Consistency With Rule 17Ad–22(e)(18)*

Rule 17Ad–22(e)(18) requires that ICE Clear Europe establish, implement, maintain and enforce written policies and procedures reasonably designed to, as applicable, establish objective, risk-based, and publicly disclosed criteria for participation, which permit fair and open access by direct and, where relevant, indirect participants and other financial market utilities, require participants to have sufficient financial resources and robust operational capacity to meet obligations arising from participation in the clearing agency, and monitor compliance with such participation requirements on an ongoing basis.[19] As discussed above, the proposed rule change would require that Clearing Members provide, as part of the Annual Member Return, updated information about the legal entity that is the Clearing Member, such as its address and legal name. The Commission believes this requirement is an objective, risk-based, and publicly disclosed criteria for participation by Clearing Members.

Therefore, the Commission finds that the proposed rule change is consistent with Rule 17Ad–22(e)(18).[20]

[17] 17 CFR 240.17Ad–22(e)(2)(i).

[18] *Id.*

[19] 17 CFR 240.17Ad–22(e)(18).

[20] *Id.*

## IV. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the requirements of the Act, and in particular, with the requirements of Section 17A(b)(3)(F) of the Act[21] and Rules 17Ad–22(e)(2)(i) and 17Ad–22(e)(18).[22]

*It is therefore ordered* pursuant to section 19(b)(2) of the Act[23] that the proposed rule change (SR–ICEEU–2022–010) be, and hereby is, approved.[24]

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

**J. Matthew DeLesDernier,**

*Deputy Secretary.*

[FR Doc. 2022–23481 Filed 10–27–22; 8:45 am]

**BILLING CODE 8011–01–P**

[21] 15 U.S.C. 78q–1(b)(3)(F).

[22] 17 CFR 240.17Ad–22(e)(2)(i) and (e)(18).

[23] 15 U.S.C. 78s(b)(2).

[24] In approving the proposed rule change, the Commission considered the proposal's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[25] 17 CFR 200.30–3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

**[SEC File No. 270–244, OMB Control No. 3235–0208]**

## Submission for OMB Review; Comment Request; Extension: Rule 17a–1

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for approval of extension of the previously approved collection of information provided for in Rule 17a–1 (17 CFR 240.17a–1) under the Securities Exchange Act of 1934, as amended (the ''Act'') (15 U.S.C. 78a *et seq.*).

Rule 17a–1 requires that every national securities exchange, national securities association, registered clearing agency, and the Municipal Securities Rulemaking Board keep on file for a period of not less than five years, the first two years in an easily accessible place, at least one copy of all documents, including all correspondence, memoranda, papers, books, notices, accounts, and other such records made or received by it in the course of its business as such and in the conduct of its self-regulatory activity, and that such documents be available for examination by the Commission.

There are 35 entities required to comply with the rule: 24 national securities exchanges, 1 national securities association, 9 registered clearing agencies, and the Municipal Securities Rulemaking Board. The Commission staff estimates that the average number of hours necessary for compliance with the requirements of Rule 17a–1 is 52 hours per year. In addition, 4 national securities exchanges notice-registered pursuant to section 6(g) of the Act (15 U.S.C. 78f(g)) are required to preserve records of determinations made under Rule 3a55–1 under the Act (17 CFR 240.3a55–1), which the Commission staff estimates will take 1 hour per exchange per year, for a total of 4 hours per year. Accordingly, the Commission staff estimates that the total number of hours necessary to comply with the requirements of Rule 17a–1 is 1,824 hours per year. The total internal cost of compliance for all respondents is $142,272 per year, based on an average cost per hour of $78.

Compliance with Rule 17a–1 is mandatory. Rule 17a–1 does not assure confidentiality for the records maintained pursuant to the rule. The records required by Rule 17a–1 are available only for examination by the Commission staff, state securities authorities, and the self-regulatory organizations. Subject to the provisions of the Freedom of Information Act, 5 U.S.C. 522, and the Commission's rules thereunder (17 CFR 200.80(b)(4)(iii)), the Commission does not generally publish or make available information contained in any reports, summaries, analyses, letters, or memoranda arising out of, in anticipation of, or in connection with an examination or inspection of the books and records of any person or any other investigation.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent by November 28, 2022 to (i) *MBX.OMB.OIRA.SEC_desk_officer@omb.eop.gov* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: October 24, 2022.

**Sherry R. Haywood,**

*Assistant Secretary.*

[FR Doc. 2022–23471 Filed 10–27–22; 8:45 am]

**BILLING CODE 8011–01–P**

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–96130; File No. SR–CboeBZX–2022–051]**

## Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule

October 24, 2022.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 11, 2022, Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') proposes to amend its Fee Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

The Exchange proposes to update its Fee Schedule for its equity options platform (''BZX Options'') to correct inadvertent marking errors in the Standard Rates table in the Fee Schedule made in connection with previous rule changes.

First, the Exchange proposes to update the Add rebates for Customer, Non-Penny Program Securities transactions (fee code ''NY'') in the Standard Rates table. Initially, the Exchange submitted a rule filing in August 2021 (''August Filing''), which among other things, amended the enhanced rebates provided under the Customer Non-Penny Add Volume Tiers under Footnote 12 to range from between $0.92 and $1.06 per contract across 5 tiers, to between $0.90 and $1.05 per contract across eight tiers.[3] On January 4, 2022, the Exchange submitted a cleanup rule filing (''January Filing''),[4] to amend the Fee Schedule to reflect the new volume tier enhanced rebates that were proposed in the August Filing under the Customer Non-Penny Add Volume Tiers under Footnote 12, but inadvertently not added to the corresponding Standard Rates table for Customer, Non-Penny Program Securities Add transactions. In the January Filing however, the Exchange also inadvertently removed the standard rebate for Customer, Non-Penny Program Securities Add transactions (which was, and still is, $0.85) in its entirety. The Exchange now proposes to add the standard rebate of $0.85 back in the Standard Rates table under the Non-Penny Program Securities for Add transactions for corresponding fee code ''NY.''

Next, the Exchange proposes to add a reference to fee code ''PD'' in the Standard Rates table for Firm, Broker Dealer and Joint Back Office orders in Penny Program Securities, which are subject to a standard rate of $0.50 per contract. On May 3, 2021, the Exchange submitted a filing (''May Filing''), which among other things, adopted new fee code ''PD''.[5] Particularly, prior to the May Filing, fee code ''PP'' was appended to all Non-Customer (*i.e.,* Firm, Broker Dealer, Joint Back Office, Market Maker, Away Market Maker and Professional capacities) orders that removed liquidity in Penny securities and which were assessed a fee of $0.50 per contract. In the May Filing, the Exchange proposed to create a remove Penny liquidity fee code specific to Firm, Broker Dealer and Joint Back Office orders (*i.e.,* fee code ''PD''), which would continue to yield the same standard rate of $0.50 per contract. The Exchange however inadvertently omitted adding new fee code ''PD'' to the Standard Rates table applicable to Firm Broker Dealer and Joint Back Office orders that remove volume in Penny Program Securities. The Exchange now proposes to add in the fee code ''PD'' in the Standard Rates table.

Next, the Exchange proposes to update the Remove fees listed for Market Maker, Away Market Maker, and Professional transactions in Penny Program Securities in the Standard Rates table. Specifically, in the previously mentioned August Filing, the Exchange also amended the reduced fees offered under Tiers 1–3 of the Market Maker, Away Market Maker, and Professional Penny Take Volume Tiers under Footnote 3 from $0.45, $0.45 [sic] and $0.47 [sic] to $0.47 [sic], $0.48 and $0.49 [sic] across the three tiers.[6] The Exchange however at that time inadvertently omitted to also update the corresponding rates listed in the Standard Rates table of the Fees Schedule applicable to Market Maker, Away Market Maker, and Professional orders that remove volume in Penny Program Securities (*i.e.,* the current Standard Rates table still only reflects

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 92635 (August 11, 2021), 86 FR 46028 (August 17, 2021) (SR–CboeBZX–2021–055).

[4] *See* Securities Exchange Act Release No. 93974 (January 13, 2022), 87 FR 3160 (January 20, 2022) (SR–CboeBZX–2022–002).

[5] *See* Securities Exchange Act Release No. 91831 (May 10, 2021), 86 FR 26577 (May 14, 2021) (SR–CboeBZX–2021–038).

[6] *See* Securities Exchange Act Release No. 92635 (August 11, 2021), 86 FR 46028 (August 17, 2021) (SR–CboeBZX–2021–055).

reduced fees of $0.45 and $0.47, instead of $0.47, $0.48, and $0.49, in addition to the standard fee of $0.50). The Exchange now proposes to update the rates listed in the Standard Rates table under fee code ''PP'' for Market Maker, Away Market Maker, and Professional orders that remove volume in Penny Program Securities to reflect the rates proposed in the August Filing applicable to such orders.[7]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of section 6 of the Act,[8] in general, and furthers the objectives of section 6(b)(4),[9] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and issuers and other persons using its facilities. The Exchange also believes that the proposed rule change is consistent with the objectives of section 6(b)(5) [10] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and, particularly, is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed changes are reasonable, equitable and not unfairly discriminatory as it does not change the fees or rebates currently assessed by the Exchange, but rather updates the Standard Rates table to reflect previously filed fee changes which inadvertently were not carried over into the Standard Rates table at the time the original filings were submitted. Indeed, the proposed rule changes are merely corrective changes made to the Fee Schedule designed to accurately reflect the current rates for the respective orders, which increases transparency in the Fees Schedule and reduces potential confusion regarding the appropriate rates for such orders.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange does not believe that the proposed rule changes will impose any burden on intramarket or intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed rule change merely corrects inadvertent marking errors in the Fee Schedule, which is designed to accurately reflect the current rates for the corresponding applicable orders, thereby increasing transparency in the Fee Schedule and reducing potential confusion regarding the appropriate rates applicable to such orders without having any impact on competition.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

The Exchange neither solicited nor received comments on the proposed rule change.

## III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3)(A) of the Act [11] and paragraph (f) of Rule 19b–4 [12] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

## IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

*Electronic Comments*

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeBZX–2022–051 on the subject line.

*Paper Comments*

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeBZX–2022–051. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeBZX–2022–051 and should be submitted on or before November 18, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

**J. Matthew DeLesDernier,**

*Deputy Secretary.*

[FR Doc. 2022–23479 Filed 10–27–22; 8:45 am]

**BILLING CODE 8011–01–P**

[7] The Exchange notes that as a result of adding fee code ''PD'' to the Fees Schedule, Penny Program Securities Remove rates for Market Makers and Away Market Makers are now separate from rates for Professionals (notwithstanding all such orders yielding fee code ''PP''). As such, the Exchange proposes to replicate and add Fee Code PP and the corresponding fees under the Market Maker and Away Market rows.

[8] 15 U.S.C. 78f.

[9] 15 U.S.C. 78f(b)(4).

[10] 15 U.S.C. 78f.(b)(5).

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f).

[13] 17 CFR 200.30–3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–96136; File No. SR–FICC–2022–006]**

## Self-Regulatory Organizations; Fixed Income Clearing Corporation; Order Granting Approval of Proposed Rule Change To Increase the Minimum Required Fund Deposit for Government Securities Division Netting Members and Sponsoring Members, and Make Other Changes

October 24, 2022.

### I. Introduction

On September 9, 2021, Fixed Income Clearing Corporation (''FICC'') filed with the Securities and Exchange Commission (''Commission'') proposed rule change SR–FICC–2022–006 (the ''Proposed Rule Change'') pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder [2] to increase the minimum Required Fund Deposit for members of FICC's Government Securities Division (''GSD'') [3] members, as well as make certain clarifying and technical changes.

The Proposed Rule Change was published for comment in the **Federal Register** on September 22, 2022,[4] and the Commission has received no comments on the changes proposed therein. This order approves the Proposed Rule Change.

### II. Description of the Proposed Rule Change

Currently, FICC requires from each Netting Member a minimum required margin amount, referred to as the Required Fund Deposit, of $100,000 that must be made and maintained in cash, and does not require any specific minimum amount for Sponsoring Members.[5] FICC proposes to increase each member's minimum Required Fund Deposit amount to $1,000,000.

#### *A. Background*

A key tool that FICC uses to manage its respective credit exposures to its members is the daily collection of margin from each member, which is referred to as each member's Required Fund Deposit. The aggregated amount of all members' margin constitutes the Clearing Fund, which FICC would access should a defaulted member's own margin be insufficient to satisfy losses to FICC caused by the liquidation of that member's portfolio.

FICC conducts daily backtesting to evaluate whether each member's Required Fund Deposit is sufficient to cover FICC's credit exposures to that member based on a simulated liquidation of the member's portfolio on that day.[6] Backtesting is an ex-post comparison of actual outcomes with expected outcomes derived from the use of margin models.[7] A backtesting deficiency occurs when FICC determines that the projected liquidation losses to FICC arising in the event of a member's default would be greater than the member's Required Fund Deposit.[8] Therefore, backtesting deficiencies highlight exposure that could subject FICC to potential losses under normal market conditions in the event that a member defaults.[9]

FICC regularly reviews backtesting results to assess the effectiveness of its margin requirements.[10] As part of its review, FICC investigates the causes of any backtesting deficiencies, paying particular attention to repeat backtesting deficiencies that would result in the member's backtesting coverage to fall below the 99% confidence target to determine if there is an identifiable cause of repeat backtesting deficiencies.[11] FICC also evaluates whether multiple members may experience backtesting deficiencies for the same underlying reason.[12]

Based on its regular reviews, FICC has found that members with Required Fund Deposits below $100,000 disproportionately experience repeat backtesting deficiencies because, should the member's settlement activity abruptly increase, the additional exposure to FICC would not be mitigated until the collection of the Required Fund Deposit either intraday or on the next business day.[13] FICC states it has also found that its current minimum margin requirement of $100,000 is disproportionately lower than the minimum margin requirements of other CCPs that clear similar securities products.[14]

#### *B. Proposal*

In the Proposed Rule Change, FICC proposes to increase its minimum Required Fund Deposit for its members to $1,000,000.

Specifically, to implement this change for Netting Members, FICC would revise Section 2(a) of Rule 4 to state that each Netting Member shall be required to make a Required Fund Deposit to the Clearing Fund equal to the greater of (i) the Minimum Charge or (ii) the Total Amount. FICC would also revise section 3 of GSD Rule 4 to replace the minimum cash amount from $100,000 to $1 million, to match the proposed

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] FICC operates two divisions, GSD and the Mortgage Backed Securities Division (''MBSD''). GSD provides trade comparison, netting, risk management, settlement, and central counterparty (''CCP'') services for the U.S. Government securities market, including repos. MBSD provides the same services for the U.S. mortgage-backed securities market. GSD and MBSD maintain separate sets of rules, margin models, and clearing funds. The proposed rule change relates solely to GSD, except as discussed in section II.B at note 19 *infra*.

[4] Securities Exchange Act Release No. 95806 (Sept. 16, 2022), 87 FR 57960 (Sept. 22, 2022) (File No. SR–FICC–2022–006) (''Notice of Filing'').

[5] Rule 4, section 3 (for Netting Members) and Rule 3A, section 10(c) (for Sponsoring Members). Capitalized terms not defined herein are defined in the GSD Rules & Procedures (''Rules''), *available at https://www.dtcc.com/~/media/Files/Downloads/legal/rules/ficc_gov_rules.pdf*. For purposes of this order, ''member'' will be used to describe Netting Members and Sponsoring Members, collectively.

[6] The Model Risk Management Framework (''Model Risk Management Framework'') sets forth the model risk management practices of FICC and states that Value at Risk (''VaR'') and Clearing Fund requirement coverage backtesting is performed on a daily basis or more frequently. *See* Securities Exchange Act Release Nos. 81485 (Aug. 25, 2017), 82 FR 41433 (Aug. 31, 2017) (SR–FICC–2017–014), 84458 (Oct. 19, 2018), 83 FR 53925 (Oct. 25, 2018) (SR–FICC–2018–010), 88911 (May 20, 2020), 85 FR 31828 (May 27, 2020) (SR–FICC–2020–004), 92380 (July 13, 2021), 86 FR 38140 (July 19, 2021) (SR–FICC–2021–006), and 94271 (Feb. 17, 2022), 87 FR 10411 (Feb. 24, 2022) (SR–FICC–2022–001).

[7] *See* 17 CFR 240.17Ad–22(a)(1).

[8] *See* Notice of Filing, *supra* note 4, at 57691.

[9] *Id.*

[10] *Id.*

[11] FICC states that a member's backtesting coverage would fall below the 99% confidence target if the member has more than two backtesting deficiency days in a rolling twelve-month period. *Id.* In other words, if a member has three or more backtesting deficiency days during a twelve-month period, then the member's margin would not be sufficient 99% of the time. FICC believes that its targeted 99% confidence level is consistent with its regulatory requirements under Rule 17Ad–22(e)(4)(i) and (e)(6)(iii). *Id.; see also* 17 CFR 240.17Ad–22 (e)(4)(i), and (e)(6)(iii).

[12] *See* Notice of Filing, *supra* note 4, at 57961.

[13] *Id.* at 57961–62.

[14] *See* Notice of Filing, *supra* note 4, at 57962 (citing the following requirements: the Options Clearing Corporation's (''OCC'') minimum initial contribution of $500,000, *see* OCC Rule 1002(d), *available at https://www.theocc.com/getmedia/9d3854cd-b782-450f-bcf7-33169b0576ce/occ_rules.pdf;* the Chicago Mercantile Exchange's (''CME'') minimum requirement of $500,000 or $2.5 million depending on the product types being cleared, *see* CME Rule 816, *available at https://www.cmegroup.com/content/dam/cmegroup/rulebook/CME/I/8/8.pdf;* the National Securities Clearing Corporation's (''NSCC'') minimum required fund deposit of $250,000, *see* NSCC Rule 4, *available at https://dtcc.com/~/media/Files/Downloads/legal/rules/nscc_rules.pdf.;* LCH Limited's minimum default fund contribution of GBP 500,000 (approximately $566,000 based on current foreign currency exchange rate) and of GBP 2,000,000 (approximately $2.3 million based on the current foreign currency exchange rate) for RepoClear, *see* LCH Limited Default Rules definition of ''Minimum Contribution'' and ''Minimum RepoClear Contribution'' *available at https://www.lch.com/system/files/media_root/210609_Default%20Rules_Clean_0.pdf;* and Ice Clear U.S.'s minimum contribution to Guaranty Fund of $2 million, *see* ICE Clear U.S. Rule 301, *available at https://www.ice.com/publicdocs/rulebooks/clear/ICE_Clear_US_Rules.pdf*).

increased minimum Required Fund Deposit amount. To implement this change for Sponsoring Members, FICC would revise section 10(c) of Rule 3A (Sponsoring Members and Sponsored Members) to state that the Sponsoring Member Omnibus Account Required Fund Deposit shall be equal to the greater of: (i) $1 million or (ii), which is what is currently in the Rules, the sum of the following: (1) the sum of the VaR Charges [15] for all of the Sponsored Members whose activity is represented in the Sponsoring Member Omnibus Account as derived pursuant to, and (2) all amounts representing other components of the Sponsoring Member's Required Fund Deposit computed at the level of the Sponsoring Member Omnibus Account, other than the VaR Charge. In addition, Section 10(d) of Rule 3A would be revised to replace the minimum cash amount from $100,000 to $1 million to match the proposed increased minimum Required Fund Deposit amount for the Sponsoring Members.[16]

For Repo Brokers, FICC would not propose to change the current minimum Required Fund Deposit of $5 million.[17] However, for clarity, FICC would propose to move the minimum Required Fund Deposit to a different section of the Rules, to improve organization.[18]

Finally, FICC proposes to add a sentence to Section 2 of MBSD Rule 4, which addresses required clearing fund deposits, to make clear that, as is currently the case due to other portions of the rule, the Minimum Charge for each margin portfolio of a Clearing Member shall be no less than $100,000.[19] FICC also proposes to replace (i) ''Clearing Fund requirement'' with ''Minimum Charge for each margin portfolio'' and (ii) ''minimum Clearing Fund amounts'' with ''Minimum Charges'' in MBSD Rule 4, section 2, which FICC believes will enhance clarity. Furthermore, FICC is proposing a technical change to correct a reference to the non-Unregistered Investment Pool Clearing Member in MBSD Rule 4, section 2.

*C. Impact Study Results*

To support its proposal, FICC relies upon the results of recent analyses of backtesting and margin.[20] Specifically, FICC examines the backtesting coverage of each of its members during the period for a 12-month period ending June 30, 2022 (''Backtesting Impact Study'') under the current $100,000 minimum GSD Required Fund Deposit amount compared to hypothetical (or ''pro forma'') minimum GSD Required Fund Deposit amounts, including the proposed $1,000,000 amount. The Backtesting Impact Study shows that the number of member backtesting deficiencies that would have been eliminated during the period had FICC's minimum GSD Required Fund Deposit been $1,000,000 compared to $100,000. FICC then uses the Backtesting Impact Study to analyze the improvement to each member's backtesting coverage ratio and, taking all members' backtesting coverage ratio results together, to FICC's Clearing Fund backtesting coverage.[21]

According to FICC, the Backtesting Impact Study indicates that using $1 million as GSD's minimum Required Fund Deposit amount would have reduced the number of members with backtesting coverage below 99%. Specifically, the Backtesting Impact Study shows 70 members below 99% backtesting coverage as of June 30, 2022 with a collective 396 backtesting deficiencies in GSD. Approximately 21% (*i.e.,* 85 out of 396) of the backtesting deficiencies occurred with respect to members that had a Required Fund Deposit of less than $1 million on the relevant deficiency day(s). FICC states that if the proposed changes had been in place during the Backtesting Impact Study period, approximately 16% (*i.e.,* 65 out of 396) of the backtesting deficiencies incurred by the members would have been eliminated, and the total number of members that were below the 99% confidence target as of June 30, 2022 would have been reduced by 8. Overall, FICC states that a $1 million minimum requirement would have increased GSD's 12-month backtesting coverage 0.22%, eliminated 65 backtesting deficiencies, and improved the rolling twelve-month backtesting coverage for 8 members to above 99% confidence target.

In addition, FICC conducted a clearing fund requirement impact study for the period of July 1, 2021 to June 30, 2022 (''CFR Impact Study'') on a member-level basis, meaning that it examined the effect on each member's Required Fund Deposit had the proposal been in place. According to FICC, the CFR Impact Study indicates that under the proposal, approximately 47% (81 out of a total of 174) of the current members' Margin Portfolios would have been impacted, with an average and a weighted average (with weights based on number of impacted days) additional Required Fund Deposit of approximately $686,000 and $792,000, respectively, for each such Margin Portfolio per impacted day. When comparing the actual, total Clearing Fund deposit of the current members' Margin Portfolios (that is, including any additional resources held at FICC in addition to the Required Fund Deposit) with the proposed minimum Required Fund Deposit amount, however, only approximately 13% (23 out of a total 174) of such members' Margin Portfolios would have been impacted, requiring an average and a weighted average (with weights based on number of impacted days) additional cash deposit of approximately $649,000 and $715,000, respectively, for each such Margin Portfolio per impacted day. FICC states the result of the CFR Impact Study also shows one Repo Broker that would have

[15] For Sponsoring Member's the VaR Charge is determined pursuant to Section 1b(a)(i) of GSD Rule 4 (Clearing Fund and Loss Allocation). The VaR Charge is generally the largest component of the Required Fund Deposit. It is designed to provide an estimate of FICC's projected liquidation losses with respect to a defaulted member's portfolio at a 99 percent confidence level, and it is based on the potential price volatility of unsettled positions using a sensitivity-based Value-at-Risk model. As an alternative to this calculation, FICC also uses a haircut-based calculation as the member's VaR Charge if that charge exceeds the amount determined by the model-based calculation. Fixed Income Clearing Corporation Disclosure Framework for Covered Clearing Agencies and Financial Market Infrastructures, at 64, *available at https://www.dtcc.com/media/Files/Downloads/legal/policy-and-compliance/FICC_Disclosure_Framework.pdf; see also* Exchange Act Release No. 92303 (June 30, 2021), 86 FR 35855 (July 7, 2021).

[16] *See* Notice of Filing, *supra* note 4, at 57963.

[17] Rule 4, section 1b, *supra* note 5. Currently, if a Repo Broker has two Margin Portfolios, with Broker Account(s) in one Margin Portfolio and Dealer Account(s) in the other Margin Portfolio, the total minimum Required Fund Deposit applicable to the Repo Broker would be $5.1 million, *i.e.,* $5 million minimum Required Fund Deposit for the Margin Portfolio with Broker Account(s) and $100,000 minimum Required Fund Deposit for the Margin Portfolio with Dealer Account(s).

[18] FICC would also make revisions to state that the Minimum Charge applicable to each Repo Broker shall be no less than $5 million for each Margin Portfolio with Broker Account(s) and no less than $1 million for each Margin Portfolio with Dealer Account(s), and to refer to additional payments, charges and premiums being applied by FICC after application of Minimum Charges, which term replaces the current term ''minimum Clearing Fund amounts.''

[19] Specifically, Rule 4, section 3 of the MBSD Rules, which addresses the form of a member's required fund deposit, states that a member must make deposit the lesser of $5,000,000 or 10 percent of its required fund deposit, with a minimum of $100,000, in cash. The MBSD Rules are available at *https://www.dtcc.com/~/media/Files/Downloads/legal/rules/ficc_mbsd_rules.pdf* (''MBSD Rules'').

[20] FICC provided a public summary of the information in this Section II.B in its Notice of Filing, upon which this discussion is based. *See* Notice of Filing, *supra* note 4, at 57962–3. FICC submitted the data underlying these analyses as a confidential Exhibit 3 to the Proposed Rule Change pursuant to 17 CFR 240.24b–2.

[21] The backtesting coverage represents the daily sufficiency of the aggregate of all members' margin over a rolling 12-month period. As described in Section II.A above, FICC would be able to access its clearing fund to cover any losses to it should a member with insufficient margin default. GSD Rule 4, Section 3, *supra* note 3.

been impacted, requiring additional Clearing Fund deposit of approximately $392,000 in either cash or Eligible Clearing Fund Securities per impacted day. Overall, FICC states that the proposed changes would have resulted in an average increase in the daily required margin amount, for all members' deposits in the aggregate, of $31.4 million (or 0.17%) at GSD during the CFR Impact Study period.

## III. Discussion and Commission Findings

Section 19(b)(2)(C) of the Act [22] directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to such organization. After careful consideration, the Commission finds that the Proposed Rule Change is consistent with the requirements of the Act and the rules and regulations applicable to FICC.[23] In particular, the Commission finds that the Proposed Rule Change is consistent with Section 17A(b)(3)(F) and (b)(3)(I) [24] of the Act and Rules 17Ad–22(e)(4) and (e)(6) thereunder.[25]

### *A. Consistency With Section 17A(b)(3)(F) of the Act*

Section 17A(b)(3)(F) of the Act requires, in part, that the rules of a clearing agency, such as FICC, be designed, in part, to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible.[26] The Commission believes that the Proposed Rule Change is consistent with Section 17A(b)(3)(F) of the Act.

As discussed in Section II.A above, backtesting deficiencies highlight when a member's margin is insufficient to cover FICC's credit exposure to that member. If a defaulted member's margin is insufficient to satisfy losses caused by the closeout of that member's positions, FICC and its non-defaulting members may be subject to losses. As summarized in Section II.B above, and based on the Commission's review and analysis of the material submitted by FICC,[27] the proposed increase would have provided FICC with additional resources, which would have resulted in a decrease in backtesting deficiencies and thus a reduction in credit exposure to its members under the proposal. Therefore, the Commission believes FICC would improve the probability that the increased minimum margin amount it collects is sufficient to cover FICC's credit exposure to those members, particularly in instances where the defaulted member's clearing activity abruptly increases following a period of low or no activity because FICC would have additional resources available to cover that additional exposure before collecting additional margin for that increased activity. This increase could reduce the possibility that FICC or its non-defaulting members face losses from the close-out process, in the event that FICC were to have to allocate losses amongst non-defaulting losses pursuant to its Rules.

Moreover, FICC would continue to require that members pay an amount equal to the minimum Required Fund Deposit amount in cash. The proposal therefore would enable FICC to have available additional collateral that is easier for FICC to access quickly to complete end of day settlement upon a member's default, further reducing the risk of losses to FICC or non-defaulting members. Accordingly, the Commission believes the Proposed Rule Change would promote the safeguarding of securities and funds which are in the custody or control of FICC or for which FICC is responsible, consistent with Section 17A(b)(3)(F) of the Act.

Finally, as discussed in Section II.B above, FICC proposes clarifying and technical changes to the GSD and MBSD Rules. Such changes provide clarifications to members regarding the definitions and applications of Rules. The Commission believes that such changes would ensure that the Rules are accurate and clear to members, thus promoting prompt and accurate clearance and settlement, which is consistent with Section 17A(b)(3)(F) of the Act.[28]

### *B. Consistency With Section 17A(b)(3)(I) of the Act*

Section 17A(b)(3)(I) of the Act requires that the rules of a clearing agency do not impose any burden on competition not necessary or appropriate in furtherance of the Act.[29] This provision does not require the Commission to find that a proposed rule change represents the least anti-competitive means of achieving the goal.[30] Rather, it requires the Commission to balance the competitive considerations against other relevant policy goals of the Act.

The Commission acknowledges that the impact of increased margin requirements may present higher costs to some members with lower operating margins, lower cash reserves or higher costs of capital compared to other members, which may weaken those members' competitive positions relative to others. Although some of FICC's members could experience a burden on competition because of these higher costs, the Commission concludes any burden to these members is necessary and appropriate in furtherance of the policy goals under the Act [31] for the following reasons.

As discussed in Section II.A above, FICC seeks to maintain sufficient resources (*i.e.,* margin) to cover its credit exposures to its members fully with a high degree of confidence. Conversely, FICC uses backtesting to determine when a member's margin would have been insufficient to cover FICC's credit exposure to that member. As previously discussed, the Backtesting Impact Study shows the proposed $1,000,000 minimum Required Fund Deposit would have decreased the number of backtesting deficiencies, thereby increasing the number of members for which FICC maintained sufficient coverage at a confidence level of at least 99%. Therefore, the Proposed Rule Change would enable FICC to better manage its credit exposure to its members by ensuring it holds sufficient collateral to cover that exposure, thereby reducing the likelihood that FICC or non-defaulting members would incur losses resulting from a member default.

Additionally, as described in Section II.B, FICC conducted a Clearing Fund impact study. Specifically, when comparing the actual, total Clearing Fund deposit of the current members' Margin Portfolios with the proposed minimum Required Fund Deposit amount, approximately 13% (23 out of a total 174) of such members' Margin Portfolios would have been impacted, requiring an average and a weighted average (with weights based on number of impacted days) additional cash deposit of approximately $649,000 and $715,000, respectively, for each such

[22] 15 U.S.C. 78s(b)(2)(C).

[23] The Commission's findings are based on its review of the Proposed Rule Change, including its analysis of the Backtesting and CFR Impact Studies, which are summarized in Section II.B above. *See supra* note 20 and accompanying text.

[24] 15 U.S.C. 78q–1(b)(3)(F).

[25] 17 CFR 240.17Ad–22(e)(4) and (e)(6).

[26] 15 U.S.C. 78q–1(b)(3)(F).

[27] *See supra* note 20.

[28] 15 U.S.C. 78q–1(b)(3)(F).

[29] 15 U.S.C. 78q–1(b)(3)(I).

[30] *See* Bradford National Clearing Corp., 590 F.2d 1085, 1105 (D.C. Cir. 1978).

[31] 15 U.S.C. 78q–1(b)(3)(I). Specifically, as discussed in greater detail in Section III.C and III.D below, the Proposed Rule Change is necessary and appropriate to further the policy goals under Rule 17Ad–22(e)(4)(i) and (e)(6)(iii), 17 CFR 240.17Ad–22(e)(4)(i) and (e)(6)(iii).

Margin Portfolio per impacted day. The result of the CFR Impact Study also shows one Repo Broker that would have been impacted, requiring an additional margin deposit of approximately $392,000 in either cash or Eligible Clearing Fund Securities per impacted day. Overall, the proposed changes would have resulted in an average increase in daily Required Fund Deposit of $31.4 million (or 0.17%) at GSD during the CFR Impact Study period.

Finally, according to FICC, when comparing the average additional cash deposit amounts that members would be required to make if the minimum Clearing Fund cash deposit at GSD had been increased to $1,000,000 with their respective average Net Capital during the CFR Impact Study period, the largest average additional cash deposit amount represented approximately 0.49% of the affected member's average Net Capital.[32] In addition, when comparing the average additional Clearing Fund deposit that members would be required to make, either in cash or Eligible Clearing Fund Securities, if the minimum Required Fund Deposit amount at GSD had been increased as proposed with their respective average Net Capital during the CFR Impact Study period, the largest average additional Clearing Fund deposit amount represented approximately 1.46% of the affected member's average Net Capital.[33] In light of this analysis, and our review of the confidential data underlying the CFR Impact Study, the Commission believes that the majority of impacted members likely would not experience a weakened competitive position compared to others as a result of the Proposed Rule Change.

Therefore, the Commission concludes that any competitive burden to members imposed by the Proposed Rule Change is necessary and appropriate in furtherance of the Act. Accordingly, the Commission finds that the Proposed Rule Change is consistent with the requirements of Section 17A(b)(3)(I) of the Act.[34]

*C. Consistency With Rule 17Ad–22(e)(4)(i)*

Rule 17Ad–22(e)(4)(i) requires that FICC establish, implement, maintain and enforce written policies and procedures reasonably designed to effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by maintaining sufficient financial resources to cover its credit exposure to each participant fully with a high degree of confidence.[35]

As described above in Section II.A, FICC and its non-defaulting members may be subject to losses should a defaulted member's own Required Fund Deposit be insufficient to satisfy losses caused by the liquidation of that member's portfolio. As summarized in Section II.B above and based on the Commission's review and analysis of the underlying data,[36] the Backtesting Impact Study shows a $1,000,000 minimum Required Fund Deposit would have decreased the number of backtesting deficiencies, which would likely help FICC better manage its credit exposure to each of its members and credit exposures arising from its payment, clearing, and settlement processes.

Additionally, as discussed in Section II.B above, FICC would continue to require that members pay an amount equal to the minimum Required Fund Deposit amount in cash, which should enable FICC to better maintain sufficient prefunded margin to mitigate potential future exposures to its members. Therefore, requiring the proposed minimum $1,000,000 deposit to be made in cash should reduce the probability that FICC or non-defaulting members would incur losses resulting from a member default. Accordingly, the Commission finds that FICC's proposed increase to its minimum Required Fund Deposit would be consistent with Rule 17Ad–22(e)(4)(i).[37]

*D. Consistency With Rule 17Ad–22(e)(6)(iii)*

Rule 17Ad–22(e)(6)(iii) under the Act requires that a covered clearing agency establish, implement, maintain and enforce written policies and procedures reasonably designed to cover its credit exposures to its participants by establishing a risk-based margin system that, at a minimum, calculates margin sufficient to cover its potential future exposure to members in the interval between the last margin collection and the close out of positions following a member default.[38]

As summarized in Section II.A above, FICC employs daily backtesting to determine the adequacy of each member's Required Fund Deposit paying particular attention to members that have backtesting deficiencies below the 99% confidence target. Such backtesting deficiencies highlight exposure that could subject FICC to potential losses if a member defaults.

Based on the Backtesting Impact Study, which the Commission has reviewed and analyzed, approximately 21% of all backtesting deficiencies occur for those members that maintain a Required Fund Deposit of less than $1,000,000, and approximately 16% of the deficiencies of those members would have been eliminated during the Impact Study Period if the Required Fund Deposit were $1,000,000 or higher. By raising the minimum Required Fund Deposit amount to $1,000,000, the Commission believes the proposal should enable FICC to decrease the number of backtesting deficiencies by members, thereby improving FICC's backtesting coverage, and thus decrease FICC's exposure to such members in the event of a member default.

Therefore, the Commission concludes FICC's Proposed Rule Change should better ensure FICC maintains sufficient margin to cover its potential future exposure to its members in the interval between the last margin collection and the close out of positions following a member default, thereby reducing the likelihood FICC or non-defaulting members would incur losses as a result. Accordingly, the Commission finds that FICC's proposed increase to its minimum Required Fund Deposit would be consistent with Rule 17Ad–22(e)(6)(iii).[39]

## IV. Conclusion

On the basis of the foregoing, the Commission finds that the Proposed Rule Change is consistent with the requirements of the Act and in particular with the requirements of Section 17A of the Act[40] and the rules and regulations promulgated thereunder.

*It is therefore ordered,* pursuant to Section 19(b)(2) of the Act[41] that Proposed Rule Change SR–FICC–2022–006, as modified by Partial Amendment No. 1, be, and hereby is, *approved*.[42]

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[43]

**J. Matthew DeLesDernier,**

*Deputy Secretary.*

[FR Doc. 2022–23482 Filed 10–27–22; 8:45 am]

**BILLING CODE 8011–01–P**

[32] Notice of Filing, *supra* note 4, at 57965.

[33] *Id.*

[34] 15 U.S.C. 78q–1(b)(3)(I).

[35] 17 CFR 240.17Ad–22(e)(4)(i).

[36] *See supra* note 23.

[37] 17 CFR 240.17Ad–22(e)(4)(i).

[38] 17 CFR 240.17Ad–22(e)(6)(iii).

[39] 17 CFR 240.17Ad–22(e)(6)(iii).

[40] 15 U.S.C. 78q–1.

[41] 15 U.S.C. 78s(b)(2).

[42] In approving the Proposed Rule Change, the Commission considered the proposals' impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f). *See* discussion *supra* Section III.B.

[43] 17 CFR 200.30–3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–96132; File No. SR–NASDAQ–2022–058]**

## Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Relocate Equity 2, Section 3

October 24, 2022.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 19, 2022, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to relocate Equity 2, Section 3, Nasdaq Market Center Participant Registration.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

The Exchange proposes to relocate Equity 2, Section 3, Nasdaq Market Center Participant Registration, to proposed new General 3, Rule 1032.[3] The Exchange proposes to reserve Equity 2, Section 3.

Today, Equity 2, Section 3 applies to Nasdaq members who trade equity and options products.[4] The Exchange believes that relocating Equity 2, Section 3, Nasdaq Market Center Participant Registration, to proposed new General 3, Rule 1032 will make clear the applicability of this rule to equity members and Options Participants alike.

Equity 2, Section 3 would be relocated to proposed new General 3, Rule 1032 without change.

2. Statutory Basis

The Exchange believes that its proposal is consistent with section 6(b) of the Act,[5] in general, and furthers the objectives of section 6(b)(5) of the Act,[6] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest by relocating Equity 2, Section 3 to proposed new General 3, Rule 1032, without change, to make the applicability of this rule to equity members and Options Participants alike.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Relocating Equity 2, Section 3 to proposed new General 3, Rule 1032, without change, does not create an undue burden on competition. Equity 2, Section 3 will continue to apply to all equity members and Options Participants alike.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

No written comments were either solicited or received.

### III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to section 19(b)(3)(A)(iii) of the Act[7] and subparagraph (f)(6) of Rule 19b–4 thereunder.[8]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

### IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

*Electronic Comments*

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2022–058 on the subject line.

*Paper Comments*

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2022–058. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The General Rules applies to both equity and options products.

[4] An Options Participant of The Nasdaq Options Market LLC (''NOM'') must be a member of Nasdaq.

[5] 15 U.S.C. 78f(b)

[6] 15 U.S.C. 78f(b)(5).

[7] 15 U.S.C. 78s(b)(3)(A)(iii).

[8] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2022–058 and should be submitted on or before November 18, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

**J. Matthew DeLesDernier,**

*Deputy Secretary.*

[FR Doc. 2022–23480 Filed 10–27–22; 8:45 am]

**BILLING CODE 8011–01–P**

## SECURITIES AND EXCHANGE COMMISSION

### Sunshine Act Meetings

**TIME AND DATE:** Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission will hold an Open Meeting on Wednesday, November 2, 2022 at 10:00 a.m.

**PLACE:** The meeting will be webcast on the Commission's website at *www.sec.gov.*

**STATUS:** This meeting will begin at 10:00 a.m. (ET) and will be open to the public via webcast on the Commission's website at *www.sec.gov.*

**MATTERS TO BE CONSIDERED:**

1. The Commission will consider whether to adopt form amendments to enhance the information registered management investment companies report about their proxy votes. The Commission will also consider whether to adopt a new rule and form amendments to require institutional investment managers subject to section 13(f) of the Securities Exchange Act of 1934 to report proxy votes relating to certain executive compensation matters, as required by section 14A of the Exchange Act.

2. The Commission will consider whether to propose amendments to rules and forms for open-end management investment companies related to liquidity risk management programs, swing pricing, and other pricing requirements. The amendments the Commission will consider also include reporting and disclosure requirements for certain registered investment companies, including open-end funds (other than money market funds), registered closed-end funds, and unit investment trusts.

**CONTACT PERSON FOR MORE INFORMATION:** For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

*Authority:* 5 U.S.C. 552b.

Dated: October 26, 2022.

**Vanessa A. Countryman,**

*Secretary.*

[FR Doc. 2022–23677 Filed 10–26–22; 4:15 pm]

**BILLING CODE 8011–01–P**

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–96144; File No. SR–MRX–2022–22]**

### Self-Regulatory Organizations; Nasdaq MRX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend MRX's Pricing Schedule at Options 7, Section 7

October 24, 2022.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 14, 2022, Nasdaq MRX, LLC (''MRX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend MRX's Pricing Schedule at Options 7, Section 7.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/mrx/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

On May 2, 2022, MRX initially filed this proposal to amend its Pricing Schedule at Options 7, Section 7, to assess market data fees, which had not been assessed since MRX's inception in 2016.[3] The proposed changes are designed to update data fees to reflect their current value—rather than their value when it was a new exchange six years ago—based on increased market share. Newly-opened exchanges often charge no fees for market data to attract order flow to an exchange, and later amend their fees to reflect the true value of those services.[4] Allowing newly-

[9] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange initially filed the proposed pricing changes on May 2, 2022 (SR–MRX–2022–04), instituting fees for membership, ports and market data. *See* Securities Exchange Act Release No. 94901 (May 12, 2022), 87 FR 30305 (May 18, 2022) (SR–MRX–2022–04). On June 29, 2022, the Exchange withdrew that filing, and submitted separate filings for membership (SR–MRX–2022–07), market data (SR–MRX–2022–08) and ports (SR–MRX–2022–09). On August 25, 2022, the Exchange withdrew the market data filing (SR–MRX–2022–08) and replaced it with SR–MRX–2022–14. See Securities Exchange Act Release No. 95708 (September 8, 2022), 87 FR 56457 (September 14, 2022) (SR–MRX–2022–14). On October 14, 2022, the Exchange withdrew SR–MRX–2022–14 and replaced it with the instant filing in order to reflect changes to the information contained within each of the five MRX market data feeds proposed in SR–MRX–2022–18. *See* Securities Exchange Act Release No. 95982 (October 4, 2022), 87 FR 61391 (October 11, 2022) (SR–MRX–2022–18).

[4] *See, e.g.,* Securities Exchange Act Release No 88211 (February 14, 2020), 85 FR 9847 (February 20, 2020) (SR–NYSENAT–2020–05), also available at *https://www.nyse.com/publicdocs/nyse/markets/nyse-national/rule-filings/filings/2020/SR-NYSENat-2020-05.pdf.* (initiating market data fees for the NYSE National exchange after initially setting such fees at zero).

opened exchanges time to build and sustain market share before charging for their market data encourages market entry and promotes competition.

This Proposal reflects MRX's assessment that it has gained sufficient market share to compete effectively against other 15 options exchanges without waiving market data fees. Such fees are assessed by options exchanges that compete with MRX—indeed, MRX is the only options exchange (out of the 16 current options exchanges) not to assess them today.

As explained in further detail below, MRX in 2022 is in the same position as NYSE National in 2020, when it sought approval for the ''NYSE National Integrated Feed.'' [5] The Commission approved the NYSE National Integrated Feed based on a finding that it ''was subject to significant substitution-based competitive forces'' based on ''NYSE National's consistently low percentage of market share, the relatively small number of subscribers to the NYSE National Integrated Feed, and the sizeable portion of subscribers that terminated their subscriptions following the proposal of the fees.'' [6]

The three factors cited in the Commission's approval order for NYSE National are present in MRX today. First, MRX has a consistently low percentage of market share, starting at approximately 0.2 percent when it opened as an Exchange and ending in approximately 1.8 percent today. Second, only a small number of firms purchase market data from MRX relative to its affiliated options exchanges. Third, a sizeable portion of subscribers—approximately 15 percent—have terminated their subscriptions following the implementation of the proposed fees, demonstrating that customers can and do exercise choice in deciding whether to purchase the Exchange's market data feeds.

Disapproval of the Proposal—given that the three factors cited in the Commission's approval order for NYSE National two years ago are present in MRX today—would result in differential treatment of similarly-situated exchanges. Under such circumstances, disapproval of the Proposal should be rejected as arbitrary and capricious.

Disapproval would also place a substantial burden on competition. MRX would be uniquely disadvantaged as the only options exchange unable to charge for its market data. If the Commission were to disapprove this Proposal, that action, and not market forces, would determine whether MRX is successful in its competition with other options exchanges.

New exchanges commonly waive data fees to attract market participants, facilitating their entry into the market and, once there is sufficient depth and breadth of liquidity, ''graduate'' to compete against established exchanges and charge fees that reflect the value of their services. If MRX is incorrect in its assessment, that error will be reflected in MRX's ability to compete with other options exchanges.[7]

The Exchange proposes to amend fees for the following market data feeds within Options 7, Section 7: (1) Nasdaq MRX Depth of Market Data Feed (''Depth of Market Feed''); [8] (2) Nasdaq MRX Order Feed (''Order Feed''); [9] (3) Nasdaq MRX Top of Market Feed (''Top Feed''); [10] (4) Nasdaq MRX Trades Feed (''Trades Feed''); [11] and (5) Nasdaq MRX Spread Feed (''Spread Feed'').[12] Prior to the initial filing of these proposed price changes on May 2, 2022, no fees had been assessed for these feeds.

In addition to the proposed fees for each data feed, the Exchange proposes an Internal Distributor Fee [13] of $1,500 per month for the Depth of Market Feed, Order Feed, and Top Feed, an Internal Distributor Fee of $750 per month for the Trades Feed, and an Internal Distributor Fee of $1,000 per month for the Spread Feed. If a Member subscribes to both the Trades Feed and the Spread Feed, both Internal Distributor Fees would be assessed.

The Exchange also proposes to assess an External Distributor Fee of $2,000 per month for the Depth of Market Feed, Order Feed, and Top Feed, an External Distributor Fee of $1,000 per month for the Trades Feed, and an External Distributor Fee of $1,500 per month for the Spread Feed.

MRX will also assess Professional [14] and Non-Professional [15] subscriber fees.

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[5] NYSE National stated that the proposed integrated feed included depth-of-book order data, last sale data, security status updates, and stock summary messages. *See* Securities Exchange Act Release No 88211 (February 14, 2020), 85 FR 9847 (February 20, 2020) (SR–NYSENAT–2020–05), also available at *https://www.nyse.com/publicdocs/nyse/markets/nyse-national/rule-filings/filings/2020/SR-NYSENat-2020-05.pdf.*

[6] *See id.*

[7] Nasdaq announced that, beginning in 2022, it will migrate its North American markets to Amazon Web Services in a phased approach, starting with MRX. The MRX migration will take place in November 2022. The proposed fee changes are entirely unrelated to this effort.

[8] Nasdaq MRX Depth of Market Data Feed is a data feed that provides full order and quote depth information for individual orders and quotes on the Exchange book and last sale information for trades executed on the Exchange. The data provided for each option series includes the symbols (series and underlying security), put or call indicator, expiration date, the strike price of the series, and whether the option series is available for trading on the Exchange and identifies if the series is available for closing transactions only. The feed also provides order imbalances on opening/reopening (size of matched contracts and size of the imbalance). *See* Options 3, Section 23(a)(1).

[9] Nasdaq MRX Order Feed provides information on new orders resting on the book (*e.g.,* price, quantity, market participant capacity and Attributable Order tags when provided by a Member). The data provided for each option series includes the symbols (series and underlying security), displayed order types, order attributes (*e.g.,* OCC account number, give-up information, CMTA information), put or call indicator, expiration date, the strike price of the series, and whether the option series is available for trading on MRX and identifies if the series is available for closing transactions only. The feed also provides order imbalances on opening/reopening (size of matched contracts and size of the imbalance), auction and exposure notifications. *See* Options 3, Section 23(a)(2).

[10] Nasdaq MRX Top of Market Feed calculates and disseminates MRX's best bid and offer position, with aggregated size (including total size in aggregate, for Professional Order size in the aggregate and Priority Customer Order size in the aggregate), based on displayable order and quote interest in the System. The feed also provides last trade information and for each option series includes the symbols (series and underlying security), put or call indicator, expiration date, the strike price of the series, and whether the option series is available for trading on MRX and identifies if the series is available for closing transactions only. The feed also provides order imbalances on opening/reopening. *See* Options 3, Section 23(a)(3).

[11] Nasdaq MRX Trades Feed displays last trade information. The data provided for each option series includes the symbols (series and underlying security), put or call indicator, expiration date, the strike price of the series, and whether the option series is available for trading on MRX and identifies if the series is available for closing transactions only. *See* Options 3, Section 23(a)(4).

[12] Nasdaq MRX Spread Feed is a feed that consists of: (1) options orders for all Complex Orders (*i.e.,* spreads, buy-writes, delta neutral strategies, etc.); (2) full Complex Order depth information, including prices, side, size, capacity, Attributable Complex Order tags when provided by a Member, and order attributes (*e.g.,* OCC account number, give-up information, CMTA information), for individual Complex Orders on the Exchange book; (3) last trades information; and (4) calculating and disseminating MRX's complex best bid and offer position, with aggregated size (including total size in aggregate, for Professional Order size in the aggregate and Priority Customer Order size in the aggregate), based on displayable Complex Order interest in the System. The feed also provides Complex Order auction notifications. *See* Options 3, Section 23(a)(5).

[13] A ''distributor'' of Nasdaq MRX data is any entity that receives a feed or data file of data directly from Nasdaq MRX or indirectly through another entity and then distributes it either internally (within that entity) or externally (outside that entity). All distributors shall execute a Nasdaq Global Data Agreement.

[14] A Professional Subscriber is any Subscriber that is not a Non-Professional Subscriber.

[15] A Non-Professional Subscriber is a natural person who is neither: (i) registered or qualified in any capacity with the Commission, the Commodities Futures Trading Commission, any state securities agency, any securities exchange or association, or any commodities or futures contract market or association; (ii) engaged as an ''investment adviser'' as that term is defined in section 201(11) of the Investment Advisors Act of 1940 (whether or not registered or qualified under that Act); nor (iii) employed by a bank or other

The Professional Subscriber will be $25 per month, and the Non-Professional Subscriber will be $1 per month. These subscriber fees (both Professional and Non-Professional) cover the usage of all five MRX data products identified above and would not be assessed separately for each product.[16]

MRX also proposes a Non-Display Enterprise License for $7,500 per month. This license would lower costs for internal professional subscribers and lower administrative costs overall by permitting the distribution of all MRX proprietary direct data feed products to an unlimited number of internal non-display Subscribers without incurring additional fees for each internal Subscriber, or requiring the customer to count internal subscribers.[17] The Non-Display Enterprise License is in addition to any other associated distributor fees for MRX proprietary direct data feed products.

2. Statutory Basis

The Exchange believes that its proposal is consistent with section 6(b) of the Act,[18] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[19] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The proposed changes to the pricing schedule are reasonable in several respects. As a threshold matter, the Exchange is subject to significant competitive forces in the market for order flow, which constrains its pricing determinations. The fact that the market for order flow is competitive has long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission,* the D.C. Circuit stated, ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .'' [20]

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention to determine prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues, and also recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [21]

Congress directed the Commission to ''rely on 'competition, whenever possible, in meeting its regulatory responsibilities for overseeing the SROs and the national market system.' '' [22] As a result, the Commission has historically relied on competitive forces to determine whether a fee proposal is equitable, fair, reasonable, and not unreasonably or unfairly discriminatory. ''If competitive forces are operative, the self-interest of the exchanges themselves will work powerfully to constrain unreasonable or unfair behavior.'' [23] Accordingly, ''the existence of significant competition provides a substantial basis for finding that the terms of an exchange's fee proposal are equitable, fair, reasonable, and not unreasonably or unfairly discriminatory.'' [24] In its 2019 guidance on fee proposals, Commission staff indicated that they would look at factors beyond the competitive environment, such as cost, only if a ''proposal lacks persuasive evidence that the proposed fee is constrained by significant competitive forces.'' [25]

History of MRX Operations

Over the years, MRX has amended its transactional pricing to attract order flow to the Exchange.[26] In June 2019,

organization exempt from registration under federal or state securities laws to perform functions that would require registration or qualification if such functions were performed for an organization not so exempt.

[16] For example, if a firm has one Professional (Non-Professional) Subscriber accessing Top Quote Feed, Order, and Depth of Market Feed the firm would only report the Subscriber once and pay $25 ($1 for Non-Professional).

[17] The Non-Display Enterprise License of $7,500 per month is optional. A firm that does not have a sufficient number of subscribers to benefit from purchase of the license need not do so.

[18] *See* 15 U.S.C. 78f(b).

[19] *See* 15 U.S.C. 78f(b)(4) and (5).

[20] *See NetCoalition,* 615 F.3d at 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[21] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[22] *See NetCoalition,* 615 F.3d at 534–35; *see also* H.R. Rep. No. 94–229 at 92 (1975) (''[I]t is the intent of the conferees that the national market system evolve through the interplay of competitive forces as unnecessary regulatory restrictions are removed.'').

[23] *See* Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74,770 (December 9, 2008) (SR–NYSEArca–2006–21).

[24] *Id.*

[25] *See* U.S. Securities and Exchange Commission, ''Staff Guidance on SRO Rule filings Relating to Fees'' (May 21, 2019), available at *https://www.sec.gov/tm/staff-guidance-sro-rule-filings-fees.*

[26] *See, e.g.,* Securities Exchange Act Release Nos. 77292 (March 4, 2016), 81 FR 12770 (March 10, 2016) (SR–ISEMercury–2016–02) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Establish the Schedule of Fees); 77409 (March 21, 2016), 81 FR 16240 (March 25, 2016) (SR–ISEMercury–2016–05) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Schedule of Fees); 81 FR 16238 (March 21, 2016), 81 FR 16238 (March 25, 2016) (SR–ISEMercury–2016–06) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Schedule of Fees); 77841 (May 16, 2016), 81 FR 31986 (SR–ISEMercury–2016–11) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Schedule of Fees); 82537 (January 19, 2018), 83 FR 3784 (January 26, 2018) (SR–MRX–2018–01) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Schedule of Fees To Introduce a New Pricing Model); 82990 (April 4, 2018), 83 FR 15434 (April 10, 2018) (SR–MRX–2018–10) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Chapter IV of the Exchange's Schedule of Fees); 28677 (June 14, 2018), 83 FR 28677 (June 20, 2018) (SR–MRX–2018–19) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Increase Certain Route-Out Fees Set Forth in Section II.A of the Schedule of Fees); 84113 (September 13, 2018), 83 FR 47386 (September 19, 2018) (SR–MRX–2018–27) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Relocate the Exchange's Schedule of Fees); 85143 (February 14, 2019), 84 FR 5508 (February 21, 2019) (SR–MRX–2019–02) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Pricing Schedule at Options 7, Section 3); 85313 (March 14, 2019), 84 FR 10357 (March 20, 2019) (SR–MRX–2019–05) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to PIM Fees and Rebates); 86326 (July 8, 2019), 84 FR 33300 (July 12, 2019) (SR–MRX–2019–14) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Adopt Complex Order Pricing); 88022 (January 23, 2020), 85 FR 5263 (January 29, 2020) (SR–MRX–2020–02) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend MRX Pricing Schedule); 89046 (June 11, 2020), 85 FR 36633 (June 17, 2020) (SR–MRX–2020–11) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Pricing Schedule at Options 7); 89320 (July 15, 2020), 85 FR 44135 (July 21, 2020) (SR–MRX–2020–14) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Pricing Schedule at Options 7, Section 5, Other Options Fees and Rebates, in Connection With the Pricing for Orders Entered Into the Exchanges Price Improvement Mechanism); 90503 (November 24, 2020), 85 FR 77317 (December 1, 2020) (SR–MRX–2020–18) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Pricing Schedule at Options 7 for Orders Entered Into the Exchange's Price Improvement Mechanism); 90434 (November 16, 2020), 85 FR 74473 (November 20, 2020) (SR–MRX–2020–19) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To the Exchange's Pricing Schedule at Options 7 To Amend Taker Fees for

Continued

MRX commenced offering complex orders.[27] With the addition of complex order functionality, MRX offered Members certain order types, an opening process, auction capabilities and other trading functionality that was nearly identical to functionality available on ISE.[28] The added functionality attracted order flow, which has enhanced the value of its market data and is the basis for these proposed fee changes.

Market Data Products Are Subject to Significant Substitution-Based Competitive Forces

An Exchange can show that a product is ''subject to significant substitution-based competitive forces'' by introducing evidence that customers can substitute that product with products offered by other exchanges.

NYSE National was able to prove exactly this when it sought approval for the ''NYSE National Integrated Feed'' [29] in 2020. NYSE National at the time of its filing was in a similar position to MRX today—the exchange had an approximately 1.9% market share of executed volume of equity trades.[30] The Commission approved the proposal to establish fees for NYSE National based on a finding that the exchange ''was subject to significant substitution-based competitive forces.'' Citing *NetCoalition I,*[31] the Commission stated that ''whether a market is competitive notwithstanding potential alternatives depends on factors such as the number of buyers who consider other products interchangeable and at what prices.'' [32] Noting that ''many market participants . . . do not subscribe to . . . the NYSE National Integrated Feed, even when the feed is offered without charge,'' the Commission concluded that ''NYSE National's consistently low percentage of market share, the relatively small number of subscribers to the NYSE National Integrated Feed, and the sizeable portion of subscribers that terminated their subscriptions following the proposal of the fees,'' demonstrated that the exchange ''was subject to significant substitution-based competitive forces'' in setting fees such that the proposed rule change was consistent with the Act.[33]

MRX today is in essentially the same position as NYSE National in 2020, and all three of the factors cited in the Commission's approval order for NYSE National are present in MRX today. First, MRX has a consistently low percentage of market share, starting at approximately 0.2 percent when it opened as an Exchange and ending in approximately 1.8 percent today. Second, only a small number of firms purchase market data from MRX relative to its affiliated options exchanges. Third, a sizeable portion of subscribers—approximately 15 percent—have terminated their subscriptions following the implementation of the proposed fees, demonstrating that customers can and do exercise choice in deciding whether to purchase the Exchange's market data feeds.

As of May 2, 2022, the date that MRX initially proposed these market data fees, MRX reported that two customers had terminated their market data subscriptions.[34] As of now, a total of five firms have cancelled, amounting to approximately 15 percent of the 34 customers that had been taking MRX feeds in the first quarter of 2022.[35]

Commission Staff have requested additional information pertaining to: (i) the types of feeds available to these customers prior to termination, (ii) the characteristics of the customers that terminated their feeds, and (iii) whether such customers traded on the Exchange.

With respect to the types of data feeds accessed, two of the five customers had access to all five feeds: the Depth of Market Data, the Order Feed, the Top Feed, the Trades Feed, and the Spread Feed. The three remaining customers had access to only two feeds: the Order Feed and the Top Feed. All five customers cancelled all feeds that they had access to.

With respect to the types of customers cancelling feeds, three of the five were either data vendors or technology suppliers. Data vendors purchase exchange data and redistribute it to downstream customers, while technology suppliers incorporate exchange data into software solutions, which are sold to downstream customers. The remaining two firms engage in options trading, either on their own behalf or that of a customer.

With respect to trading, the three data vendors/technology suppliers do not trade on their own behalf or on the behalf of any downstream customs, although their customers may do so. The Exchange understands that these three firms cancelled due to insufficient demand from their downstream customers for MRX data. The two remaining firms, which do engage in options trading, have not traded on MRX, but are active traders on other Nasdaq options exchanges.[36]

Detailed information supporting the first step in the analysis of substitution-based competitive forces—low market share—is set forth in Chart 1, which shows the January 2022 market share for multiply-listed options by exchange. Of the 16 operating options exchanges, none currently has more than a 13.1% market share, and MRX has the smallest market share at 1.8%. Customers widely distribute their transactions across exchanges according to their business needs and the ability of each exchange to meet those needs through technology, liquidity and functionality. Average market share for the 16 options exchanges is 6.26 percent, with the median at 5.8, and a range between 1.8 and 13.1 percent.

Regular Orders); 90455 (November 18, 2020), 85 FR 75064 (November 24, 2020) (SR–MRX–2020–21) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Pricing Schedule); and 91687 (April 27, 2021), 86 FR 23478 (May 3, 2021) (SR–MRX–2021–04) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Exchange's Pricing Schedule at Options 7). Note that ISE Mercury is an earlier name for MRX.

[27] *See* Securities Exchange Act Release No. 86326 (July 8, 2019), 84 FR 33300 (July 12, 2019) (SR–MRX–2019–14) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Adopt Complex Order Pricing).

[28] One distinction is that ISE offered its Members access to Nasdaq Precise in 2019 and since that time. MRX has never offered Precise. ''Nasdaq Precise'' or ''Precise'' is a front-end interface that allows EAMs and their Sponsored Customers to send orders to the Exchange and perform other related functions. Features include the following: (1) order and execution management: enter, modify, and cancel orders on the Exchange, and manage executions (*e.g.,* parent/child orders, inactive orders, and post-trade allocations); (2) market data: access to real-time market data (*e.g.,* NBBO and Exchange BBO); (3) risk management: set customizable risk parameters (*e.g.,* kill switch); and (4) book keeping and reporting: comprehensive audit trail of orders and trades (*e.g.,* order history and done away trade reports). *See* ISE Supplementary Material .03(d) of Options 3, Section 7. Precise is also available on GEMX.

[29] *See* Securities Exchange Act Release No 88211 (February 14, 2020), 85 FR 9847 (February 20, 2020) (SR–NYSENAT–2020–05), also available at *https://www.nyse.com/publicdocs/nyse/markets/nyse-national/rule-filings/filings/2020/SR-NYSENat-2020-05.pdf.*

[30] *See id.*

[31] *See NetCoalition* v. *SEC,* 615 F.3d 525, 535 (D.C. 2010) (''*NetCoalition I*'').

[32] *See* NYSE National Approval Order (citing *NetCoalition I*).

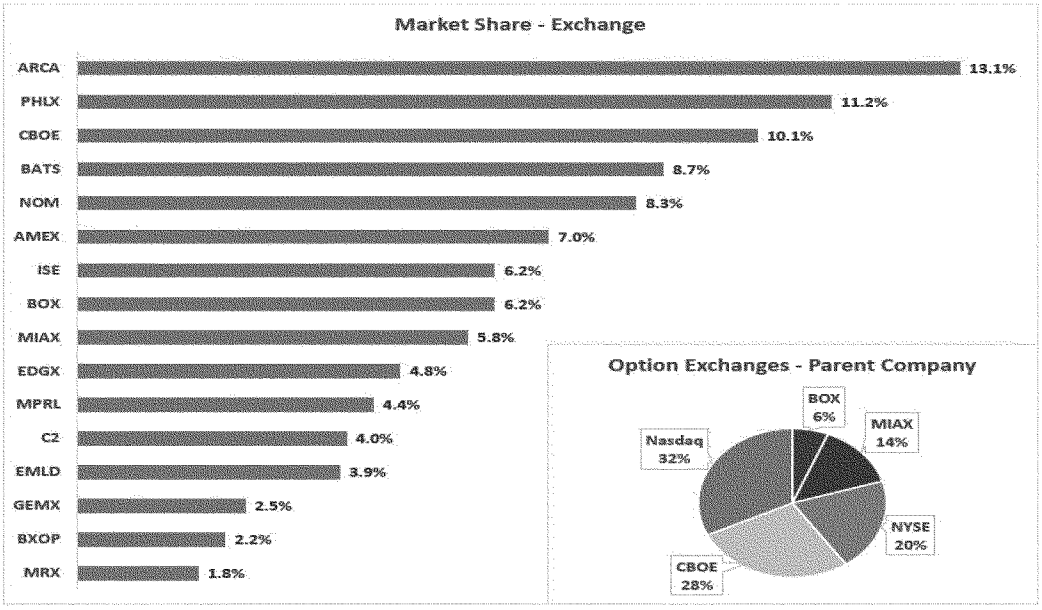
[33] *See id.*

[34] *See* Securities Exchange Act Release No. 94901 (May 12, 2022), 87 FR 30305 (May 18, 2022) (SR–MRX–2022–04).

[35] These terminations were limited to market data; none of these customers were members of MRX and therefore purchased neither memberships nor ports from the Exchange.

[36] NYSE National did not provide similarly detailed information regarding the characteristics of cancelling customers. Nevertheless, the Exchange believes that the characteristics of such customers are similar for both NYSE National and MRX, and the same competitive forces apply to all exchanges.

**Chart 1: Market Share by Exchange for January 2022**




Market share is the percentage of volume on a particular exchange relative to the total volume across all exchanges, and indicates the amount of order flow directed to that exchange. High levels of market share enhance the value of market data.

The second step in this analysis—demonstrating that only a small number of firms purchase market data relative to affiliated options exchanges—is shown in Chart 2, which compares the number of firms with access to market data from MRX to the number of firms purchasing market data from the four MRX-affiliated options exchanges, GEMX, ISE, The Nasdaq Stock Market LLC (''NOM'') and Nasdaq PHLX, LLC (''Phlx'').

**Chart 2: Number of Firms with Access to Market Data and Purchasing Trading Services from Options Venues (March 2022)**

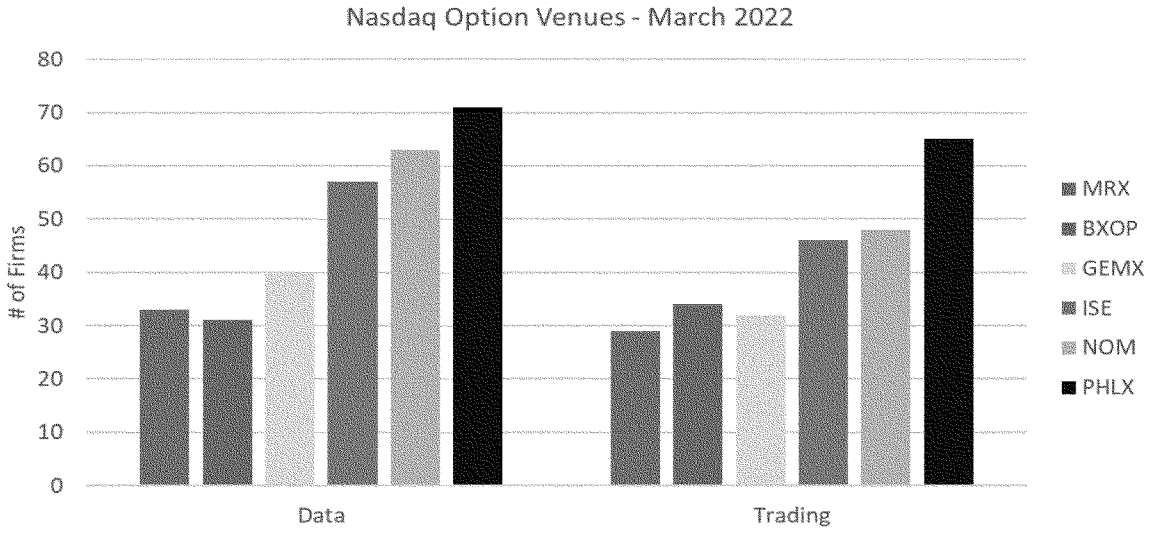



Chart 2 shows that 34 firms subscribed to at least one market data product from MRX in the first quarter of 2022. This is the second lowest number of firms purchasing market data from the Nasdaq-affiliated options exchanges.

The third step in this analysis—showing that a sizable number of customers terminated subscriptions following the proposal of the fees—is confirmed by the five customer cancellations. As explained above, all five customers terminated all feeds available to them. Although not all customers took all of the MRX feeds, each one of these feeds was cancelled by at least one customer, demonstrating that customers can and do exercise

choice with respect to each feed. These cancellations reduced the number of firms with access to at least one MRX market data feed from 34 to 29, an approximately 15 percent reduction in usage, demonstrating that firms can and do exercise choice in determining whether to purchase market data from the Exchange.

MRX lists no proprietary options products that are entirely unique to MRX. Firms can substitute MRX market data with feeds from exchanges that provide a high degree of functionality, including complex orders. Full market data options are available, for example, from Cboe,[37] MIAX,[38] and NYSE Arca Options.[39] Because MRX does not list options on products that are exclusively available on MRX, consumers can substitute MRX data with data from any exchange that lists such multiply-listed options, or through OPRA. Moreover, all broker-dealers involved in order routing must take consolidated data from OPRA, and proprietary data feeds cannot be used to meet that particular requirement. As such, all proprietary data feeds are optional.

This analysis must be viewed in the context of a field with relatively low barriers to entry. MRX, like many new entrants to the field, offered market data for free to establish itself and gain market share. As new entrants enter the field, MRX can also expect competition from these new entrants. Those new entrants, like MRX, are likely to set market data fees to zero, increasing marketplace competition.

The Proposal is not unfairly discriminatory. The five market data feeds at issue here—the Depth of Market Feed, Order Feed, Top Feed, Trades Feed, and Spread Feed—are used by a variety of market participants for a variety of purposes. Users include regulators, market makers, competing exchanges, media, retail, academics, portfolio managers. Market data feeds will be available to members of all of these groups on a non-discriminatory basis.

With respect to the proposed Non-Display Enterprise License, enterprise licenses in general have been widely recognized as an effective and not unfairly discriminatory method of distributing market data. Enterprise licenses are widely employed by options exchanges, and the proposal here is typical of such licenses.

After 6 years, MRX proposes to assess market data fees, just as all other options exchanges do now.[40] These fees will not impede access to MRX, but rather will allow MRX to continue to compete and grow its marketplace so that it may continue to offer a robust trading architecture, a quality opening process, an array of simple and complex order types and auctions, and competitive transaction pricing. If MRX is incorrect in its assessment of the value of its services, that assessment will be reflected in MRX's ability to compete with other options exchanges.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. For all of the reasons set forth above, the Exchange is subject to ''significant substitution-based competitive forces'': (i) it has a consistently low percentage of market share, starting at approximately 0.2 percent when it opened as an Exchange and ending in approximately 1.8 percent today; (ii) only a small number of firms purchase market data from MRX relative to its affiliated options exchanges; and (iii) a sizeable portion of subscribers—approximately 15 percent—have terminated their subscriptions following the implementation of the proposed fees, demonstrating that customers can and do exercise choice in deciding whether to purchase market data.

Nothing in the Proposal burdens inter-market competition (the competition among self-regulatory organizations) because approval of the Proposal does not impose any burden on the ability of other options exchanges to compete. Each of the remaining 15 options exchanges currently sells its market data, and is capable of modifying its fees in response to the proposed changes by MRX. Moreover, allowing MRX, or any new market entrant, to waive fees for a period of time to allow it to become established encourages market entry and thereby ultimately promotes competition.

Nothing in the Proposal burdens intra-market competition (the competition among consumers of exchange data) because each customer will be able to decide whether or not to purchase the Exchange's market data, as demonstrated by the fact that a significant number of the Exchange's customers have already elected to terminate their access to such feeds.

The Exchange operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. If the changes proposed herein are unattractive to market participants, it is likely that the Exchange will lose market share.[41]

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

No written comments were either solicited or received.

**III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

The foregoing rule change has become effective pursuant to section 19(b)(3)(A)(ii) of the Act.[42]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

**IV. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

*Electronic Comments*

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or

[37] *See* Cboe DataShop, available at *https://datashop.cboe.com/*.

[38] *See* MIAX Options Market Data & Offerings, available at *https://www.miaxoptions.com/market-data-offerings.*

[39] *See* NYSE Options Markets, available at *https://www.nyse.com/options.*

[40] Prior to submission of the proposed pricing changes on May 2, 2022, MRX was the only options exchange not assessing market data fees.

[41] The Exchange notified market participants of the new fees on December 20, 2021. *See* Data News #2021–11 (December 20, 2021, available at *http://www.nasdaqtrader.com/TraderNews.aspx?id=dn2021-11*). As such, market participants have had ample notice of the proposed fee changes and will be able to adjust their purchases of exchange services accordingly.

[42] 15 U.S.C. 78s(b)(3)(A)(ii).

• Send an email to *rule-comments@sec.gov.* Please include File Number SR–MRX–2022–22 on the subject line.

*Paper Comments*

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–MRX–2022–22. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MRX–2022–22 and should be submitted on or before November 18, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[43]

**J. Matthew DeLesDernier,**

*Deputy Secretary.*

[FR Doc. 2022–23483 Filed 10–27–22; 8:45 am]

**BILLING CODE 8011–01–P**

[43] 17 CFR 200.30–3(a)(12).

## SMALL BUSINESS ADMINISTRATION

**[License No. 03/03–0290]**

### Canapi Ventures SBIC Fund II, L.P.; Notice Seeking Exemption Under Section 312 of the Small Business Investment Act, Conflicts of Interest

Notice is hereby given that Canapi Ventures SBIC Fund II, L.P., 801 17th Street NW, Suite 1050, Washington, DC 20006, a Federal Licensee under the Small Business Investment Act of 1958, as amended (''the Act''), in connection with the financing of a small concern, has sought an exemption under Section 312 of the Act and 13 CFR 107.730, Financings which constitute conflicts of interest of the Small Business Administration (''SBA'') regulations. An Associate of Canapi Ventures SBIC Fund II, L.P. owns more than 10% of the equity interests in Elpha Secure Technology Inc., 576 Fifth Avenue, Suite 903, New York, NY 10036, thereby making Elpha Secure Technology Inc. an Associate.

The financing is brought within the purview of § 107.730(a) of the regulations because Canapi Ventures SBIC Fund II, L.P. and Elpha Secure Technology Inc. are Associates and Canapi Ventures SBIC Fund II, L.P. is seeking to invest capital in Elpha Secure Technology Inc. Therefore, this transaction is considered financing an Associate, requiring a prior SBA exemption.

Notice is hereby given that any interested person may submit written comments on the transaction, within fifteen days of the date of this publication, to the Associate Administrator, Office of Investment and Innovation, U.S. Small Business Administration, 409 Third Street SW, Washington, DC 20416.

**Bailey DeVries,**

*Associate Administrator, Office of Investment and Innovation, U.S. Small Business Administration.*

[FR Doc. 2022–23522 Filed 10–27–22; 8:45 am]

**BILLING CODE 8026–09–P**

## DEPARTMENT OF STATE

**[Public Notice: 11905]**

### Determination Under Section 610 of the Foreign Assistance Act (FAA) of 1961 To Provide Assistance for International Energy and Climate Security Objectives and for Assistance for the Pacific Islands

Pursuant to the authority vested in me by section 610 of the FAA, and the President's Memorandum of Delegation dated September 16, 2022, I hereby determine that it is necessary for the purposes of the FAA that up to $130,000,000 of FY 2020 Foreign Military Financing funds be transferred to, and consolidated with, the Economic Support Fund account to provide assistance for international energy and climate security objectives ($90 million) and for assistance for the Pacific Islands ($40 million). Such funds are hereby so transferred and consolidated.

This determination shall be reported to Congress and published in the **Federal Register**.

Dated: September 26, 2022.

**Antony J. Blinken,**

*Secretary of State.*

[FR Doc. 2022–23476 Filed 10–27–22; 8:45 am]

**BILLING CODE 4710–10–P**

## DEPARTMENT OF STATE

**[Public Notice: 11901]**

### Determination Under Section 614(a)(1) of the Foreign Assistance Act of 1961 for Assistance To Advance Food Security and Energy Resilience and To Counter the People's Republic of China's Efforts

Pursuant to the authority vested in me by section 614(a)(1) of the Foreign Assistance Act of 1961 (FAA), and the President's Memorandum of Delegation dated August 26, 2022, I hereby determine that it is important to the security interests of the United States to use up to $205 million from the Economic Support Fund under title IX of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2021 (Div. K, Pub. L. 116–260) to furnish assistance to advance food security and energy resilience and to counter the People's Republic of China's efforts, without regard to any other provision of law within purview of section 614(a)(1) of the FAA.

This determination shall be reported to Congress and published in the **Federal Register**.

Dated: September 1, 2022.

**Antony J. Blinken,**

*Secretary of State.*

[FR Doc. 2022–23473 Filed 10–27–22; 8:45 am]

**BILLING CODE 4710–10–P**

## DEPARTMENT OF STATE

**[Public Notice: 11903]**

### Determination Under Section 610 of the Foreign Assistance Act of 1961

Pursuant to the authority vested in me by section 610 of the Foreign Assistance Act of 1961 (FAA) and section 8003(d) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2017 (Div. J, Pub. L. 115–31), I hereby determine that it is necessary for the purposes of the FAA that up to $10,000,000 from FY 2017 Peacekeeping Operations-Overseas Contingency Operations (PKO–OCO) funds be transferred to, and consolidated with, Economic Support Fund-Overseas Contingency Operations (ESF–OCO) funds. Such funds are so hereby transferred and consolidated.

This determination shall be reported to Congress and published in the **Federal Register**.

Dated: September 7, 2022.

**Antony J. Blinken,**

*Secretary of State.*

[FR Doc. 2022–23475 Filed 10–27–22; 8:45 am]

**BILLING CODE 4710–10–P**

## OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

### Section 301 Petition on Mexico's Acts, Policies, and Practices Concerning Seasonal and Perishable Agricultural Products

**AGENCY:** Office of the United States Trade Representative.

**ACTION:** Notice.

**SUMMARY:** On September 8, 2022, the Office of the United States Trade Representative (USTR) received a petition requesting an investigation of certain alleged acts, policies, and practices of the government of Mexico concerning seasonal and perishable agricultural products. Due to the complexities of the factual and legal issues raised in the petition, the U.S. Trade Representative could not conclude during the 45-day statutory review period that an investigation would be effective and is not opening an investigation at this time. In light of challenges faced by U.S. producers, USTR in coordination with the U.S. Department of Agriculture (USDA) will establish a private-sector industry advisory panel to recommend measures to promote the competitiveness of producers of seasonal and perishable produce in the southeastern United States. Furthermore, USTR and USDA will work with the petitioners and producers to examine the issues raised in the petition and to consider any further actions that may be appropriate.

**DATES:** This notice is applicable on October 23, 2022.

**FOR FURTHER INFORMATION CONTACT:** Assistant General Counsels David Lyons at (202) 395–9446 or Rachel Hasandras at (202) 395–5725, or Director for Agricultural Affairs Colby Branch at (202) 395–9070.

**SUPPLEMENTARY INFORMATION:** On September 8, 2022, certain members of Florida's congressional delegation filed a petition under section 302(a) of the Trade Act of 1974, as amended (Trade Act) alleging that certain acts, policies, and practices of the government of Mexico concerning seasonal and perishable agricultural products constitute an export targeting scheme, and that the alleged scheme is unreasonable and burdens or restricts U.S. commerce. The alleged export targeting scheme has two components. First, the petition alleges that beginning in the early 2000s Mexico has used certain programs specifically to subsidize its seasonal and perishable agricultural industry, and to enable that industry to expand its exports to the United States. Second, the petition alleges that wage rates in Mexico give Mexico's seasonal and perishable agriculture industry an unfair competitive advantage. The petition claims that the alleged export targeting scheme has resulted in a surge in imports of seasonal and perishable agricultural products from Mexico, and that Florida producers are adversely affected.

Section 302(a)(2) of the Trade Act provides that the U.S. Trade Representative must determine whether to initiate an investigation not later than 45 days after the filing of a petition (in this case, by October 23, 2022). Section 302(c) of the Trade Act provides that in determining whether to initiate a Section 301 investigation, the U.S. Trade Representative has discretion to determine whether action under Section 301 would be effective in addressing an alleged act, policy, or practice. Section 305(b) of the Trade Act provides for a private-sector advisory panel as a specific response to export targeting.

Evaluation of the petition entails a detailed review and analysis of multiple government measures, and legal analyses of the interplay between the measures and legal standards under Section 301. Due to the complexity of the legal and factual issues raised in the petition, the U.S. Trade Representative could not conclude within the 45-day statutory period that a formal 301 investigation would be effective and is not opening an investigation at this time. The U.S. Trade Representative made the decision under Section 302(c) on October 22, 2022.

In light of challenges faced by southeastern U.S. producers as described in the petition, USTR announced on October 23, 2022, that USTR in coordination with USDA will establish a private-sector industry advisory panel to recommend measures to promote the competitiveness of producers of seasonal and perishable produce in the southeastern United States. USTR and USDA will consider recommendations of the advisory panel and work with Members of Congress as appropriate to develop possible administrative actions and legislation that would benefit U.S. producers. Furthermore, USTR and USDA will work with the petitioners and producers to examine the issues raised in the petition and to consider any further actions that may be appropriate.

**Greta Peisch,**

*General Counsel, Office of the United States Trade Representative.*

[FR Doc. 2022–23502 Filed 10–27–22; 8:45 am]

**BILLING CODE 3390–F3–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### Noise Compatibility Program for Duluth International Airport, St. Louis County, Minnesota

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Approval of a Duluth International Airport (DLH) noise compatibility program.

**SUMMARY:** The Federal Aviation Administration (FAA) announces its findings for the noise compatibility program submitted by DLH, see **SUPPLEMENTARY INFORMATION** for details. On April 11, 2022 the FAA determined that the noise exposure maps submitted by DLH were in compliance with applicable requirements. On October 6, 2022, the FAA approved the DLH noise compatibility program. All of the recommendations of the program were approved. No program elements relating to new or revised flight procedures for noise abatement were proposed by the DLH.

**DATES:** The effective date of the FAA's approval of the DLH noise compatibility program is October 6. 2022.

**FOR FURTHER INFORMATION CONTACT:** Josh Fitzpatrick, Federal Aviation Administration, Environmental Protection Specialist, 6020 South 28th Avenue, Room 102, Minneapolis, MN 55450, (612) 253–4639.

**SUPPLEMENTARY INFORMATION:** This notice announces FAA's approval of the noise compatibility program for DLH, effective on October 6, 2022. Per United States Code section 47504 (49 U.S.C. 47504) and Title 14, Code of Federal Regulations (CFR), part 150, an airport sponsor who previously submitted a noise exposure map may submit to the FAA a noise compatibility program which sets forth the measures taken or proposed by the airport sponsor for the reduction of existing non-compatible land uses and prevention of additional non-compatible land uses within the area covered by the noise exposure maps. As required by 49 U.S.C. 47504, such programs must be developed in consultation with interested and affected parties including local communities, government agencies, airport users, and the FAA. The FAA does not substitute its judgment for that of the airport sponsor with respect to which measures should be recommended for action. The FAA approval or disapproval of an airports recommendations in their noise compatibility program are made in accordance with the requirements and standards pursuant to 49 U.S.C. 47504 and 14 CFR part 150, which is limited to the following determinations:

a. The noise compatibility program was developed in accordance with the provisions and procedures of 14 CFR 150.23;

b. Program measures are reasonably consistent with achieving the goals of reducing existing non-compatible land uses around the airport and preventing the introduction of additional non-compatible land uses;

c. Program measures would not create an undue burden on interstate or foreign commerce, unjustly discriminate against types or classes of aeronautical uses, violate the terms of airport grant agreements, or intrude into areas preempted by the Federal Government; and

d. Program measures relating to the use of flight procedures can be implemented within the period covered by the program without derogating safety, adversely affecting the efficient use and management of the navigable airspace and air traffic control systems, or adversely affecting other powers and responsibilities of the Administrator prescribed by law.

Specific limitations of FAA's approval of noise compatibility programs are delineated in 14 CFR 150.5. Approval is not a determination concerning the acceptability of land uses under Federal, state, or local law. Approval does not by itself constitute an FAA implementing action. A request for Federal action or approval to implement specific noise compatibility measures may be required, and an FAA decision on the request may require an environmental assessment of the proposed action. Approval does not constitute a commitment by the FAA to financially assist in the implementation of the noise compatibility program nor a determination that all measures covered by the noise compatibility program are eligible for grant-in-aid funding from the FAA. Where federal funding is sought, requests must be submitted to the FAA Airports District Office at 6020 South 28th Avenue, Room 102, Minneapolis, MN 55450.

DLH submitted to the FAA on December 13, 2021 the noise exposure maps, descriptions, and other documentation produced during the noise compatibility planning study conducted from October 2, 2019 and December 13, 2021. The DLH noise exposure maps were determined by FAA to be in compliance with applicable requirements on April 11, 2022. Notice of this determination was published in the **Federal Register** on April 15, 2022 ''87 FR 22616''.

The DLH proposed noise compatibility program is comprised of actions designed for phased implementation by airport management and adjacent jurisdictions from December 13, 2021 to 2026. It was requested that the FAA evaluate and approve this material as a noise compatibility program as described in 49 U.S.C. 47504. The FAA began its review of the program on April 11, 2022 and was required by a provision of 49 U.S.C. 47504 to approve or disapprove the program within 180 days, other than the use of new or modified flight procedures for noise control. Failure to approve or disapprove such program within the 180-day period shall be deemed an approval of such program.

The submitted program contained 12 proposed measures to minimize impacts of aviation noise on and off the airport. The FAA completed its review and determined that the procedural and substantive requirements of the 49 U.S.C. 47504 and 14 CFR part 150 were satisfied. The overall program, therefore, was approved by the FAA effective October 6, 2022.

Outright approval was granted for all the specific program elements. Program elements include:

*Measure M–A:* Offer Residential Sound-insulation Treatment to Single- and Multi-Family Homes (47 units) within the Average Day-Night Sound Level (DNL) 65 decibels (dB) and above Noise Contours. Offer Residential Sound-insulation treatment to Single-Family Homes (17 units) within the Block Rounding Area outside the DNL 65 dB Noise Contour.

*Measure M–B (1997 NCP Measure M–1):* Offer Land Acquisition Program to Single-Family Homes (7 units) within the DNL 70 dB and above Noise Contour.

*Measure M–C:* Offer Land Acquisition to Birchwood Mobile Estates (102 Mobile Homes) within the Noise Mitigation Program Area (NMPA) #1 boundary and 1 additional mobile home property located to the northwest of the airport within the DNL 65 dB and above noise contour.

*Measure M–D:* Offer Avigation Easements to owner-occupied single-family homes within NMPA #1 if acquisition (within DNL 70 dB noise contour only) and sound-insulation is declined.

*Measure M–E:* Offer Avigation Easements to one (1) mobile home within NMPA #1, located along Lavaque Bypass Road, if acquisition is declined.

*Measure M–F:* Develop an Airport Land Use Management District (ALUMD).

*Measure M–G:* Adopt Updated Subdivision Regulations.

*Measure M–H:* Adopt Improved Building Codes.

*Measure M–I:* Develop a Voluntary Fair Disclosure Program.

*Measure P–A:* Continue Logging of Noise Complaints.

*Measure P–B:* Initiate Community Roundtable or Noise Abatement Committee.

*Measure P–C:* Perform Regular Updates to the noise exposure map and review of the noise compatibility program.

These determinations are set forth in detail in the Record of Approval signed by the FAA Airports Great Lakes Division Director on October 6, 2022. The Record of Approval, as well as other evaluation materials and the documents comprising the submittal, are available for review at the FAA office listed above and at the administrative offices of the Duluth Airports Authority (DAA). The Record of Approval also will be available on the internet on the FAAs website at *http://www.faa.gov/airports/environmental/airport_noise/part_150/states/* and the DLH website at *https://duluthairport.com/noise-study/#documents.*

Issued in Chicago, IL, on October 6, 2022.

**Susan Mowery-Schalk,**

*Director, Office of Airports, AGL–600, FAA Great Lakes Region.*

[FR Doc. 2022–23464 Filed 10–27–22; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

**[Docket No. FAA–2020–0862]**

### COVID–19 Related Relief Concerning Operations at Chicago O'Hare International Airport, John F. Kennedy International Airport, Los Angeles International Airport, Newark Liberty International Airport, New York LaGuardia Airport, Ronald Reagan Washington National Airport, and San Francisco International Airport for the Winter 2022/2023 Scheduling Season

**AGENCY:** Federal Aviation Administration (FAA), Department of Transportation (DOT).

**ACTION:** Expiration of the limited, conditional waiver of the minimum slot usage requirements.

**SUMMARY:** The FAA's current COVID–19 related relief policy for U.S. slot-controlled and Level 2 airports will expire on October 29, 2022. This notice confirms resumption of the minimum slot usage requirements for Operating Authorizations (slots) at Ronald Reagan Washington National Airport (DCA), John F. Kennedy International Airport (JFK) and LaGuardia Airport (LGA) for the Winter 2022/2023 scheduling season beginning October 30, 2022. This notice announces a similar resumption of standard FAA processes at designated International Air Transport Association (IATA) Level 2 airports in the United States (U.S.) to provide priority consideration for runway timings that are scheduled and operated as approved for purposes of establishing a carrier's operational baseline in the next corresponding season. These IATA Level 2 airports include Chicago O'Hare International Airport (ORD), Los Angeles International Airport (LAX), Newark Liberty International Airport (EWR), and San Francisco International Airport (SFO). The FAA recognizes the importance of reciprocity in connection with usage alleviation policies with regard to COVID–19–related capacity and frequency restrictions at foreign airports and will consider justified requests by U.S. and foreign air carriers for usage waivers based on reciprocity and other related circumstances.

**DATES:** This action is effective on October 28, 2022.

**FOR FURTHER INFORMATION CONTACT:** Al Meilus, Slot Administration and Capacity Analysis, AJR–G5, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone number 202–267–2822; email *al.meilus@faa.gov.*

**SUPPLEMENTARY INFORMATION:**

### Background

On March 16, 2020, the FAA granted a limited waiver of the minimum slot usage requirements [1] to carriers operating at all slot-controlled airports in the United States (DCA, JFK, and LGA) [2] and related relief to carriers operating at designated IATA Level 2 airports in the United States (EWR, LAX, ORD, SFO) due to the extraordinary impacts on the demand for air travel resulting from the effects of the COVID–19 pandemic.[3] Since the initial slot usage waiver and related relief was provided, the FAA has taken action to extend relief on five occasions, subject to certain substantive changes, such as narrowing the scope of relief and adding conditions, as the effects of the COVID–19 pandemic evolved.[4] The most recent limited, conditional extension of COVID–19–related relief was issued by the FAA on March 29, 2022, and expires on October 29, 2022.[5]

### Standard Applicable to This Waiver Proceeding

The FAA reiterates the standards applicable to petitions for waivers of the minimum slot usage requirements in effect at DCA, JFK, and LGA, as discussed in FAA's initial decision granting relief due to COVID–19 impacts.[6] At JFK and LGA, each slot must be used at least 80 percent of the time.[7] Slots not meeting the minimum usage requirements will be withdrawn. The FAA may waive the 80 percent usage requirement in the event of a highly unusual and unpredictable condition that is beyond the control of the slot-holding air carrier and which affects carrier operations for a period of five consecutive days or more.[8]

At DCA, any slot not used at least 80 percent of the time over a two-month period also will be recalled by the FAA.[9] The FAA may waive this minimum usage requirement in the event of a highly unusual and

[1] The FAA has authority for developing ''plans and policy for the use of the navigable airspace'' and for assigning ''by regulation or order the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace.'' 49 U.S.C. 40103(b)(1). The FAA manages slot usage requirements under the authority of 14 CFR 93.227 at DCA and under the authority of Orders at JFK and LGA. *See* Operating Limitations at John F. Kennedy International Airport, 85 FR 58258 (Sep. 18, 2020); Operating Limitations at New York LaGuardia Airport, 85 FR 58255 (Sep. 18, 2020).

[2] Although DCA and LGA are not designated as IATA Level 3 slot-controlled airports given that these airports primarily serve domestic destinations, the FAA limits operations at these airports via rules at DCA and an Order at LGA that are equivalent to IATA Level 3. *See* FN 1. The FAA reiterates that the relief provided in the March 16, 2020, notice (85 FR 15018); the April 17, 2020, notice (85 FR 21500); the October 7, 2020, notice (85 FR 63335); the January 14, 2021, Summer 2021 FAA Policy Statement (Docket No. FAA–2020–0862–0302); and, the October 20, 2021, notice (86 FR 58134), extends to all allocated slots, including slots allocated by exemption.

[3] Orders Limiting Operations at John F. Kennedy International Airport and New York LaGuardia Airport; High Density Traffic Airports Rule at Ronald Reagan Washington National Airport, 85 FR 15018 (Mar. 16, 2020).

[4] Orders Limiting Operations at John F. Kennedy International Airport and New York LaGuardia Airport; High Density Traffic Airports Rule at Ronald Reagan Washington National Airport, 85 FR 21500 (Apr. 17, 2020); COVID–19 Related Relief Concerning Operations at Chicago O'Hare International Airport, John F. Kennedy International Airport, Los Angeles International Airport, Newark Liberty International Airport, New York LaGuardia Airport, Ronald Reagan Washington National Airport, and San Francisco International Airport for the Winter 2020/2021 Scheduling Season, 85 FR 63335 (Oct. 7, 2020); FAA Policy Statement: Limited, Conditional Extension of COVID–19 Related Relief for the Summer 2021 Scheduling Season (Docket No. FAA–2020–0862–0302); COVID–19 Related Relief Concerning Operations at Chicago O'Hare International Airport, John F. Kennedy International Airport, Los Angeles International Airport, Newark Liberty International Airport, New York LaGuardia Airport, Ronald Reagan Washington National Airport, and San Francisco International Airport for the Winter 2021/2022 Scheduling Season, 86 FR 58134 (Oct. 20, 2021); and COVID–19 Related Relief Concerning Operations at Chicago O'Hare International Airport, John F. Kennedy International Airport, Los Angeles International Airport, Newark Liberty International Airport, New York LaGuardia Airport, Ronald Reagan Washington National Airport, and San Francisco International Airport for the Summer 2022 Scheduling Season, 87 FR 18057 (Mar. 29, 2022).

[5] COVID–19 Related Relief Concerning Operations at Chicago O'Hare International Airport, John F. Kennedy International Airport, Los Angeles International Airport, Newark Liberty International Airport, New York LaGuardia Airport, Ronald Reagan Washington National Airport, and San Francisco International Airport for the Summer 2022 Scheduling Season, 87 FR 18057 (Mar. 29, 2022).

[6] *See* Orders Limiting Operations at John F. Kennedy International Airport and New York LaGuardia Airport; High Density Traffic Airports Rule at Ronald Reagan Washington National Airport, 85 FR 15018 (Mar. 16, 2020).

[7] Operating Limitations at John F. Kennedy International Airport, 85 FR 58258 at 58260 (Sep. 18, 2020); Operating Limitations at New York LaGuardia Airport, 85 FR 58255 at 58257 (Sep. 18, 2020).

[8] At JFK, historical rights to operating authorizations and withdrawal of those rights due to insufficient usage will be determined on a seasonal basis and in accordance with the schedule approved by the FAA prior to the commencement of the applicable season. See JFK Order, 85 FR at 58260. At LGA, any operating authorization not used at least 80 percent of the time over a two-month period will be withdrawn by the FAA. See LGA Order, 85 FR at 58257.

[9] See 14 CFR 93.227(a).

unpredictable condition that is beyond the control of the slot-holding carrier and which exists for a period of nine or more days.[10]

When making decisions concerning historical rights to allocated slots, including whether to grant a waiver of the usage requirement, the FAA seeks to ensure the efficient use of valuable aviation infrastructure while maximizing the benefits to airport users and the traveling public. This minimum usage requirement is expected to accommodate routine cancelations under all but the most unusual circumstances. Carriers proceed at risk if, at any time prior to a final decision, they make decisions in anticipation of the FAA granting a slot usage waiver.

**Summary of Petitions Submitted**

Airlines for America (A4A) and the IATA, on behalf of their member airlines, filed a petition with the FAA on August 25, 2022, to extend the FAA's current waiver policy for international operations through the Winter 2022/2023 scheduling season from October 30, 2022, through March 25, 2023. A4A and IATA indicate the industry faces ''considerable challenges as it attempts to ramp up operations to meet pre-COVID level air travel demands. Shortfalls in resourcing and staffing at airports, security and immigration, air traffic control and at some airlines are well documented across the globe.'' A4A and IATA cite ''a number of major airports declaring lower levels of capacity, which has a negative impact on individual airline's ability to restore historic operations.'' In addition, A4A and IATA state that ''the COVID–19 pandemic continues to impact airline, air traffic control and airport operations, especially at the international level.'' In support of this claim, A4A and IATA provide that ''infection rates have been increasing globally as variants cycle through phases of dominance and some countries continue to maintain COVID–19 policies impacting aviation, particularly in the Asia-Pacific and Middle East-Africa regions. United States-Asia traffic remains down 65% in some key Asian markets and down 90% from Hong Kong and China compared to 2019 levels.'' Further, A4A and IATA note the aviation impacts resulting from the Russian invasion of Ukraine, inflation and economic downturn, and concerns about some airports' ability to provide sufficient capacity and resources to support a return to 80% slot use rate. Finally, A4A and IATA express concern that without continued relief ''U.S. carriers will not be granted reciprocal relief from other leading countries and non-U.S. carriers are prevented from a sustainable recovery of their U.S. network.''

**Analysis**

Waivers are reserved for highly unusual and unpredictable conditions beyond the control of carriers. The concerns identified in the petitions, such as general economic conditions, reduced demand, operating costs, inability to recruit or retain staff or similar factors are not highly unusual and unpredictable conditions that justify broad proactive relief from minimum slot usage rules. Access to slot-controlled airports is limited; slots are scarce resources and use of those scarce resources should be prioritized by the slot holder. It is the policy of the Department of Transportation (DOT) to encourage high utilization of scarce public infrastructure. Further, it is not the policy of DOT to use slot and Level 2 rules to reserve capacity for historic incumbent carriers until demand returns to predetermined levels. The FAA has extended COVID–19 related relief five times since first providing relief in March of 2020. As FAA and DOT have previously stated, at some point in time, continuing waivers to preserve pre-COVID slot holdings may impede the ability of airports and airlines to provide services that benefit the overall national economy and make appropriate use of scarce public assets.[11] Initial COVID–19 related relief was provided for all operations at the slot controlled and Level 2 airports and has been scaled back as improvements to the public health emergency supported increased demand in domestic markets and a resumption of international demand in most markets. To date, based on carrier scheduling data some carriers have even started new services and entered new markets not served previously to meet demand for travel during the initial recovery phases.

In addition, COVID–19 travel restrictions in the United States and many other countries have decreased significantly over the course of the Summer 2022 scheduling season; however, the FAA acknowledges that demand in some international markets is constrained due to continuing COVID–19 related restrictions that impact international operations in certain countries or regions. These COVID–19 related restrictions may include flight frequency or flight capacity limitations, crew treatment protocols that do not allow crews to safely rest in certain jurisdictions, and other restrictions that impede the ability of carriers to operate flights that they would otherwise intend to operate. These remaining COVID–19 related restrictions in certain foreign jurisdictions for which usage relief might be appropriate, do not, however, support a broad waiver of the minimum slot usage rules for all international operations or for carriers that may not operate for other reasons.

Therefore, the FAA denies the petition by A4A and IATA for an extension of the Summer 2022 alleviation polices to the Winter 2022/2023 scheduling season as the requested relief is overly broad and justified relief for slot holders can be addressed through other more narrowly tailored means. The FAA slot usage waiver standards are sufficient to provide targeted relief for U.S. or foreign air carriers that are affected by the remaining COVID–19-related restrictions imposed in foreign jurisdictions. The FAA recognizes that relief may be appropriate in consideration of reciprocal treatment of air carriers and foreign air carriers with various alleviation policies at foreign airports related to restrictions and recovery from COVID–19 impacts. The FAA intends to work closely with the Office of the Secretary of Transportation (OST) in reviewing requests for relief based on foreign government restrictions or reciprocity. To the extent that U.S. carriers operate to jurisdictions that do not offer reciprocal relief to U.S. carriers, the FAA may determine not to grant a waiver to carriers of that jurisdiction.

The aviation industry is not unique in its challenges as other industries also face issues with employee resources, illnesses, and onboarding and training as we emerge from the pandemic's effects. The air transportation industry, however, has a unique role that supports the movement of passengers and cargo. Carriers need to recognize the operating environment, constraints, and opportunities and plan operations and slot use accordingly. The FAA recognizes the significant impact slot usage waiver policies have on airports, consumers, and aviation industry partners; the FAA and OST are acutely interested in seeing the return to full utilization of valuable and limited public resources in the Winter 2022/2023 scheduling season.

The FAA reminds operators that the slot rules treat slots as being used for several of the days around certain holiday periods in the U.S. Specifically, in the Winter 2022/2023 scheduling season, this includes Thanksgiving Day

[10] See 14 CFR 93.227(j).

[11] *See* 85 FR 63345.

and the day after (November 24 and 25, 2022) and from Saturday, December 24, 2022, through January 7, 2023. These periods effectively are automatically waived and treated as operated for usage purposes and may assist carriers in planning schedules and usage rates.

**Decision**

The FAA's current, limited COVID–19 related relief policies for international flights at the slot-controlled and Level 2 airports during the Summer 2022 scheduling season will expire as planned on October 29, 2022.[12] The FAA will rely on existing standards [13] to determine whether relief from usage rules and procedures is warranted on an individual carrier basis.

The FAA anticipates there will be a limited number of carrier requests for relief in Winter 2022/2023 based on foreign government-imposed travel restrictions or highly restrictive temporary limitations on flights. The FAA will work closely with OST on any such requests to determine appropriate action based on the circumstances and factors such as reciprocal treatment for U.S. carriers.

Carriers requesting relief from minimum usage requirements or similar relief for runway timings at the FAA-designated Level 2 airports should submit a petition to the FAA Slot Administration Office at *7-awa-slotadmin@faa.gov.*

Issued in Washington, DC, on October 26, 2022.

**Alyce Hood-Fleming,**

*Acting Vice President, System Operations Services.*

**Marc A. Nichols,**

*Chief Counsel.*

[FR Doc. 2022–23619 Filed 10–26–22; 4:15 pm]

**BILLING CODE 4910–13–P**

[12] COVID–19 Related Relief Concerning Operations at Chicago O'Hare International Airport, John F. Kennedy International Airport, Los Angeles International Airport, Newark Liberty International Airport, New York LaGuardia Airport, Ronald Reagan Washington National Airport, and San Francisco International Airport for the Summer 2022 Scheduling Season, 87 FR 18057, (Mar. 29, 2022).

[13] Operating Limitations at John F. Kennedy International Airport, 85 FR 58258 at 58260 (Sep. 18, 2020); Operating Limitations at New York LaGuardia Airport, 85 FR 58255 at 58257 (Sep. 18, 2020); 14 CFR 93.227(j).

## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

**[Docket No. FHWA 2022–0029]**

### Agency Information Collection Activities: Notice of Request for New Information Collection

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Notice and request for comments.

**SUMMARY:** The FHWA invites public comments about our intention to request the Office of Management and Budget's (OMB) approval to submit one information collection, which is summarized below under **SUPPLEMENTARY INFORMATION**. We published a **Federal Register** Notice with a 60-day public comment period on this information collection on June 2, 2022. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

**DATES:** Please submit comments by November 28, 2022.

**ADDRESSES:** You may submit comments within 30 days to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503, Attention DOT Desk Officer. You are asked to comment on any aspect of this information collection. All comments should include the Docket number FHWA–2022–0029.

**FOR FURTHER INFORMATION CONTACT:** Ms. Cynthia Essenmacher, (202) 366–780–6178, Department of Transportation, Federal Highway Administration, Office of Operations, Office of Transportation Management (HOTM–1), 1200 New Jersey Avenue SE, Washington, DC 20590. Office hours are from 7 a.m. to 4:30 p.m., Monday through Friday, except Federal holidays.

**SUPPLEMENTARY INFORMATION:**

*Title:* Innovative Finance and Equal Access for Over the Road Busses.

*Abstract for Innovative Finance:* The Federal Highway Administration (FHWA), Office of Operations and Office of the Chief Financial Officer, jointly collects information related to State Infrastructure Banks (SIB), Grant Anticipation Revenue Vehicles, and Toll Credits. This information is published on FHWA's public websites to monitor activity in each innovative finance program. This information satisfies the requirement under 23 U.S.C. 610(g)(7) for each SIB to make an annual report to the Secretary on its status no later than September 30 of each year and such other reports as the Secretary may require. The data will also satisfy new requirements under section 11503 of the Infrastructure Investment and Jobs Act (IIJA), Public Law 117–58, effective November 15, 2021, requiring the Secretary to make available a publicly accessible website on which States shall post the amount of toll credits that are available for sale or transfer.

The data includes activity, volume, and balances. The data is published annually on the Center for Innovative Finance's website. Information from this collection is used for the proper stewardship and oversight of each program, as well as compliance with each program's Federal statute.

*Abstract for Equal Access for Over the Road Busses:* Section 11523 of the recently enacted Bipartisan Infrastructure Law (BIL), enacted as the Infrastructure Investment and Jobs Act, Public Law 117–58 (Nov. 15, 2021) amended 23 U.S.C. 129 to add reporting requirements to the equal access provisions for over the road busses. Specifically, not later than 90 days after the date of enactment of the BIL, a public authority that operates a toll facility shall report to the Secretary any rates, terms, or conditions for access to the toll facility by public transportation vehicles that differ from the rates, terms, or conditions applicable to over-the-road buses.

Further, a public authority that operates a toll facility shall report to the Secretary any change to the rates, terms, or conditions for access to the toll facility by public transportation vehicles that differ from the rates, terms, or conditions applicable to over-the-road buses by not later than 30 days after the date on which the change takes effect.

*Respondents:* State governments of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the Northern Marianas, and the Virgin Islands share this burden.

*Estimated Average Burden per Response:* The estimated average reporting burden per response for the annual collection and processing of the data is 149 hours for each of the States (including local governments), the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the Northern Marianas, and the Virgin Islands.

*Estimated Total Annual Burden:* The estimated total annual burden for all respondents is 8,195 hours.

**Public Comments Invited**

You are asked to comment on any aspect of these information collections, including: (1) Whether the proposed

collections are necessary for the FHWA's performance; (2) the accuracy of the estimated burdens; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burdens could be minimized, including use of electronic technology, without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of these information collections.

*Authority:* The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; and 49 CFR 1.48.

Issued On: October 25, 2022.

**Michael Howell,**

*Information Collection Officer.*

[FR Doc. 2022–23529 Filed 10–27–22; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF TRANSPORTATION

### Federal Railroad Administration

### Safety Advisory 2022–01; Use of Portable Derails

**AGENCY:** Federal Railroad Administration (FRA), Department of Transportation (DOT).

**ACTION:** Notice of safety advisory.

**SUMMARY:** FRA is issuing Safety Advisory 2022–01 to emphasize the importance of, first, ensuring that portable derails are clearly visible to train crews and operators of other on-track equipment, particularly at night and in other low-light conditions; and, second, having processes in place to ensure portable derails are removed when not necessary for on-track safety. This Safety Advisory recommends that railroads, and railroad contractors, review and revise their on-track safety manuals, as necessary, to ensure they include procedures and rules for the use of portable derails.

**FOR FURTHER INFORMATION CONTACT:** Yu-Jiang Zhang, Staff Director, Track and Structures Division, Office of Railroad Safety, FRA, 1200 New Jersey Avenue SE, Washington, DC 20590, telephone: (202) 493–6460, email: *yujiang.zhang@dot.gov.*

*Disclaimer:* This Safety Advisory is considered guidance pursuant to DOT Order 2100.6A (June 7, 2021). Except when referencing laws, regulations, policies, or orders, the information in this Safety Advisory does not have the force and effect of law and is not meant to bind the public in any way. This document does not revise or replace any previously issued guidance.

**SUPPLEMENTARY INFORMATION:**

**Background**

On August 29, 2022, a train crew operating in a railroad yard at night encountered a portable derail placed on the track earlier that day to protect multiple engineering work groups working on the track. The train crew, which did not see the derail, operated their train directly into the derail, striking it at approximately nine miles per hour and derailing the first two cars of their train. The conductor, who was riding the lead car, was fatally injured when the car rolled over.

FRA's blue signal protection (BSP) requirements have long required mechanical derails to be used for the protection of workers on, under, or between rolling equipment to have a blue light illuminated at night. *See* 49 CFR part 218, subpart B. Typically, in BSP work areas (*e.g.,* mechanical shops), derails are located at known or fixed locations. Roadway workers, however, use portable maintenance-of-way (MOW) derails, which may be installed almost anywhere on non-controlled track for protection.[1] Because portable MOW derails are not required to be marked or otherwise illuminated for conspicuity, even under conditions of limited visibility, they can become hazards themselves if not highly visible in low-light conditions. Accordingly, best practice dictates that portable derails installed on track should be equipped with a portable light or, at a minimum, reflectorized flags in low-light conditions.

In addition, portable derails should not be left on the track when they are no longer necessary. For example, some railroads require their roadway workers in charge (RWICs) to fill out a form before installing the portable derails. This form typically requires the RWIC to record the date, location, installation time, and removal time of the portable derail. Formalizing the process for installation and removal of portable derails heightens the awareness of the presence of portable derails and the importance of removing these derails from the track when they are no longer necessary.

FRA notes that some railroads require employees to place a tag on the steering wheel of their hi-rail vehicles when placing shunts on the track. A similar process for placing portable derails would safeguard against roadway workers unintentionally leaving portable derails on the track.

[1] *See* 49 CFR 214.327.

**Recommendations**

In light of the above discussion, FRA recommends that railroads and railroad contractors:

1. Review with their employees the circumstances of the fatal accident described in this Safety Advisory.

2. Review and revise as necessary, their on-track safety manuals to ensure the use of portable derails is adequately addressed and, at a minimum, that these manuals:

a. Provide that portable derails be equipped with a functioning light or a reflectorized flag when used at night or under other conditions of limited visibility; and

b. Include procedures to ensure that portable derails are removed when no longer necessary, such as procedures to track the location and use of portable derails.

FRA encourages all railroad industry members to take actions consistent with the recommendations of this Safety Advisory. FRA may modify this Safety Advisory, issue additional safety advisories, or take other appropriate action necessary to ensure the highest level of safety on the Nation's railroads, including pursuing other corrective measures under its rail safety authority.

Issued in Washington, DC.

**John Karl Alexy,**

*Associate Administrator for Railroad Safety Chief Safety Officer.*

[FR Doc. 2022–23486 Filed 10–27–22; 8:45 am]

**BILLING CODE 4910–06–P**

## DEPARTMENT OF THE TREASURY

### Office of Foreign Assets Control

### Notice of OFAC Sanctions Actions

**AGENCY:** Office of Foreign Assets Control, Treasury.

**ACTION:** Notice.

**SUMMARY:** The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

**DATES:** See **SUPPLEMENTARY INFORMATION** section for effective date(s).

**FOR FURTHER INFORMATION CONTACT:** OFAC: Andrea Gacki, Director, tel.:

202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or the Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

**SUPPLEMENTARY INFORMATION:**

### Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

### Notice of OFAC Actions

On October 24, 2022, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

### Individual

1. CERNA JUAREZ, Reinaldo Gregorio Lenin (a.k.a. CERNA JUAREZ, Lenin), Nicaragua; DOB 29 Sep 1947; alt. DOB 29 Sep 1946; POB Nicaragua; nationality Nicaragua; citizen Nicaragua; Gender Male; Passport A005297 (Nicaragua) (individual) [NICARAGUA].

Designated pursuant to section 1(a)(iii) of Executive Order 13851 of November 27, 2018, ''Blocking Property of Certain Persons Contributing to the Situation in Nicaragua (''E.O. 13851''), for being an official of the Government of Nicaragua or having served as an official of the Government of Nicaragua at any time on or after January 10, 2007.

### Entity

1. GENERAL DIRECTORATE OF MINES (Latin: DIRECCIÓN GENERAL DE MINAS), Barrio Largaespada, Hospital Bautista 1c Oeste 1c Norte, Managua, Nicaragua; Organization Type: Mining of other non-ferrous metal ores; Target Type State-Owned Enterprise [NICARAGUA] (Linked To: MANSELL CASTRILLO, Salvador).

Designated pursuant to section 1(a)(v) of E.O. 13851, for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Salvador MANSELL CASTRILLO, a person whose property and interests in property are blocked pursuant to E.O. 13851.

Dated: October 24, 2022.

**Andrea M. Gacki,**

*Director, Office of Foreign Assets Control, U.S. Department of the Treasury.*

[FR Doc. 2022–23493 Filed 10–27–22; 8:45 am]

**BILLING CODE 4810–AL–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### Proposed Extension of Information Collection Request Submitted for Public Comment; Comment Request Concerning Information Reporting for Payments Made in Settlement of Payment Card and Third-Party Network Transactions

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently, the IRS is soliciting comments concerning information reporting for payments made in settlement of payment card and third-party network transactions.

**DATES:** Written comments should be received on or before December 27, 2022 to be assured of consideration.

**ADDRESSES:** Direct all written comments to Andrés Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov.* Please include, ''OMB Number: 1545–2205—Public Comment Request Notice'' in the Subject line.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the form and instructions should be directed to Ronald J. Durbala, at (202) 317–5746, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *RJoseph.Durbala@irs.gov.*

**SUPPLEMENTARY INFORMATION:**

*Title:* Information Reporting for Payments Made in Settlement of Payment Card and Third-Party Network Transactions.

*OMB Number:* 1545–2205.

*Regulation Project Number:* TD 9496, Form 1099–K.

*Abstract:* This information collection covers final regulations implementing amendments to the Income Tax Regulations (26 CFR part 1) relating to information reporting under sections 6041, 6041A, 6050W, and 6051 of the Internal Revenue Code (Code). The form reflects payments made in settlement of merchant card and third-party network transactions for purchases of goods and/or services made with merchant cards and through third-party networks.

*Current Actions:* There is an increase in the estimated number of respondents previously approved by OMB.

*Type of Review:* Revision of a currently approved collection.

*Affected Public:* Individuals or households, Business or other for-profit groups, Not-for-profit institutions, Farms, Federal Government, State, Local, or Tribal Governments.

*Estimated Number of Respondents:* 10,000,000.

*Estimated Time per Respondent:* 28 minutes.

*Estimated Total Annual Burden Hours:* 4,800,000.

The following paragraph applies to all the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

*Desired Focus of Comments:* The Internal Revenue Service (IRS) is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* by permitting electronic submissions of responses.

Comments submitted in response to this notice will be summarized and/or included in the ICR for OMB approval of the extension of the information collection; they will also become a matter of public record.

Approved: October 25, 2022.

**Ronald J. Durbala,**

*IRS Tax Analyst.*

[FR Doc. 2022–23521 Filed 10–27–22; 8:45 am]

**BILLING CODE 4830–01–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### Proposed Extension of Information Collection Request Submitted for Public Comment; Comment Request Concerning Source of Income From Certain Space and Ocean Activities; Source of Communications Income

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently, the IRS is soliciting comments concerning source of income from certain space and ocean activities, source of communications income.

**DATES:** Written comments should be received on or before December 27, 2022 to be assured of consideration.

**ADDRESSES:** Direct all written comments to Andrés Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov.* Please include, ''OMB Number: 1545–1718—Public Comment Request Notice'' in the subject line.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the form and instructions should be directed to Ronald J. Durbala, at (202) 317–5746, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *RJoseph.Durbala@irs.gov.*

**SUPPLEMENTARY INFORMATION:**

*Title:* Source of Income from Certain Space and Ocean Activities; Source of Communications Income.

*OMB Number:* 1545–1718.

*Regulation Project Number:* TD 9305.

*Abstract:* TD 9305 contains final regulations under section 863(d) governing the source of income from certain space and ocean activities. The final regulations primarily affect persons who derive income from activities conducted in space, or on or under water not within the jurisdiction of a foreign country, possession of the United States, or the United States (in international water). The final regulations also affect persons who derive income from transmission of communications.

*Current Actions:* There is no change to the burden previously approved by OMB.

*Type of Review:* Extension of a currently approved collection.

*Affected Public:* Business or other for-profit organizations.

*Estimated Number of Respondents:* 250.

*Estimated Time per Respondent:* 6 hours.

*Estimated Total Annual Burden Hours:* 1,500.

The following paragraph applies to all the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

*Desired Focus of Comments:* The Internal Revenue Service (IRS) is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* by permitting electronic submissions of responses.

Comments submitted in response to this notice will be summarized and/or included in the ICR for OMB approval of the extension of the information collection; they will also become a matter of public record.

Approved: October 25, 2022.

**Ronald J. Durbala,**

*IRS Tax Analyst.*

[FR Doc. 2022–23495 Filed 10–27–22; 8:45 am]

**BILLING CODE 4830–01–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### Internal Revenue Service Advisory Council; Meeting

**AGENCY:** Internal Revenue Service, Department of Treasury.

**ACTION:** Notice of meeting.

**SUMMARY:** The Internal Revenue Service Advisory Council will hold a public meeting.

**DATES:** The meeting will be held Wednesday, Nov. 16, 2022.

**ADDRESSES:** The meeting will be held in person.

**FOR FURTHER INFORMATION CONTACT:** Ms. Stephanie Burch, Office of National Public Liaison, at 202–317–4219 or send an email to *PublicLiaison@irs.gov.*

**SUPPLEMENTARY INFORMATION:** Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988), that a public meeting of the Internal Revenue Service Advisory Council (IRSAC) will be held on Wednesday, Nov. 16, 2022, from 9:00 a.m. to 1:00 p.m. EST.

The meeting will be held in person at 1111 Constitution Ave. NW, Washington, DC. To register, members of the public may contact Ms. Stephanie Burch at 202–317–4219 or send an email to *PublicLiaison@irs.gov.* Attendees are encouraged to arrive at the IRS visitor center at 1111 Constitution Ave. NW at least 30 minutes before the meeting begins.

Issues to be discussed may include, but are not limited to: *IRS Business and IT Modernization; Reduction in Electronic Filing Threshold for Information Reporting Filers; Alignment of Electronic Signature Requirements on Withholding Certificates; Section 1446(f): Withholding on Transfers of Interests in Publicly Traded Partnerships; Enabling Business Online Accounts and Electronic Communications and Transactions; Wage Reporting for Payments to Incarcerated Individuals; Accelerate Issuance of IRS Form 6166, Certification of U.S. Residency; Retaining Different Corporate Addresses for Different Types of Tax; Procedures for Partners that Receive Late Schedule K–1 Filings;*

*Improvements to the Bridge Phase of the CAP; Examination Customer Coordination and Innovation Office; Improving the Taxpayer Experience in Docketed Cases within the Jurisdiction of the Independent Office of Appeals that Arise from Compliance Actions by the IRS' Correspondence Examination to Automated Underreporter Functions as well as Feedback Regarding Examination's efforts to Improve Taxpayer Experience with Respect to those Functions; Series 8038 Form Redesign and Updates; Recommendations for Employee Plan Examination Compliance Approaches; Recommendations for Changes to Group Trust Rules; Recommendations to TEOS Improvements; Recommendations for Effective State Engagement to Promote Employment Tax Compliance; Business Master File (BMF) Transcript Delivery Service (TDS); Artificial Intelligence BOTS for Customer Service; Tax Pro Account Online Features; Form SS–4, EIN Application, Daily Limit per Responsible Party.* Last-minute agenda changes may preclude advance notice.

Time permitting, at the end of the meeting, interested persons may make oral statements germane to the Council's work. Persons wishing to make oral statements should contact Ms. Stephanie Burch at *PublicLiaison@irs.gov* and include the written text or outline of comments they propose to make orally. Such comments will be limited to five minutes in length. In addition, any interested person may file a written statement for consideration by the IRSAC by sending it to *PublicLiaison@irs.gov.*

Dated: October 25, 2022.

**John A. Lipold,**

*Designated Federal Officer, Internal Revenue Service Advisory Council.*

[FR Doc. 2022–23555 Filed 10–27–22; 8:45 am]

**BILLING CODE 4830–01–P**

## UNIFIED CARRIER REGISTRATION PLAN

### Sunshine Act Meetings

**TIME AND DATE:** November 3, 2022, 12:00 p.m. to 2:00 p.m., Eastern time.

**PLACE:** This meeting will be accessible via conference call and via Zoom Meeting and Screenshare. Any interested person may call (i) 1–929–205–6099 (US Toll) or 1–669–900–6833 (US Toll) or (ii) 1–877–853–5247 (US Toll Free) or 1–888–788–0099 (US Toll Free), Meeting ID: 970 7034 2913, to listen and participate in this meeting. The website to participate via Zoom Meeting and Screenshare is *https://kellen.zoom.us/meeting/register/tJMtcOmrqjkjG9cEqwF5TiaK9zDVwh0Km7e4.*

**STATUS:** This meeting will be open to the public.

**MATTERS TO BE CONSIDERED:** The Unified Carrier Registration Plan Audit Subcommittee (the ''Subcommittee'') will continue its work in developing and implementing the Unified Carrier Registration Plan and Agreement. The subject matter of this meeting will include:

**Proposed Agenda**

**I. Call to Order—UCR Audit Subcommittee Chair**

The UCR Audit Subcommittee Chair will welcome attendees, call the meeting to order, call roll for the Audit Subcommittee, confirm whether a quorum is present, and facilitate self-introductions.

**II. Verification of Publication of Meeting Notice—UCR Executive Director**

The UCR Executive Director will verify the publication of the meeting notice on the UCR website and distribution to the UCR contact list via email followed by the subsequent publication of the notice in the **Federal Register**.

**III. Review and Approval of Subcommittee Agenda and Setting of Ground Rules—UCR Audit Subcommittee Chair**

*For Discussion and Possible Audit Subcommittee Action*

The agenda will be reviewed, and the Subcommittee will consider adoption.

Ground Rules

➢ Subcommittee action only to be taken in designated areas on the agenda.

**IV. Review and Approval of Subcommittee Minutes From the September 8, 2022 Meeting—UCR Audit Subcommittee Chair**

*For Discussion and Possible Subcommittee Action*

Draft minutes from the September 8, 2022 Subcommittee meeting via teleconference will be reviewed. The Subcommittee will consider action to approve.

**V. Review the Compliance Evaluation Tools for the Annual State Audit Progress Report—UCR Audit Subcommittee Chair**

The UCR Audit Subcommittee Chair will discuss the recently adopted evaluation tools for the participating states' audit programs that are currently required by the UCR Agreement.

**VI. Discuss Options for DSL Transportation Services, Inc. (DSL) to Close Out FARs in the National Registration System (NRS) on Behalf of the States Once the Motor Carrier Makes the Appropriate Adjustment—UCR Audit Subcommittee Chair, UCR Audit Subcommittee Vice-Chair and DSL Transportation Services, Inc. (DSL)**

The UCR Audit Subcommittee Chair, Vice-Chair and DSL Representative will provide an update on how this service is working with the non-participating States Focused Anomaly Reviews (FARs.)

**VII. Review Recent Updates to the UCR Handbook—UCR Audit Subcommittee Chair, UCR Executive Director**

The UCR Audit Subcommittee Chair and UCR Executive Director will lead a discussion on updating and clarifying the language in the UCR Handbook in regard to the usage of the term ''operated'' as it relates to a motor carrier beginning operations. A general update on other revisions to the UCR Handbook will also be provided.

**VIII. Update on the State Compliance Review Program—UCR Audit Subcommittee Chair**

The UCR Audit Subcommittee Chair and Contractors will lead discussion on program objectives and states scheduled for review in 2022.

**IX. Maximizing the Value of the Should Have Been (SHB) and Enforcement Efficiency Tools—UCR Audit Subcommittee Chair, UCR Audit Subcommittee Vice-Chair and DSL Transportation Services, Inc. (DSL)**

The UCR Audit Subcommittee Chair, Vice-Chair and DSL will provide an update on the value achieved by utilizing Shadow MCMIS and other tools in the NRS. The discussion will highlight the financial value to the states of vetting businesses for UCR compliance, Commercial registration, IFTA, intrastate, and interstate Operating Authority.

**X. Discuss Options for Future Audit Zoom Training Sessions for States Auditors—UCR Audit Subcommittee Chair**

The UCR Audit Subcommittee Chair, UCR Audit Subcommittee Vice-Chair, DSL and Kellen representatives will lead a discussion regarding the value of a series of 30-minute virtual audit training sessions.

**XI. Discuss Options for Hosting a Monthly Question and Answer Session for States Auditors—UCR Audit Subcommittee Chair and UCR Audit Subcommittee Vice-Chair**

The UCR Audit Subcommittee Chair and UCR Audit Subcommittee Vice-Chair will lead a discussion regarding the value of a series of 60-minute virtual question and answer sessions.

**XII. Discuss Future Audit Subcommittee Meetings—UCR Audit Subcommittee Chair and UCR Audit Subcommittee Vice-Chair**

The UCR Audit Subcommittee Chair and Vice-Chair will lead discussion regarding virtual and in person meetings.

**XIII. Other Items—UCR Audit Subcommittee Chair**

The UCR Audit Subcommittee Chair will call for any other items Subcommittee members would like to discuss.

**XIV. Adjournment—UCR Audit Subcommittee Chair**

The UCR Audit Subcommittee Chair will adjourn the meeting.

The agenda will be available no later than 5:00 p.m. Eastern time, October 26, 2022 at: *https://plan.ucr.gov.*

**CONTACT PERSON FOR MORE INFORMATION:** Elizabeth Leaman, Chair, Unified Carrier Registration Plan Board of Directors, (617) 305–3783, *eleaman@board.ucr.gov.*

**Alex B. Leath,**

*Chief Legal Officer, Unified Carrier Registration Plan.*

[FR Doc. 2022–23632 Filed 10–26–22; 4:15 pm]

**BILLING CODE 4910–YL–P**

## DEPARTMENT OF VETERANS AFFAIRS

### Advisory Committee on Tribal and Indian Affairs, Notice of Meeting, Amended

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2., that the Advisory Committee on Tribal and Indian Affairs will meet at the VA Central Office, 810 Vermont Avenue NW, C–7 Conference Center, Washington, DC on November 8, 9, and 10, 2022. The meeting sessions will begin, and end as follows:

| Dates | Times |
|---|---|
| November 8, 2022. | 1:00 p.m.–4:00 p.m.—Eastern Standard Time (EST). |
| November 9, 2022. | 11:00 a.m.–4:00 p.m. EST. |
| November 10, 2022. | 10:00 a.m.–12:00 p.m. EST. |

The Advisory Committee on Tribal and Indian Affairs meetings will be open to the public (virtually) during the meeting times listed.

The purpose of the Committee is to advise the Secretary on all matters relating to Indian tribes, tribal organizations, Native Hawaiian organizations, and Native American Veterans. This includes advising the Secretary on the administration of healthcare services and benefits to American Indians/Alaska Native and Native Hawaiian Veterans; thereby assessing those needs and whether VA is meeting them. The Advisory Committee on Tribal and Indian Affairs is a newly formed FACA Committee.

On November 8, 2022, from 1:00 p.m. to 4:00 p.m. EST, the agenda will include opening remarks from the Committee Chair, Executive Sponsor, and other VA officials. There will be updates and proposed recommendations from the health subcommittee.

On November 9, 2022, from 11:00 a.m. to 4:00 p.m. EST, the agenda will include updates from the benefits and administrative subcommittees for proposed recommendations from each of the subcommittees. From 2:45 p.m. to 3:30 p.m. there will be Public Comment from those public members who have provided a written summary.

On November 10, 2022, from 10:00 a.m. to 12 p.m. EST, the Committee will receive updates from the VA Office of Tribal Health. The committee will hold open discussion on topics relevant to the Committee and address follow-up and action items including dates for next meeting.

The meetings are open to the public (virtually) and will be recorded. Members of the public can attend the meeting by joining the Zoom meeting at the link below. The link will be active from 12:00 p.m.–4:00 p.m. on Tuesday, 11:00 a.m.–4:00 p.m. on Wednesday, and 10:00 a.m.–12:00 p.m. on Thursday, November 8–10, 2022.

*Meeting Link: https://www.zoomgov.com/meeting/register/vJItcOmvpj0iE4NNl8171rq4-5GHvmMQHyk.*

Individuals who speak are invited to submit a 1–2-page summary of their comments no later than October 31, 2022, for inclusion in the official meeting record. Members of the public may also submit written statements for the Committee's review to Mr. David Clay Ward, at *david.ward@va.gov.* Any member of the public seeking additional information should contact Mr. David Clay Ward at 202–461–7445.

Dated: October 25, 2022.

**Jelessa M. Burney,**

*Federal Advisory Committee Management Officer.*

[FR Doc. 2022–23501 Filed 10–27–22; 8:45 am]

**BILLING CODE P**

# FEDERAL REGISTER

Vol. 87 Friday,

No. 208 October 28, 2022


Part II

## Federal Trade Commission

HISA Anti-Doping and Medication Control Rule; Notice

## FEDERAL TRADE COMMISSION

**[Matter No. P222100]**

## HISA Anti-Doping and Medication Control Rule

**AGENCY:** Federal Trade Commission.

**ACTION:** Notice of Horseracing Integrity and Safety Authority (HISA) proposed rule; request for public comment.

**SUMMARY:** The Horseracing Integrity and Safety Act of 2020 recognizes a self-regulatory nonprofit organization, the Horseracing Integrity and Safety Authority, which is charged with developing proposed rules on a variety of subjects. Those proposed rules and later proposed rule modifications take effect only if approved by the Federal Trade Commission. The proposed rules and rule modifications must be published in the **Federal Register** for public comment. Thereafter, the Commission has 60 days from the date of publication to approve or disapprove the proposed rule or rule modification. The Authority submitted to the Commission a proposed rule on Anti-Doping and Medication Control on August 17, 2022 and supplemented on October 13, 2022. The Office of the Secretary of the Commission determined that the proposal complied with the Commission's rule governing such submissions. This document publicizes the Authority's proposed rule text and explanation, and it seeks public comment on whether the Commission should approve or disapprove the proposed rule.

**DATES:** If approved, the HISA proposed rule would become effective January 1, 2023. Comments must be received on or before November 14, 2022.

**ADDRESSES:** Interested parties may file a comment online or on paper by following the instructions in the Comment Submissions part of the **SUPPLEMENTARY INFORMATION** section below. Write ''HISA Anti-Doping and Medication Control'' on your comment and file your comment online at *https://www.regulations.gov.* If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex B), Washington, DC 20580.

**FOR FURTHER INFORMATION CONTACT:** Austin King (202–326–3166), Associate General Counsel for Rulemaking, Office of the General Counsel, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

**SUPPLEMENTARY INFORMATION:**

### Table of Contents



### Background

The Horseracing Integrity and Safety Act of 2020 [1] recognizes a self-regulatory nonprofit organization, the Horseracing Integrity and Safety Authority, which is charged with developing proposed rules on a variety of subjects. Those proposed rules and later proposed rule modifications take effect only if approved by the Federal Trade Commission.[2] The proposed rules and rule modifications must be published in the **Federal Register** for public comment.[3] Thereafter, the Commission has 60 days from the date of publication to approve or disapprove the proposed rule or rule modification.[4]

Pursuant to Section 3053(a) of the Horseracing Integrity and Safety Act of 2020 and Commission Rule 1.142, notice is hereby given that, on August 17, 2022, and as supplemented on October 13, 2022, the Horseracing Integrity and Safety Authority (''HISA'' or the ''Authority'') filed with the Federal Trade Commission a proposed Anti-Doping and Medication Control rule and supporting documentation as described in Items I, II, III, IV, and IX below, which Items have been prepared by HISA. The Office of the Secretary of the Commission determined that the filing complied with the Commission's rule governing such submissions.[5] The Commission publishes this document to solicit comments on the proposed rule from interested persons.

[1] 15 U.S.C. 3051 through 3060.

[2] 15 U.S.C. 3053(b)(2).

[3] 15 U.S.C. 3053(b)(1).

[4] 15 U.S.C. 3053(c)(1).

[5] 16 CFR 1.140 through 1.144; *see also* Fed. Trade Comm'n, Procedures for Submission of Rules Under the Horseracing Integrity and Safety Act, 86 FR 54819 (Oct. 5, 2021).

### I. Self-Regulatory Organization's Statement of the Background, Purpose of, and Statutory Basis for, the Proposed Rule

*a. Background and Purpose*

The Act recognizes that the establishment of a national set of uniform standards for racetrack safety and medication control will enhance the safety and integrity of horseracing. As part of this endeavor, section 3053(a) of the Act directs the Authority to develop proposed rules relating to ''(2) a list of permitted and prohibited medications, substances, and methods, including allowable limits of permitted medications, substances, and methods; (3) laboratory standards for accreditation and protocols; [. . .] (8) a description of safety, performance, and anti-doping and medication control rule violations applicable to covered horses and covered persons; (9) a schedule of civil sanctions for violations; and (10) a process or procedures for disciplinary hearings.'' [6]

With the review, input, and ultimate approval of the Anti-Doping and Medication Control Standing Committee (''ADMC'') and the Authority's Board of Directors, the proposed rules: (1) set forth a list of anti-doping and controlled medication rules; (2) set forth a list of prohibited substances and methods; (3) set forth a framework for the testing of covered horses and the investigation of possible rule violations by the Horseracing Integrity and Welfare Unit (the ''Agency''); (4) set forth a framework by which laboratories will be accredited and will analyze samples for prohibited substances and markers of prohibited methods; (5) specify the civil sanctions that apply to anti-doping and controlled medication violations; (6) create procedures for disciplinary hearings, tailored to the nature of the charge. The Agency participated in the development of the proposed rule and approves of the rules as filed.

In compliance with 16 CFR 1.142(a), the Authority states that the reason for adopting the Protocol is that the Horseracing Integrity and Safety Act of 2020 (''Act'') mandates and empowers the Horseracing Integrity and Safety Authority (the ''Authority'') to establish a uniform anti-doping and controlled medication program to improve the integrity and safety of horseracing in the United States (''Program''). The Equine Anti-Doping and Controlled Medication Protocol (''Protocol'') has been developed and issued by the Authority as part of that mandate. It contains or incorporates by reference rules,

[6] 15 U.S.C. 3053(a)(2)–(3), (8)–(10).

standards, and procedures to improve and protect the integrity and safety of horseracing in the United States by deterring and penalizing the improper administration or application of Prohibited Substances and Prohibited Methods to Covered Horses. The Protocol is split into five chapters: (1) the purpose, scope, and organization of the Protocol; (2) the Prohibited List, rules of proof, and testing and investigations; (3) the Equine Anti-Doping Rules; (4) the Equine Controlled Medication Rules; and (5) other violations and general procedure/administration.

The Protocol has intentionally divided the regulation of Anti-Doping Rule Violations and Controlled Medication Rule Violations into separate chapters to reflect the Authority's view that the treatment of such violations should be separate and distinct from each other. Anti-Doping Rule Violations involve Banned Substances or Banned Methods, which are substances/methods that should never be in a horse's system or used on a horse as they serve no legitimate treatment purpose. Conversely, Controlled Medication Rule Violations involve Controlled Medication Substances or Controlled Medication Methods, which are substances/methods that have been determined to have appropriate and therapeutic purposes, and so may be used outside the Race Period, except if specified otherwise.

The Protocol and related rules are intended to address the need for uniformity in horseracing, to protect the welfare of Covered Horses, to safeguard the integrity of horseracing, and to ensure the confidence of stakeholders (including the betting public) in the sport. Prior to the implementation of the Authority, horseracing has been regulated in the United States by the States. By its nature, this results in a lack of uniformity in the rules of horseracing, including in many vital areas of equine safety and the proper regulation of the use of prohibited substances. Congress acted to impose a comprehensive program that would effectively regulate horseracing with a common set of rules. The Protocol was developed in collaboration with industry experts and stakeholders who brought to the endeavor an unparalleled depth of equine safety, anti-doping, veterinary medicine, sports integrity, and compliance experience. The Protocol will provide one standard set of rules that apply to doping and medication control, laboratory drug testing methods and techniques, sample collection procedures, investigatory procedures, and hearing and adjudication procedures that will enhance the effective regulation of horse safety and medication issues.

In considering reasonable alternatives to the proposed rule or modification that may accomplish the stated objective, it is important to underline that the Authority and the development of the Protocol is unprecedented. As a consequence, there are of course countless ''alternatives'' on various issues, but the Authority has sought to combine the best practice elements from various sources, including rules and practices developed by the global anti-doping community, horseracing authorities (national and international), and other equine sport organizations.

The Protocol will affect Covered Persons, Covered Horses, and Covered Horseraces by ensuring that horseracing is conducted in a manner that is consistent with the highest standards of integrity and that prioritizes the safety of Covered Horses and Covered Persons. The welfare of Covered Horses is secured by rules that strictly ban and penalize the use of doping substances and methods, and that sanction the misuse of therapeutic medications. All Covered Persons are required to comply with the Protocol and related rules, and to cooperate with the Authority and the Agency in relation to all aspects of doping and medication control, including sample collection, testing, and investigation procedures. The manner in which the Protocol implements these requirements is outlined in detail in Item II of this Document.

In developing the Protocol and related rules in a manner that is consistent with the Act and the rules and regulations applicable to the Authority, the Authority took the following principles and mandates into consideration, as directed by section 3055(b) of the Act:

(1) Covered Horses should compete only when they are free from the influence of medications, other foreign substances, and methods that affect their performance. The entire Protocol is dedicated to this principle, and the elaborate anti-doping and controlled medication rules work toward the objective of ensuring that Covered Horses compete in a manner that is free of the influence of doping substances, medications, and methods that affect their performance. The Prohibited List and related Technical Document prescribe the substances and methods that are prohibited and permitted under certain circumstances. The Standards (Rules 5000 and 6000 Series) set out comprehensive investigatory and sample collection provisions and an accreditation system that ensures accurate laboratory testing, and the Arbitration Procedures establish a set of disciplinary procedures to deal fairly but firmly with violations of the rules.

(2) Covered Horses that are injured or unsound should not train or participate in covered races, and the use of medications, other foreign substances, and treatment methods that mask or deaden pain in order to allow injured or unsound horses to train or race should be prohibited. In the Protocol, Rule 3111 operates together with the Prohibited List to ban substances and methods for which there exists medical, veterinary, or other scientific evidence or experience to a support their actual or potential masking properties (''Banned Substances'' and ''Banned Methods'') and to restrict the use of medications during the Race Period (''Controlled Medication Substances'' and ''Controlled Medication Methods''). Certain Controlled Medication Substances are also prohibited during workouts, as set out in the Prohibited List. The Protocol also operates in conjunction with the Rule 2000 Racetrack Safety Program, which sets forth stringent rules for placing Covered Horses on the Veterinarians' List and requires the Regulatory Veterinarian to oversee removal from the list. These processes help to ensure that injured and unsound horses do not train or participate in Covered Horseraces. It should also be noted that Rule 2271 in the Racetrack Safety Program prohibits the ''[u]se of physical or veterinary procedures to mask the effects or signs of injury so as to allow training or racing to the detriment of the Horse's health and welfare.''

(3) Rules, standards, procedures, and protocols regulating medication and treatment methods for Covered Horses and Covered Horseraces should be uniform and uniformly administered nationally. The Protocol preempts state laws and provides instead a uniform set of comprehensive rules that embrace all of the areas previously addressed in state anti-doping and medication control regulation schemes. The entire scheme will be administered nationally by the Authority and the Agency to ensure uniform and consistent application of the law. The Protocol and related rules will create a comprehensive program that is unprecedented in horseracing as previously conducted and regulated in the United States.

(4) Consideration should be given to international anti-doping and medication control standards of the International Federation of Horseracing Authorities (''IFHA'') and the Principles of Veterinary Medical Ethics of the

American Veterinary Medical Association. As directed by the Act, the ADMC has scrutinized the IFHA standards and rules very closely and also considered the Principles of Veterinary Medical Ethics of the American Veterinary Medical Association in preparing the Protocol. The World Anti-Doping Code also provided much of the inspiration for the Protocol, adapted as necessary for horseracing, taking into account national and international horseracing rules and Equine Anti-Doping and Controlled Medication Regulations of the International Equestrian Federation (*i.e.,* the global governing body for equestrian sport).

(5) The administration of medications and treatment methods to Covered Horses should be based upon an examination and diagnosis that identifies an issue requiring treatment for which the medication or method represents an appropriate component of treatment. The Protocol addresses the requirement for a sound diagnosis as a prerequisite for treatment and the need for such treatment not to be administered in a manner contrary to horse welfare. Specifically, Rule 3040(b)(3) states that it is the personal responsibility of each Responsible Person to ensure that treatments and medications administered to his or her Covered Horses (i) are administered only on the advice of a Veterinarian or (if a prescription is not required) following sufficient due diligence regarding the treatment or medication; (ii) are not administered in a manner detrimental or contrary to horse welfare; (iii) are the minimum necessary to address the diagnosed health concerns identified during the veterinary examination and diagnostic process; (iv) do not contain a Banned Substance or involve a Banned Method; and (v) do not otherwise violate the Protocol. Further, Rule 3314 penalizes use of a Controlled Medication Substance or Method in a manner that is contrary to horse welfare. In particular, Rule 3314(a) specifically mandates that any use of a Controlled Medication Substance or a Controlled Medication Method on a Covered Horse must ''(i) be justified by the Covered Horse's medical condition(s) as diagnosed by a Veterinarian, (ii) have been recommended by a Veterinarian in the context of a valid veterinarian-patient-client relationship, (iii) go no further than the minimum necessary to address the diagnosed health concerns, and (iv) be in the best interests of the Covered Horse's health and welfare.'' Rule 3314(b) also states that it is ''the personal and non-delegable duty of the Responsible Person'' to ensure the above requirements in Rule 3314(a) are complied with. The Protocol also establishes in Rules 3227 and 3327 that an aggravating circumstance that may be taken into account in assessing sanctions for a rule violation may include ''administration of a Controlled Medication Substance that is detrimental to the health and welfare of the horse or is designed to deceive the betting public.'' It should also be noted that Rule 2221 (of the previously approved Racetrack Safety Rule) also establishes examination and diagnoses requirements in the context of the veterinarian-client-patient relationship.

(6) The amount of therapeutic medication that a Covered Horse receives should be the minimum necessary to address the diagnosed health concerns identified during the examination and diagnostic process. As noted above, Rule 3040(b)(3) and Rule 3314 specifically address the requirement that any use of a Controlled Medication Substance or a Controlled Medication Method on a Covered Horse must go no further than ''the minimum necessary to address the diagnosed health concerns.''

(7) The welfare of Covered Horses, the integrity of the sport, and the confidence of the betting public require full disclosure to regulatory authorities regarding the administration of medications and treatments to Covered Horses. The Protocol addresses this issue in several ways. It requires all Covered Persons to cooperate promptly and completely with the Authority and the Agency in the exercise of their respective powers under the Act and the Protocol and related rules (Rule 3040(a)). Each Responsible Persons is required to maintain accurate, complete, and up-to-date treatment records of his or her Covered Horses in a form specified by the Agency, and to provide the records on request to the Agency (Rule 3040(b)(8)). Responsible Persons must declare to the Agency any use of Banned Substances or Banned Methods on a horse prior to it becoming a Covered Horse (Rule 3040(b)(9)). To facilitate out-of-competition testing, Responsible Persons must file whereabouts information if their Covered Horses are moved to a private facility (Rule 3040(b)(10)). Attending Veterinarians must keep updated treatment records in an electronic database designated by the Agency or in any other form designated by the Agency and must provide access on request to copies of these records (Rule 3040(d)). Refusal or failure to cooperate with the Authority or the Agency, or the commission of a Whereabouts Failure, constitutes a violation of the Protocol under Rule 3510. Several provisions in the Rule 2000 Series complement the Protocol's disclosure requirements. Rule 2551, for example, requires every Veterinarian who examines or treats a Covered Horse to submit to the Authority, within 24 hours of such examination or treatment medications, treatment records with details as prescribed in the Rule.

In further compliance with the Act, the Protocol establishes a comprehensive set of violations and hearing procedures to prohibit certain conduct, to provide a process for determining the existence of a violation; of charging a Covered Person with a violation; and with resolving the matter in a full and fair hearing process. The Protocol authorizes the imposition of sanctions that comport with the severity of the violation. Consistent with 15 U.S.C. 3057(d)(2), the violation and sanction system is tailored to the unique aspects of horseracing in that it has the power to declare a Covered Person or Covered Horse ineligible to race for a specified time, imposes substantial fines upon Covered Persons, and establishes a points system to implement a system of penalties for multiple violations of the Protocol. These penalties are common in the adjudication and sanction of violations in the world of horseracing. The sanctions also include forfeiture of purse, disqualification of horses, and changes to the order of finish in horse races. The elaborate hearing procedures and penalty rules ensure that violations are consistently and fairly penalized, which in turn deters future violations, and maintains the integrity and conduct of fair and transparent horseraces. Effective sample collection and testing techniques, as set forth in Rule Series 5000 and 6000 also serve to enhance successful prosecution of violations, which deter future violations. The goal of transparency is also served by operation of the public disclosure rules in the Protocol, which mandate that the public be informed of information concerning specific cases as the cases are adjudicated or otherwise resolved.

The components of the Protocol and related rules comport with the baseline standards in 15 U.S.C. 3055(g)(2)(a), which include: (1) the lists of permitted and prohibited substances (including drugs, medications, and naturally occurring substances and synthetically occurring substances) in effect for the International Federation of Horseracing Authorities, including the International Federation of Horseracing Authorities International Screening Limits for urine,

dated May 2019, and the International Federation of Horseracing Authorities International Screening Limits for plasma, dated May 2019; (2) the World Anti-Doping Agency International Standard for Laboratories (version 10.0), dated November 12, 2019; (3) the Association of Racing Commissioners International out-of-competition testing standards, Model Rules of Racing (version 9.2); and (4) the Association of Racing Commissioners International penalty and multiple medication violation rules, Model Rules of Racing (version 6.2). Any deviations from the baseline standards have been approved by the Authority and the Agency following detailed consideration and adoption of an approach that is either stricter or more consistent with horseracing.

[Technical document insert]

*b. Statutory Basis*

The Horseracing Integrity and Safety Act of 2020, 15 U.S.C. 3051 through 3060.

**II. Self-Regulatory Organization's Statement of the Terms of Substance of the Registration Proposed Rule and Discussion of Alternatives**

*a. Existing Standards*

Anti-doping and controlled medication rules currently vary from State to State, but the overall structure of the rules governing horseracing is generally consistent among the States. In particular, the rules of horseracing center around a number of common subject areas, including the licensing of racing associations and of individual participants in horseracing, medication control rules, pari-mutuel wagering rules, the operation of various incentive funds, rules concerning the running of the race, and rules establishing disciplinary measures and hearing procedures. The basic precepts of many of the rules pertaining to violations, sanctions, hearing procedures, and investigatory powers have been in force in racing states for many years, and the Authority has reviewed and considered key provisions from numerous states in developing these rules.

The Association of Racing Commissioners International (''ARCI'') sets forth standards and protocols in its Model Rules of Racing (''ARCI Rules''). Relying upon the collective expertise of regulatory personnel in member jurisdictions in consultation with regulated entities, industry stakeholders, and individuals, ARCI committees regularly consider ways to improve and enhance the regulation of racing. The Authority considered the ARCI Model Rules of Racing when developing the Protocol and related rules. Likewise, the Authority considered rules from other racing jurisdictions such as the British Horseracing Authority's Rules of Racing.

The Authority also considered and relied heavily on international anti-doping standards, including the World Anti-Doping Code (applicable to human athletes) and the International Equestrian Federation (''FEI'') Equine Anti-Doping and Controlled Medication Regulations (applicable at the international level to various equestrian disciplines). Those regulations provide a robust anti-doping framework that has been tested before arbitration tribunals for many years, and that has generated a well-developed body of precedent and guidance for interpreting the provisions in those frameworks.

The Authority, in consultation with the ADMC and the Agency, reviewed these existing standards and tailored them to the Authority's regulatory structure and goals, and to the specificities of horseracing.

The provisions of these Series were made publicly available on the Authority website at *www.hisaus.org/regulations* on June 1, 2022. A number of stakeholder comments were received, which are addressed further in Item III below. Additionally, the Authority consulted directly with a number of industry officials and participants in obtaining feedback on the proposed Rules. The Authority is submitting those comments along with this Notice of Filing as Exhibit A, which is available for public inspection at the corresponding docket at *https://www.regulations.gov*. Furthermore, all the important source materials on which the Authority relied in developing its proposed rule are also collected at that docket as Exhibit B.

*b. Terms of Substance: Rule Series 3000—Equine Anti-Doping and Controlled Medication Protocol*

1. Purpose, Scope, and Organization—Rules 3010–3090

Chapter I of the Protocol has been developed taking account of the requirements of the Act, including, in particular, those set out at sections 3054 and 3055 of the Act.

With the approval of the Commission, the Protocol will go into effect on January 1, 2023. It contains or incorporates by reference rules, standards, and procedures to improve and protect the integrity and safety of horseracing in the United States by deterring and penalizing the improper administration or application of Prohibited Substances and Prohibited Methods to Covered Horses. The Protocol is divided into five substantive chapters: (1) the purpose, scope, and organization of the Protocol; (2) the Prohibited List, rules of proof, and testing and investigations; (3) the Equine Anti-Doping Rules; (4) the Equine Controlled Medication Rules; and (5) other violations and general procedure/administration.

The Protocol has intentionally divided the regulation of Anti-Doping Rule Violations and Controlled Medication Rule Violations into separate chapters to reflect the Authority's view that the treatment of such violations should be separate and distinct from each other. Anti-Doping Rule Violations involve Banned Substances or Banned Methods, which are substances/methods that should never be in a horse's system or used on a horse as they serve no legitimate treatment purpose. Conversely, Controlled Medication Rule Violations involve Controlled Medication Substances or Controlled Medication Methods, which are substances/methods that have been determined to have appropriate and therapeutic purposes, and so may be used outside the Race Period, except if specified otherwise. This division accords with international best practices. However, the two distinct processes share many common features and rules, and therefore the Protocol is streamlined to make the processes consistent with each other wherever possible.

The Protocol will be implemented and enforced on behalf of the Authority by the Agency, which has created an entity designated as the Horseracing Integrity and Welfare Unit (''Agency''). In addition, and only where so agreed, State Racing Commissions acting under the delegated authority of the Authority or the Agency (Rule 3010(e)) may also assist in implementation.

In accordance with section 3055(a)(1) of the Act, the Protocol applies to all Covered Horses, Covered Persons, and Covered Horseraces (Rule 3020). Pursuant to section 3054 of the Act, Covered Persons must register with the Authority.

In developing the Protocol, the Authority reviewed and considered various anti-doping and controlled medication rules, including:

Exhibit B.2. ARCI Model Rules of Racing, including, in particular, the penalty provisions and rules on multiple medication violation.

Exhibit B.3. FEI Equine Anti-Doping & Controlled Medication Regulations.

Exhibit B.4. FEI Atypical Findings Policy.

Exhibit B.5. World Anti-Doping Code.

Exhibit B.6. British Horseracing Authority Equine Anti-Doping Rules.

2. Prohibited List, Rules of Proof, and Testing and Investigations—Rules 3110–3140

The Protocol incorporates the Prohibited List, which identifies the Banned Substances and Banned Methods that are prohibited at all times on the basis of the Agency's determination that medical, veterinary, or other scientific evidence or experience supports their actual or potential (i) ability to enhance the performance in Covered Horses, (ii) masking properties, or (iii) detrimental impact on horse welfare. The Prohibited List also identifies Controlled Medication Substances and Controlled Medication Methods, which are prohibited for Use on or Administration to a Covered Horse during the Race Period and must not be present in a Post-Race Sample or Post-Work Sample, except as specified otherwise. In other words, the phrase ''Prohibited Substances and Prohibited Methods'' refers to Banned Substances and Banned Methods as well as Controlled Substances and Controlled Medication Methods that are only restricted during the Race Period. The Prohibited List will be published at least annually (Rule 3112).

The Prohibited List is supplemented by the ''Technical Document—Prohibited Substances,'' which enumerates the Prohibited Substances that fall into the general categories listed in the Prohibited List and sets forth detection times, screening limits, and thresholds for those Prohibited Substances. The Technical document also designates certain Prohibited Substances as Specified Substances, which are those that pose a higher risk of being the result of contamination and that are, therefore, subject to more flexible sanctions.

In disciplinary cases brought under the Protocol, the Agency will have the burden of establishing that a violation of the Protocol has occurred to the comfortable satisfaction of the hearing panel, bearing in mind the seriousness of the allegation made (Rule 3121), and facts may be established by any reliable means (Rule 3122). The ''comfortable satisfaction'' standard of proof is greater than a mere balance of probability (*i.e.,* a preponderance of the evidence) but less than clear and convincing evidence or proof beyond a reasonable doubt (Rule 3121).

Only the Agency (and those authorized by the Agency) may initiate and direct testing on any Covered Horse. The Agency will have broad authority to conduct testing both in and out of competition (Rule 3132), and samples collected will be owned by the Authority (Rule 3135). Samples obtained from Covered Horses will be analyzed primarily to detect the presence of Prohibited Substances (Rule 3137).

State Racing Commissions, Racetracks, Race Organizers, and Training Facilities shall not initiate or direct any Testing of Covered Horses. However, they may request that the Agency initiate and direct enhanced or additional Testing (*e.g.,* in relation to a particular Covered Horserace). The Agency may accept or decline such request at its absolute discretion. Where the Agency accepts the request, the costs of Sample collection and analysis shall be borne by the entity requesting the additional or enhanced Testing. The Agency may conduct the Testing itself or delegate the Testing to the relevant State Racing Commission. (Rule 3132).

3. Equine Anti-Doping Rules—Rules 3210–3260

The Equine Anti-Doping Rules set out in Chapter III of the Protocol apply to conduct involving Banned Substances or Banned Methods, *i.e.,* substances and methods prohibited at all times. The violations set out in this Chapter are included as directed by section 3057(a)(2) of the Act, and are also substantively modelled on World Anti-Doping Code violations. The violations prohibit use, possession, trafficking, and administration to a Covered Horse of Banned Substances or Banned Methods (Rules 3213 and 3214). It is a violation to evade, refuse or fail to submit a Covered Horse to sample collection (Rule 3215), and the presence of a Banned Substance in a sample collected from a Covered Horse is also a violation (Rule 3212). In accordance with section 3057(a)(2) of the Act, presence and use violations are strict liability offenses for the Responsible Person, although other Covered Persons may also be liable to the same extent if they are complicit in the violation. Other prohibited conduct includes tampering with doping control, complicity with another person's violation, associating with a person who is banned, and improper retaliation against actual or potential whistle-blowers or intimidation of witnesses (Rule 3216). Attempts to commit Anti-Doping Rule Violations are also sanctionable.

As directed by the Act, the Authority has developed a list of civil sanctions for Anti-Doping Rule Violations. The Protocol and Prohibited List establish uniform rules imposing civil sanctions against Covered Persons and Covered Horses for Anti-Doping Rule Violations (and also for Controlled Medication Rule Violations, addressed under chapter IV of the Protocol), as directed by section 3057(d) of the Act. The range of civil sanctions (a) take into account the unique aspects of horseracing; (b) are designed to ensure fair and transparent Covered Horseraces; and (c) are intended to deter violations. The severity of the sanctions depends on the nature of the violation, and allows an opportunity for adjustment in penalty depending on the violation and facts involved.

A mandatory part of each sanction will include Public Disclosure of relevant information, including the Covered Person's name, the violation, and consequences imposed (Rules 3231 and 3620).

If the violation arises from a Post-Race Sample or occurs during the Race Period, the Covered Horse's results at that Covered Horserace will automatically be disqualified, because the horse competed with a Banned Substance in its system, irrespective of the reason why the Banned Substance was there or any degree of fault on the part of the Covered Person (Rule 3221(a)). Subsequent results may also be disqualified (Rule 3221(b)) and in any case of disqualification, all purses and other compensation, prizes, trophies, points, and rankings are forfeited and must be repaid or surrendered to the race organizer, and the results of the other Covered Horses in the race in question must be adjusted accordingly (Rule 3221(c)).

The Protocol now also specifies what happens to the race classification pending the outcome of the disciplinary proceedings (Rules 3221 and 3321). Further, Rule 3221(a) allows for the Agency, the Responsible Person, and the Owner of the Covered Horse in question to agree (or to ask the Arbitral) to apply Rule 3221 immediately, *i.e.,* prior to adjudication of any other issue.

In presence or use cases, the Covered Horse will be subject to a period of ineligibility, the length of which depends on the particular Banned Substance(s) detected, as set out in the Prohibited List. During any period of ineligibility, the Covered Horse shall not participate in any Workout or Covered Horserace, but will remain subject to testing (Rule 3229).

The Covered Person will be sanctioned with a period of ineligibility commensurate to his or her level of fault, in accordance with a detailed sanctioning framework. The starting point for presence, use, possession, or administration violations is a period of

ineligibility of two years, subject to elimination or reduction if the Covered Person can demonstrate that he or she bears no or no significant fault or negligence, or subject to increase if aggravating circumstances are present (Rules 3223(b), 3224, and 3225). For other violations, the rules specify other starting points or ranges for the applicable period of ineligibility that reflect the seriousness of the violation (Rule 3223(b)). The rules also provide the Authority with the ability to eliminate or reduce an applicable period of ineligibility in circumstances where a Covered Person provides Substantial Assistance or admits the violation early or in the absence of other evidence (Rule 3226). There are also increased sanctions for repeat offenders (Rule 3228). During any period of ineligibility, the Covered Person shall not participate in any capacity in any activity involving Covered Horses or in any other activity (other than authorized anti-doping education or rehabilitation programs) taking place at a Racetrack or Training Facility; nor shall he or she permit anyone to participate in any capacity on his or her behalf in any such activities (Rule 3229(a)). The Covered Horse(s) of an Owner or Trainer subject to a Provisional Suspension or period of Ineligibility shall also be subject to restrictions (Rule 3229(b)).

The Covered Person may also be required to pay a fine, depending on the violation, and some or all of the Agency's legal costs (Rule 3223(b)).

Where a Covered Person is found based on the same facts to have committed a violation involving both (i) one or more Banned Substance(s) or Banned Method(s), and (ii) one or more Controlled Medication Substance(s) or Controlled Medication Method(s), the Covered Person shall be considered to have committed one Anti-Doping Rule Violation and the sanction imposed shall be based on the Banned Substance or Banned Method that carries the most severe sanction. Rule 3227 (Aggravating Circumstances) may also be applied to increase the sanction imposed (Rule 3228(d)).

The Equine Anti-Doping Rules provide a framework for the results management of potential anti-doping rule violations, as directed by the Act. Different types of Samples may be collected from Covered Horses, including urine, blood, and hair. Unless specified otherwise in the rules, at the time of collection, the Sample will be divided into an ''A'' and a ''B'' Sample. Review of ''A Sample'' adverse analytical findings or other evidence leads to an initial notification by the Agency to the Covered Person that he or she may have committed an anti-doping rule violation (Rule 3245). In some cases, the Covered Person will be provisionally suspended pending determination of the matter (Rule 3247), and the ''B Sample'' may be tested (Rule 3246). The Covered Person is entitled to respond to the Agency's initial notification, and if he or she does, the Agency will take any comments and additional information into account before deciding whether to formally charge the Covered Person with an anti-doping rule violation and request a more formal response (Rule 3248)).

The Covered Person is entitled to have the charge determined by the Arbitral Body (the panel hearing will consist of either one or three impartial arbitrators) in accordance with the Arbitration Procedures (Series 7000). The final decision of the Arbitral Body is subject to review in accordance with the Act (Rule 3264). The rules also provide for the Agency and Covered Person to agree to a resolution to the charge without a hearing (Rule 3249).

4. Equine Controlled Medication Rules—Rules 3310–3360

The Equine Controlled Medication Rules set out in Chapter IV of the Protocol apply to conduct involving Controlled Medication Substances or Controlled Medication Methods (*i.e.,* substances prohibited for use on or administration to a Covered Horse during the Race Period and prohibited to be present in a Post-Race Sample or Post-Work Sample, except as otherwise specified in the Prohibited List). The violations set out in this Chapter are drawn from similar provisions to those relating to Anti-Doping Rule Violations, modified to reflect the differing approaches to the use of Controlled Medication Substances and Controlled Medication Methods, as opposed to Banned Substances and Banned Methods. The violations include the use, possession, or administration to a Covered Horse of Controlled Medication Substances or Controlled Medication Methods during the Race Period (Rules 3313 and 3315). Other violations include use of a Controlled Medication Substance that is not justified by the horse's medical condition or does not meet other criteria (Rule 3314), tampering with medication control (Rule 3316), and the presence of a Controlled Medication Substance in a sample collected from a Covered Horse (Rule 3312). In accordance with section 3057(a)(2) of the Act, presence and use violations are considered strict liability offenses. Attempts to commit Controlled Medication Rule Violations are also sanctionable.

As directed by the Act, the Authority has developed a list of civil sanctions for Controlled Medication Rule Violations. The Protocol and Prohibited List establish uniform rules imposing civil sanctions against Covered Persons and Covered Horses for Controlled Medication Rule Violations, as directed by section 3057(d) of the Act. The range of civil sanctions (a) take into account the unique aspects of horseracing; (b) are designed to ensure fair and transparent Covered Horseraces; and (c) are intended to deter violations. The severity of the sanctions depends on the nature of the violation, and allows an opportunity for adjustment depending on the violation and facts involved.

A mandatory part of each sanction will include Public Disclosure of relevant information, including the Covered Person's name, the violation, and consequences imposed (Rules 3331 and 3620).

If the violation arises from a Post-Race Sample or occurs during the Race Period, the Covered Horse's results at that Covered Horserace will automatically be disqualified, with all resulting consequences, because the horse competed with a Controlled Medication Substance in its system. The results will be automatically disqualified irrespective of the reason why the Controlled Medication Substance was detected or of any degree of fault on the part of the Covered Person (Rule 3321(a)). Subsequent results will not be disqualified (Rule 3321(b)).

The Covered Horse will not be subject to a period of ineligibility if the violation involves a Controlled Medication Substance, but may be subject to a period of ineligibility if the violation involves a Controlled Medication Method as specified in the Prohibited List (Rule 3322).

Covered Persons shall be sanctioned for any Controlled Medication Rule Violations in accordance with Rule 3323(b), depending on the category or class of the violation, and the number of violations committed within that same category/class in the previous two-year period. Presence, use, and administration violations are divided into three different classes (Class A, Class B, Class C) with Class A carrying the more severe sanctions. The sanctions for Controlled Medication Rule Violations are subject to elimination (Rule 3324), reduction (Rules 3325 and 3326), or increase (Rule 3327), depending on the violation in issue and the specific circumstances of the case.

The Protocol also establishes a multiple medication violation penalty

points system for repeat offenders which takes account of violations committed in different categories/classes (Rule 3328). As directed by section 3055(g) of the Act, the Authority used the Association of Racing Commissioners International penalty and multiple medication violation rules, Model Rules of Racing, as a baseline for the multiple violations penalty points system. All adjustments and modifications to the baseline rules were approved by the Authority in consultation with the ADMC and the Agency in accordance with section 3055(g)(3) of the Act.

The penalty points system is not a substitute for the consequences that apply to the underlying Controlled Medication Rule Violations. Rather, the penalty points system is intended to apply additional uniform Consequences where the Covered Person is a repeat offender and exceeds the permissible number of points. Where the relevant cumulative point threshold is exceeded, the Covered Person shall receive an automatic additional period of ineligibility as specified in Rule 3328(c). Penalty points are assigned automatically depending on the category/class of violation in issue, save where specified otherwise in Rule 3328. Penalty points and the additional period of Ineligibility shall be applied automatically at the conclusion of the proceeding on the underlying violation, without any additional hearing or right of review. Penalty points shall be applied retroactively to start on the date on which the Controlled Medication Rule Violation occurred and shall expire after 2 years (Rule 3328(d)).

During any period of Ineligibility or Provisional Suspension, Covered Persons shall be prohibited from the same activities as anyone banned for an Anti-Doping Rule Violation. As for Anti-Doping Rule Violations, the Covered Horses of a suspended Trainer or Owner may not participate in any Timed and Reported Workout or Covered Horserace, but in contrast to Anti-Doping Rule Violations, they may participate in a Covered Horserace if they were entered in the race before the Trainer was notified of the Provisional Suspension or the period of Ineligibility was imposed (whichever is earlier) (Rule 3320(b)). Further, in contrast to Anti-Doping Rule Violations, the Covered Horses of a suspended Trainer must only be transferred to another Covered Person if the period of ineligibility imposed on the Trainer is more than 30 days (Rule 3329(b)).

The Covered Person may also be required to pay a fine depending on the category of the violation, and some or all of the Agency's legal costs (Rule 3323(b)).

The Equine Controlled Medication Rules provide a framework for the results management of potential controlled medication rule violations as directed by the Act, from review of ''A Sample'' adverse analytical findings or other evidence leading to an initial notification by the Agency to the Covered Person that he or she may have committed a controlled medication rule violation (Rule 3345). The Covered Person will not be provisionally suspended pending determination of the matter unless he or she voluntarily accepts a provisional suspension (Rule 3347), and the B Sample may be tested (Rule 3346). The Covered Person is entitled to respond to the Agency's initial notification, and if he or she does, the Agency will take any comments and additional information into account before deciding whether to formally charge the Covered Person with a controlled medication rule violation and request a more formal response (Rule 3348).

The Covered Person is entitled to request a hearing before the Internal Adjudication Panel. The hearing will ordinarily be conducted before a single member of the Internal Adjudication Panel, though three members may be assigned to hear the case where appropriate. The Internal Adjudication Panel may decide in its sole discretion to determine the matter on the written submissions alone without a hearing if the Internal Adjudication Panel considers itself sufficiently well-informed to render a decision on the written submissions alone. The Internal Adjudication Panel will issue a final decision, subject to review in accordance with the Act (Rules 3361–3364).

The rules also provide for the Agency and Covered Person to agree to a resolution to the charge without a hearing (Rule 3349).

5. Other Violations and General Procedure/Administration—Rules 3500–3800

Chapter V sets out additional disciplinary offenses that do not fall within the chapters on Equine Anti-Doping Rules or Equine Controlled Medication Rules (Rule 3510), and also prescribes sanctions (periods of ineligibility and fines) for those violations (Rule 3520). Those violations include engaging in disruptive or offensive conduct towards doping control personnel, refusing/failing to cooperate in full with the Authority or Agency in the discharge of his or her respective responsibilities under this Protocol, and committing a whereabouts failure (in effect, failing to provide the necessary information to enable a Covered Horse to be located for testing). Alleged violations will be determined by the Internal Adjudication Panel (Rule 3361).

In accordance with section 3057(c)(2) of the Act, the rules provide guidelines for confidentiality and public reporting of decisions (Rules 3610–3630). Rule 3710 also provides for the recognition of decisions by recognized, official third parties, for example, national horseracing authorities in other countries applying substantially similar rules (Rule 3700).

*c. Terms of Substance: Rule Series 1000—General Provisions*

The Protocol and other Series are supported by the general rules of interpretation (Rule 1010) and a list of defined terms (Rule 1020) to assist with clarity of meaning.

*d. Terms of Substance: Rule Series 4000—Prohibited List*

As directed by sections 3053 and 3055 of the Act, the Authority has developed a list of permitted and prohibited medications, substances, and methods, including allowable limits of permitted medications, substances, and methods, using as a baseline the lists of permitted and prohibited substances (including drugs, medications, and naturally occurring substances and synthetically occurring substances) in effect for the International Federation of Horseracing Authorities (''IFHA''), including the IFHA International Screening Limits for urine and the IFHA International Screening Limits for plasma. All adjustments and modifications to the baseline rules were approved by the Authority in consultation with the ADMC and the Agency in accordance with section 3055(g)(3) of the Act.

The Prohibited List identifies Prohibited Substances and Prohibited Methods that are: (a) prohibited at all times (''Banned Substances'' and ''Banned Methods'') on the basis of the Agency's determination that medical, veterinary, or other scientific evidence or experience supports their actual or potential (i) ability to enhance the performance in Covered Horses, (ii) masking properties, or (iii) detrimental impact on horse welfare; or (b) prohibited for Use on or Administration to a Covered Horse during the Race Period and prohibited to be present in a Post-Race Sample (which includes samples collected following a Covered Horserace or Vets' List Workout) or Post-Work Sample (which includes samples collected following a Timed

and Reported Workout), except as otherwise specified in the Prohibited List (''Controlled Medication Substances'' and ''Controlled Medication Methods''). Prohibited Substances and Prohibited Methods may be included in the Prohibited List by general category (*e.g.,* anabolic steroids) or by specific reference to a particular substance or method.

The Prohibited List is supplemented by the ''Technical Document—Prohibited Substances,'' which enumerates the Prohibited Substances that fall into the general categories listed in the Prohibited List and sets forth detection times, screening limits, and thresholds for those Prohibited Substances. The Technical Document also designates certain Prohibited Substances as Specified Substances, which are those that pose a higher risk of being the result of contamination and that are therefore subject to more flexible sanctions.

In accordance with section 3055(d) of the Act, the use or administration of Controlled Medication Substances and Controlled Medication Methods is prohibited during the ''Race Period'' (*i.e.,* 48 hours prior to post-time) except where expressly provided otherwise in the Prohibited List or Protocol. Responsible Persons are strictly liable for any substance found to be present in a Post-Race Sample or Post-Work Sample, even if such substance was used or administered before the Race Period. As specified in section 3055(e) and (f) of the Act, certain exemptions apply to furosemide (*i.e.,* Lasix/Salix), which are set out in the Prohibited List.

The Prohibited List and supporting Technical Document were prepared in consultation with the ADMC and the Agency, and approved by the Authority, as directed by section 3055(c)(5) of the Act. In preparing the Prohibited List and the ''Technical Document—Prohibited Substances,'' the Authority considered lists of prohibited substances and methods published by other organizations, including the ARCI, WADA, the FEI, and the British Horseracing Association. Documents considered in preparing the Prohibited List are exhibited below:

Exhibit B.7. IFHA International Screening Limits for urine.

Exhibit B.8. IFHA International Screening Limits for plasma.

Exhibit B.9. ARCI Uniform Classification Guidelines for Foreign Substances and Recommended Penalties Model Rule.

Exhibit B.10. WADA 2022 Prohibited List.

Exhibit B.11. 2022 FEI Equine Prohibited Substances List.

Exhibit B.12. British Horseracing Association Equine Prohibited List Code (2022).

Exhibit B.13. British Horseracing Association Published Detection Times (June 2019).

Exhibit B.14. Hong Kong Jockey Club Medication and Prohibited Substances.

The ADMC also considered a number of scientific papers when developing the Prohibited List and supporting Technical Document:

Exhibit B.15. AAS 16 Detection of Some Designer Steroids in Horse Urine: Identifies the integrity risks associated with the use of anabolic steroids in racehorses.

Exhibit B.16. AAS 29 Anabolic Effects of β2-agonists, formoterol and salbutamol on cancellous bone of ovariectomized (OVX) rat: With the banning of anabolic steroids, those seeking an anabolic effect turned to β2-agonists. Their misuse has been well-documented in horses engaged in racing and training.

Exhibit B.17. ACA 01 Effects of intravenous aminocaproic acid on exercise-induced pulmonary haemorrhage (EIPH): Although this drug has extensive anecdotal support for effect in mitigating EIPH, this article demonstrates no effect on the condition. While not regulated in human sport, the illicit use of this substance, particularly in races where furosemide is prohibited, represents an integrity threat.

Exhibit B.18. AU 04 Disposition of the anti-ulcer medications ranitidine, cimetidine, and omeprazole following administration of multiple doses to exercised Thoroughbred horses. The results of multiple RMTC administration studies supporting the use of anti-ulcer medications up to 24 hours prior to a horse's race.

Exhibit B.19. Bicarb 08 Sodium Bicarbonate as an Ergogenic Aid: Supports the use of alkalinizing agents as a Prohibited Method.

Exhibit B.20. BP Gen 04 Bisphosphonate Therapy in Equine Sports Medicine: While having legitimate use in human medicine, the documented pharmacologic effect of this class of drug (blocking remodeling) on bone represents a significant increased risk for fracture development in the racehorse.

Exhibit B.21. Cobalt 01 The Disparate Roles of Cobalt in Erythropoiesis, and Doping Relevance: Establishes the relevance of the administration of cobalt salts as a doping threat and justifies the controls established in the Prohibited List.

Exhibit B.22. Comp 18 The Disparate Roles of Cobalt in Erythropoiesis, and Doping Relevance: Published by the American Veterinary Medical Association, this document clarifies what constitutes legal compounding of drugs as the ethical use of compounded medications is important to maintaining equine health. However, the compounding or administration of illicitly compounded substances to circumvent FDA oversight represents a substantial risk to horse health and racing integrity.

Exhibit B.23. EIPH 33 Exercise-induced pulmonary hemorrhage (EIPH): mechanistic bases and therapeutic interventions: Describes this condition (rarely, but occasionally, experienced by human athletes) that affects virtually every race horse at some point(s) in its racing and training career.

Exhibit B.24. Furos 15 Efficacy of furosemide in the treatment of exercise-induced pulmonary hemorrhage in Thoroughbred racehorses: The seminal study that demonstrated the efficacy of furosemide in mitigating or preventing episodes of EIPH in the racing Thoroughbred. While not submitted as a justification for the continued use of furosemide, this study did establish furosemide as the only medication having efficacy for controlling EIPH and why the WADA total ban on furosemide cannot be, at this time, applied to horseracing. This article also then justifies the Prohibited List's exclusion for the use of furosemide in training exercise.

Exhibit B.25. PAG 13 Intra-Articular Polyacrylamide Hydrogel Injections Are Not Innocent: While the use of polyacrylamide hydrogels have a history of use in human joint disease, their introduction into the equine market as medical devices, is relatively recent, and the lack of documented method of action causes reservations about its use in that it may have the potential to mask pain and allow the progression of orthopedic disease to the overall detriment of the horse.

Exhibit B.26. PBZ 05 Effectiveness of administration of phenylbutazone alone or concurrent administration of phenylbutazone and flunixin meglumine to alleviate lameness in horses: Establishes justification for the prohibition on ''stacking'' of NSAIDs—medications that are not controlled in human sport but require control in equine sport for safety reasons and ethical considerations.

Exhibit B.27. Ract 04 Effects of Ractopamine HCl on Physical and Reproductive Parameters in the Horse: This anabolic agent is not addressed in human sport but has been detected in post-race and out of competition samples derived from racehorses. Its presence has been both the result of

contamination of commercial feed at the processing site as well as deliberate administration.

Exhibit B.28. Thyro 07 A randomised, controlled trial to determine the effect of levothyroxine on Standardbred racehorses: This prescription medication had widespread use for the (scientifically unsupported) treatment of a multitude of conditions—other than hypothyroidism which is exceedingly rare in the horse. This article elucidates the health risk in its use and justifies the ban as established in the Prohibited List.

Exhibit B.29. Tryp 03 Effects of a commercial dose of L-tryptophan on plasma tryptophan concentrations and behaviour in horses: An example of unregulated, over the counter oral nutraceuticals that have the potential to impact a horse's health, behavior, or mental state—thus exerting a drug-like effect while evading regulation by the FDA. It is for this reason that the Prohibited List is not permissive of the use of these substances during the race period, to be consistent with FDA-approved drugs having similar effects.

1. Banned Substances and Banned Methods—Rule Series 4100

Banned Substances and Banned Methods are set out in categories, including anabolic agents, peptide hormones and growth factors, beta-2 agonists, hormone and metabolic modulators, and diuretics and masking agents (Rule 4110). Banned Methods include blood manipulation, chemical castration or immunocastration, and gene and cell doping (Rule 4120).

2. Controlled Medication Substances and Controlled Medication Methods and Exceptions—Rule Series 4200

Subject to exceptions specified in the Prohibited List (Rule 4212), only feed, hay, and water are permitted during the Race Period (Rule 4211(a)). Accordingly, subject to Rule 4212, any substance administered during the Race Period or present in a Post-Race Sample (including any metabolite(s), artifact(s), and isomer(s) of such substance(s)) that does not otherwise qualify as a Banned Substance shall constitute a prohibited Controlled Medication Substance. In addition, certain Controlled Medication Substances are prohibited from presence in a Post-Work Sample (Rule 4211(b)). Exceptions are provided in Rule 4212 for emergency veterinary care, for certain substances that are permitted up to 24 hours prior to Post-Time (*e.g.,* anti-ulcer medications), electrolyte solutions consumed by the horse by free choice, furosemide (*i.e.,* Lasix/Salix), and for supplements or feed additives that do not have an action or effect on listed mammalian body systems.

Controlled Medication Methods include alkalinization, intra-articular injections, and use of a nasogastric tube within specified time periods (Rule 4220).

3. Ineligibility Periods for Covered Horses—Rule Series 4300

Consistent with section 3057(d) of the Act, Rule 4300 establishes uniform rules setting out the periods of ineligibility that apply to Covered Horses implicated in Anti-Doping Rule Violations or Controlled Medication Rule Violations. The ineligibility period ranges from zero months to lifetime bans, depending on the category of the substance or method.

Violations involving Controlled Medication Substances will not result in a period of Ineligibility for the Covered Horse. However, the Covered Horse shall be placed on the Veterinarians' List and a Vets' List Workout must be scheduled (at which the horse may be subject to Sample collection). Violations involving Controlled Medication Methods may result in a period of Ineligibility for the Covered Horse where specified in the Prohibited List at Rule 4320.

Covered Horses are not subject to increased ineligibility periods if they are involved in multiple violations.

4. Rule Series 4000 Appendix: Technical Document—Prohibited Substances

The ''Technical Document—Prohibited Substances'' supplements the Prohibited List (Rule Series 4000), and sets out additional detail concerning Prohibited Substances. The ''Technical Document—Prohibited Substances,'' enumerates specific Prohibited Substances that fall into the general categories listed in the Prohibited List and sets forth detection times, screening limits, and thresholds for those Prohibited Substances. The Technical Document also designates certain Prohibited Substances as Specified Substances, which are those that pose a higher risk of being the result of contamination and that are therefore subject to more flexible sanctions. The following paragraphs describe the rules and specifications applicable to certain categories of medications that vary from the baseline standards enumerated in 15 U.S.C. 3055(g).

i. Anti-Ulcer Medications (Cimetidine, Omeprazole, Ranitidine)

The IFHA has published a restricted administration period that prohibits administration of anti-ulcer medications within 48 hours of the post time for the race in which the horse is entered. HISA in the Protocol recommends a 24-hour restricted administration period.

The basis for this deviation is two-fold: (1) Withdrawal intervals of greater than 24 hours have been identified as an equine welfare issue. Published research demonstrates a rebound effect when anti-ulcer medications are withdrawn for more than 24 hours with resultant ulcers more severe than those originally treated. (2) The IFHA's Advisory Council on Prohibited Substances and Practices will be revisiting the control of these substances at its December 2022 meeting, and it is anticipated that the international community will adopt a withdrawal interval strategy similar to the one proposed by HISA.

ii. NSAIDs (Flunixin, Ketoprofen, Phenylbutazone)

The IFHA has published a 48-hour Detection Time (DT) for a single NSAID—meclofenamic acid. There is no FDA-approved product containing meclofenamic acid commercially available in the United States. (It is important to note that a Detection Time is the foundation for determining a withdrawal interval, but under no circumstances should the Detection Time be equated with withdrawal guidance. The withdrawal interval is decided by the veterinarian in consultation with the responsible person for the horse in consideration of their level of risk aversion and their knowledge of the specific horse's health, management, other medications or foreign substances co-administered, and other relevant factors. The withdrawal interval should always be longer than the Detection Time, and in most cases this means adding 24 hours (at a minimum) to the Detection Time.)

The HISA Protocol establishes Screening Limits corresponding to a 48-hour Detection Time for 3 commercially available NSAIDs having FDA-approval for use in the horse. The Protocol allows the veterinarian to select one NSAID that can be administered using a withdrawal interval based on the 48-hourr Detection Time. All other NSAIDs are then controlled applying IFHA Detection Times and Screening Limits, and the detection of more than one NSAID in a horse's sample is a violation. This is philosophically consistent with the IFHA and represents a far more restrictive approach to the use of NSAIDs than currently exists in the United States.

iii. Methocarbamol/Glycopyrrolate

The IFHA is silent on these substances. However, the Asian Racing Federation (a signatory to the IFHA's

International Agreement on Breeding, Racing, and Wagering (IABRW)) has published a Screening Limit for methocarbamol. So there is precedent for establishing Screening Limits in addition to those provided by the IFHA. Further, the IFHA's IABRW references the adoption of Screening Limits and advises that a regulatory authority may elect to publish Detection Times.

The Screening Limits and Detection Times for methocarbamol and glycopyrrolate were derived after reviewing the Racing Medication and Testing Consortium's administration study pharmacokinetic data. The elected Screening Limits and corresponding Detection Times ensure withdrawal intervals of sufficient length to prevent the substances from having any potential to impact a horse's racing performance.

iv. Ciclesonide/Lidocaine

The Protocol adheres to IFHA Screening Limits, but, consistent with the requirements of IABRW Article 6, HISA has elected to adopt Detection Times that vary from those of the IFHA. In the case of ciclesonide, the Detection Time is consistent with that used by Racing Australia (also an IFHA member). For lidocaine, HISA elected to use a lower dose in determining a Detection Time, as it believed that IFHA's dosing is too permissive and potentially allows illicit low-dose use on Race Day, which may be undetectable by laboratory testing.

v. Procaine Penicillin

The European Horseracing Scientific Liaison Committee (EHSLC) has established a detection time of 240 hours (10 days) for procaine penicillin. (The EHSLC is the scientific body that the IFHA consults when developing medication control policy). HISA has determined that the 240-hour detection time could negatively impact horse welfare, through the withholding of appropriate medical treatment. HISA has elected instead to adopt the current ARCI controls, which allow for the use of this safe and effective antibiotic up to 48 hours prior to a race, while still effectively controlling against the illicit use of procaine as a local anesthetic.

*e. Terms of Substance: Rule Series 5000—Equine Standards for Testing and Investigation*

In accordance with section 3055 of the Act, the Authority has developed Equine Standards for Testing and Investigations to manage test distribution planning (including intelligence-based testing), the sample collection process, and in-competition and out-of-competition testing. The Authority considered the Association of Racing Commissioners International out-of-competition testing standards as a baseline, but also relied in large part on the WADA International Standard for Testing and Investigations, given the comprehensive nature of that standard. All adjustments and modifications to the baseline rules were approved by the Authority in consultation with the ADMC and the Agency in accordance with section 3055(g)(3) of the Act.

In preparing the standards, the Authority consulted with the Agency, the ADMC, and experts in the field to tailor the standards to horseracing. The Authority considered and relied significantly on the following rules:

Exhibit B.2. The ARCI out-of-competition testing standards, Model Rules of Racing (version 11.0). The Authority notes that the Act refers to version 9.2, but the model rules have since been updated. The most recent versions of the ARCI documents are available at *https://www.arci.com/model-rules-standards/.*

Exhibit B.30. WADA International Standard for Testing and Investigations dated January 1, 2021. The most recent versions of the WADA documents are available at *https://www.wada-ama.org/en/resources/.*

1. Testing—Rules 5100–5500 and 5800

The Testing and Investigations Standards sets out how the Agency will plan effective testing by using risk assessments and prioritizing between Covered Horses and types of testing (Rule 5100). As directed by section 3055(c)(4)(C) of the Act, Sample Collection Personnel will notify the Responsible Person or Nominated Person without advance notice that his or her Covered Horse has been selected for testing (Rule 5200), following—as applicable—the procedure set out at Rule 5220 depending on when the sample is collected.

Sample Collection Sessions will be conducted by suitably qualified personnel (Rule 5450), using suitable equipment (Rule 5320), in a suitable ''test barn'' environment (Rule 5310). Samples will be collected in accordance with Rule 5400, in particular to ensure that the sample is of suitable quality and quantity, is clearly and accurately identified, is sealed in a tamper evident kit, and has not been manipulated or tampered with. Further specific procedures and requirements apply to the collection of urine samples (Rule 5420), blood samples (Rule 5430), and hair samples (Rule 5440).

Once collected, Samples will be stored and transported by Sample Collection Personnel in a manner that protects the integrity, identity, and security of the Samples (Rules 5510 and 5520).

2. Investigations—Rule 5600–5700

As directed by the Act, the Agency will put in place internal processes and procedures to ensure it is able to gather, analyze, and process anti-doping and medication control intelligence from all available sources in order to help deter and detect doping and medication abuse, to inform effective, intelligent, and proportionate test distribution planning, to plan intelligence-based Target Testing, and to conduct investigations (Rule 5600).

Further, the Agency will conduct efficient and effective investigations into (among other things) atypical findings and other sample abnormalities, and other analytical or non-analytical information or intelligence. The purpose of such investigations is to either rule out or develop evidence that supports an anti-doping or controlled medication rule violation or other violation of the Protocol (Rule 5710). The Agency will make use of all investigative resources available to it, which may include obtaining information from law enforcement authorities and other regulators (Rule 5730). The Agency may also exercise the investigative powers conferred under applicable rules, including powers of inspection, examination, seizure, production of documents, request to the Authority for the issuance of subpoenas, and the conduct of interviews). All Covered Persons are required to cooperate with the Agency's investigations in the manner set forth in the rules, and failure to cooperate may result in the imposition of sanctions (Rule 5720(f)).

*f. Terms of Substance: Rule Series 6000—Equine Standards for Laboratories and Accreditation*

As directed by sections 3053, 3055, and 3057 of the Act, the Authority has developed the Equine Standards for Laboratories and Accreditation (''Laboratory Standards'') using the WADA International Standard for Laboratories as a baseline. All adjustments and modifications to the baseline rules were approved by the Authority in consultation with the ADMC and the Agency in accordance with section 3055(g)(3) of the Act.

Exhibit B.31. WADA International Standard for Laboratories dated January 1, 2021. The Authority notes that the Act refers to the WADA International Standard for Laboratories (version 10.0) dated November 12, 2019, but that

version has since been updated by WADA. The most recent versions of the WADA documents are available at: *www.wada-ama.org/en/resources/.*

As directed by the Act at section 3057(b), the Laboratory Standards establish standards of accreditation for laboratories involved in testing samples from Covered Horses; the process for achieving and maintaining accreditation; and the standards and protocols for testing of such samples. The Laboratory Standards will be supported by technical documents, letters, notes, and laboratory guidelines, as appropriate.

The Laboratory Standards also cross refer in a number of places to the ISO/IEC 17025 standard. Laboratories must obtain ISO/IEC 17025 accreditation before receiving HISA Equine Analytical Laboratory (''HEAL'') accreditation.

Exhibit B.32. ISO/IEC 17025:2017.

The Authority consulted with laboratory experts in order to tailor the Laboratory Standards to horseracing laboratories and to reflect the specificities of equine sport. As part of its review, the Authority considered the ILAC–G7:04/2021 Accreditation Requirements and Operating Criteria for Horseracing Laboratories, which may inform subsequent Technical Documents.

Exhibit B.33. ILAC–G7:04/2021 Accreditation Requirements and Operating Criteria for Horseracing Laboratories. The most recent versions of the ILAC standards are available at: *https://ilac.org/publications-and-resources/ilac-guidance-series/.*

1. Laboratory Accreditation—Rule Series 6100 and 6500

In accordance with sections 3055(c) and 3057(b) of the Act, the Laboratory Standards establish the requirements for obtaining HISA Equine Analytical Laboratory (''HEAL'') accreditation, and the requirements and standards for maintenance of HEAL accreditation. The rules set out a procedure by which laboratories may achieve HEAL accreditation, starting with an application and the granting of ''candidate laboratory'' status. The candidate laboratory must provide specified information to the Agency, perform pre-probationary testing to identify prohibited substances in samples, and complete an on-site assessment. The Agency will assess the outcomes of those processes and any non-conformities identified, and the candidate laboratory will have a specified period of time to remedy those non-conformities with corrective actions (Rule 6110).

If a candidate laboratory is granted probationary accreditation status, it will be accredited by the Agency, with a probationary period of two years or until analysis of 2,500 samples has been performed, whichever occurs first. If the probationary period is successfully completed and the laboratory successfully completes a final accreditation test, the Agency will grant accreditation to the laboratory (Rule 6120).

The rules impose continuing obligations on each laboratory that must be satisfied in order to maintain HEAL accreditation (Rule 6130), including maintenance of ISO/IEC 17025 accreditation, satisfactory participation in the Agency External Quality Assessment Scheme (''EQAS'') whereby laboratories are sent samples to be analyzed (blind or for specified substances), compliance with the code of ethics (which is set out in full at Rule 6600), and continued research and development activities and sharing of knowledge.

The Agency will regularly monitor and review the compliance of each laboratory with its ongoing accreditation obligations (Rule 6140). A laboratory's HEAL accreditation may be suspended or revoked, or subjected to specified analytical testing restrictions if (among other things) the laboratory fails to comply with the Laboratory Standards or other Agency requirements (Rules 6510 and 6520). The rules set out the effects of such decisions on Agency-related laboratory activity and the transfer of samples to other laboratories pending resolution of the matter (Rule 6560), and provide for reinstatement of the laboratory if it has remedied the non-compliance that resulted in the Agency's decision.

2. Laboratory Quality Monitoring—Rule Series 6200, 6400, and 6600

The Agency will regularly distribute External Quality Assessment Scheme (EQAS) samples in order to monitor the capabilities of laboratories and probationary laboratories, evaluate their proficiency, and improve test result uniformity between laboratories (Rule 6210). Some of these samples are blind (the laboratory will know it is an EQAS sample but will not know its contents), some are double-blind (the laboratory will not know it is an EQAS sample or know its contents), and some are educational (the laboratory will know it is an EQAS sample and will know its contents) (Rule 6220). EQAS samples should be analyzed in a manner substantially similar to that applied to routine samples, unless otherwise specified by the Agency, and results reported to the Agency (Rules 6250 and 6260).

The Agency will evaluate laboratory EQAS results and, as necessary and appropriate, inform the laboratory of any technical, methodological, or clerical errors that should be remedied. If such errors are remedied, no penalty will be imposed (Rule 6410). The Agency may request corrective action reports that detail actions taken to correct any non-conformity or other issue (Rule 6420). The annual EQAS evaluation will be a factor in assessment of HEAL accreditation and maintenance of HEAL accreditation.

3. Analysis of Samples—Rule Series 6300

The Laboratory Standards set out a process for the withdrawal of accreditation if the relevant requirements and standards are not met. The Laboratory Standards also ensure that laboratories report valid test results based on reliable evidentiary data and facilitate harmonization in analytical testing of Samples by laboratories.

The rules also contain detailed standards for the analysis of samples (section 6300). When analyzing a sample, the laboratory will prepare an aliquot, select the analytical testing procedure, and conduct the initial testing procedure, with the objective of obtaining information about the potential presence of prohibited substances in the sample (Rule 6308). The laboratory will then conduct the confirmation procedure to obtain a result that either supports or does not support the reporting of an adverse analytical finding or atypical finding, in particular, by identifying and sometimes quantifying—for example in the case of a threshold substance—a prohibited substance in the sample (Rules 6309 and 6311). The laboratory must conduct a detailed review of the analysis (Rule 6315) and report all results to the Agency (Rule 6316).

An important amendment to the baseline rules is that any B sample analysis will be conducted by a different laboratory than the one that performed the A sample analysis, unless the Agency considers that is not possible due to (i) reasonable concerns over Sample integrity or unstable analytes; or (ii) because no other Laboratory is available to perform the B Sample procedure within a reasonable period of time (Rule 6312).

If the laboratory reports an adverse analytical finding for the A sample, and the Covered Person requests or the Agency orders that the B sample be analyzed, the laboratory will promptly transfer the B sample to the laboratory

specified by the Agency, and that (second) laboratory will perform the B sample procedure and analysis (Rule 6312). The samples will be stored and may be subject to further analysis if directed by the Agency (Rules 6313 and 6319).

*e. Terms of Substance: Rule Series 7000—Arbitration Procedures*

In accordance with sections 3053(a)(10) and 3057(c) of the Act, the Arbitration Procedures set out a disciplinary process for the hearing and adjudication of Anti-Doping Rule Violations, Controlled Medication Rule Violations, and other related offenses. As directed by section 3057(c)(3), the procedures were developed to provide for adequate due process, including impartial hearing panels commensurate with the seriousness of the alleged violation. Different procedures apply to Anti-Doping Rule Violations (heard by the Arbitral Body) as compared to Controlled Medication Rule Violations (heard by the Internal Adjudication Panel, which may adjudicate the matter on written submissions alone.

1. Dispute Resolution Frameworks—Rules 7010–7050

The arbitrators on the Arbitral Body will be appointed by the Agency for four-year terms (Rule 7030). Members of the Internal Adjudication Panel will be appointed by the Agency for four-year terms (Rule 7040). Members of the Arbitral Body and Internal Adjudication Panel will receive mandatory annual training and education on issues relating to the proper handling of cases (Rule 7050).

2. Initiating Proceedings—Rules 7060–7160

If a Covered Person is charged with an Anti-Doping Rule Violation or Controlled Medication Rule Violation, proceedings will be initiated with the appropriate adjudicator by the Agency. The adjudicator will be appointed by the arbitral body or by the coordinator of the Internal Adjudication Panel, as applicable (Rule 7130), and the rules establish a process by which parties may challenge the adjudicator's appointment in appropriate circumstances. The adjudicator has broad powers to manage the proceedings, including the power to issue orders for expedited procedures, rule on their own jurisdiction, and consolidate proceedings.

3. Hearings and Evidence—Rules 7170–7330

In cases involving Anti-Doping Rule Violations or related violations, the rules set out a procedure for the exchange of written submissions and evidence (Rule 7170), and for the conduct of hearings (Rule 7250). The Arbitral Body has broad discretion to determine the admissibility, relevance and materiality of evidence offered, and may, if necessary and appropriate, order production (Rule 7260 and 7270) or interim measures (Rule 7280) or resolve challenges to provisional suspensions at a provisional hearing (Rule 7290).

In cases involving Controlled Medication Rule Violations and related violations, and other violations of the Protocol, a more streamlined and flexible process applies (Rule 7180).

4. Decisions—Rules 7240–7450

In all cases, a final decision will be issued and the adjudicator may grant any remedy or relief authorized by the Protocol (Rule 7340–7350). Final decisions issued by the Arbitral Body or Internal Adjudication Panel are subject to review as specified in section 3058 of the Act (Rule 7400).

**III. Self-Regulatory Organization's Summary of Comments Received Pre-Submission and Its Responses to Those Comments**

As encouraged by the Commission's procedural rule, the Authority, before finalizing this submission to the Commission, made a draft of the Anti-Doping and Medication Control proposed rule available to the public for review and comment on the HISA website, *https://www.hisausregs.org/,* beginning on June 1, 2022. Comments on the Anti-Doping and Medication Control proposed rule were received from various individuals and groups in the horseracing industry.

The stakeholder feedback received was constructive and well-considered. All submitted comments were carefully reviewed by the Authority as well as by the ADMC and the Agency. Those collected comments are available as Exhibit A on the docket at *https://www.regulations.gov.* The Authority also engaged with a number of stakeholders through follow-up conference calls to further analyze their comments and discuss any questions raised. The stakeholder comments informed a number of adjustments and modifications to the proposed rules, as explained in more detail below. The open consultation process and stakeholder engagement is an important process and one that is intended to build consensus where possible within the industry.

The following is a summary of the substance of the comments received. The following also summarizes the Authority's response to the significant issues raised in the comments, and the manner in which the Authority has addressed those comments in developing the proposed rules submitted to the Commission. In a few instances the Authority declined to make a suggested change, though the Authority will consider the suggestions made in the course of future rulemaking.

1000 Series—General Provisions

The Authority revised the definition of ''Race Day'' based on comments received, amending it so that the period will end one hour after the end of the Official Workout or Covered Horserace or at the end of any Sample collection process, whichever is later, instead of ending at 23:59 (11:59 p.m.) on the day of the Official Workout/Covered Horserace as previously stated. This revision was made to take account of horse welfare, recognizing in particular that once a horse has been subject to sample collection, or it has been decided that a horse will not be selected for sample collection, the horse should not be prohibited from receiving any necessary therapeutic treatments post-race that are permitted outside the Race Period. The end of the ''Race Day'' now also coincides with the end of the ''Race Period.''

The definition of ''Tampering'' was adjusted to make clear that it does not include the actions of bona fide veterinary personnel involving a Controlled Medication Substance or Controlled Medication Method used for genuine and legal therapeutic purposes or other acceptable justification. This addition mirrors the wording used in the definition of ''Administration,'' which includes the same important carve-out.

3000 Series—Equine Anti-Doping and Controlled Medication Protocol

Some commenters expressed the strong opinion that there is a material difference between the use of doping substances to unfairly affect the performance of horses, as opposed to errors in the administration of recognized therapeutic substances. The Authority agrees that this is a vital distinction, and the Protocol recognizes the distinction in the penalty structure and other provisions throughout the Protocol.

Further detail on the meaning of ''Owner'' has been provided to take account of the varied and sometimes complex ownership structures in horseracing (Rule 3020(c)).

The term ''Responsible Person'' defined in Rule 3030 has been

simplified to make clear that the trainer of a Covered Horse is the Responsible Person for that horse. In circumstances where the horse does not have a Trainer, the Owner is the Responsible Person. The Responsible Person is personally liable for his or her Covered Horse(s). However, other Covered Persons (including veterinarians, among others) who made a relevant decision about the Covered Horse may be found to be complicit in a violation and may be liable to the same extent as the Responsible Person.

In response to comments received, the Authority removed the disciplinary provisions concerning hypodermic needles, because equivalent provisions are included in the Rule 2000 Series (Racetrack Safety Program).

Some commenters proposed increasing the sanctions applicable to repeat medication violation offenders and lengthening the period of time that such violations would remain on their ''official record.'' The limitation period and roll-off period for Controlled Medication Rule Violations has been increased from one to two years, and a multiple violation penalty points system, modelled on the ARCI system, has been added. As a consequence, in addition to any sanction received for the underlying Controlled Medication Rule Violation, a Covered Person will also receive a certain number of penalty points which accumulate over a two-year period. When the points thresholds are exceeded, additional sanctions will be imposed (in a manner similar to the points system in the driver's licensing violation system).

A number of commenters requested that Controlled Medication Substances be stratified into different classes, with individual screening limits prescribed for each category. The Authority has done so by classifying Controlled Medication Substances into Classes A to C in the Technical Document-Prohibited Substances, which supplements the Prohibited List. The sanctions in the Protocol in turn depend on the class of substance in issue.

Commenters requested clarification of the requirement that a Responsible Person make a Covered Horse available for testing ''at any time and place.'' The Protocol was clarified to specify that the Covered Horse must be available for testing at any time and place where the horse is located (*e.g.,* Racetrack, Training Facility, private facility). The Protocol was also clarified to specify that Responsible Persons shall ensure that the Covered Horse is produced for Sample collection immediately upon notification by a duly authorized Person, or, if the horse is not available at the location for Testing, within 6 hours of notification by a duly authorized Person (or if the Agency agrees to extend that time period due to extenuating circumstances, then within such extended time period). Failure to produce a Covered Horse for Sample collection within six hours (or any extended period agreed by the Agency) shall constitute a violation of Rule 3215 (evasion, or refusal or failure to submit to Sample collection). Sample collection shall ordinarily be conducted where the Covered Horse is located (*e.g.,* Racetrack, Training Facility, or private facility), unless the Agency agrees that the Covered Horse may be transported to another agreed location (*e.g.,* a nearby Racetrack).

In response to comments received, the Authority extended the period of inactivity of a Covered Horse from 12 to 18 months, after which the horse may be retired by the Authority, subject to an objection by the Owner of the horse. This change was based on the rationale that horses may suffer injuries that require a 12-month recovery period (such as tendon injuries).

The Protocol was modified to clarify that where a horse's Sample reveals the presence of more than one Controlled Medication Substance above the applicable thresholds (if any), each substance may be treated as a separate presence violation.

The Protocol was revised to clarify that Covered Persons may request clearance testing to be conducted on their Covered Horses by a Laboratory, but only if such request is authorized by the Authority in advance and paid for by the Covered Person, and provided that such samples will be treated in the same way as official Post-Race Samples, such that any violation detected may be pursued by the Agency.

Some concerns were expressed regarding how cases involving environmental contamination would be handled and publicized. The Authority has incorporated an ''Atypical Findings Policy'' as Appendix 1 to the Rule 3000 Series. The Policy allows for certain substances to be investigated first as Atypical Findings before being pursued as Adverse Analytical Findings. If further to such investigation it is determined that the positive test was the result of environmental contamination, the matter will not be pursued as an Adverse Analytical Finding, and the Atypical Finding will not be publicly disclosed.

The Authority has added provisions to the Protocol to clarify the provisions on claimed horses. Some commenters expressed the concern that testing every horse in a claiming race would be excessive. In particular, Rule 3060 provides that a claimed horse may be subject to Sample collection at a claiming race if elected (and paid for) by the claimant. If the analysis of such Sample(s) results in an Anti-Doping Rule Violation or Controlled Medication Rule Violation, the claim may be voided at the option of the claimant and the claimant shall be entitled to return of all sums paid for the claimed horse and of all expenses incurred after the date of the claim.

Commenters also expressed the opinion that use of Lasix should not be prohibited during training. The Protocol does not prohibit the use of Lasix during training (see Rule 4212(d)).

4000 Series—Prohibited List

The key change made based on comments received was the development of the ''Technical Document—Prohibited Substances,'' which supplements the Prohibited List. The Technical Document provides additional detail concerning the Prohibited Substances that fall into the general categories established in the Prohibited List, and sets forth detection times, screening limits, and thresholds for those Prohibited Substances. The Technical Document also designates certain Prohibited Substances as Specified Substances. Specified Substances are those substances that pose a higher risk of being the result of contamination, and that are therefore subject to more flexible sanctions.

Comments were also received urging that anti-ulcer medications should be permitted within 24 hours prior to a race. The ADMC considered that proposition further, including the scientific paper referenced below, which shows that the pH of gastric fluids returns to baseline 24 hours after treatment with Omeprazole (an anti-ulcer medication). Given that pH directly affects the development of ulcers, the paper supports the use of anti-ulcer medications up to 24 hours prior to Post-Time. To require a longer withdrawal interval means that the stomach lining of a horse could be vulnerable to the recrudescence of gastric ulceration.

5000 Series—Equine Testing and Investigations Standards

In addition to a number of minor revisions based on the comments received, the Authority added a section to address procedures for TCO2 testing, *i.e.,* testing blood samples for total carbon dioxide as evidence of use or administration of the Controlled Medication Method M4 (alkalinization

or use/administration of an alkalinizing agent) (see Rule 5430).

6000 Series—Equine Standards for Laboratories and Accreditation

A number of minor revisions were made based on the detailed comments received and further consultation with laboratory experts. Some duplication with ISO/IEC 17025 was also removed, in particular in section 6300.

7000 Series—Arbitration Procedures

Some commenters expressed confusion concerning the role of racing stewards in the adjudication body previously designated as the ''National Stewards Panel.'' The body is now designated as the ''Internal Adjudication Panel,'' with individual members referred to as IAP members instead of ''stewards.''

The procedure for Controlled Medication Rule Violations was developed partly in response to requests by commenters to provide for a simplified hearing process for Covered Persons charged with a violation. The procedures allow the IAP members adjudicating the case to dispense with written filings and permit the Covered Person to make an oral presentation in a hearing context. This procedure allows the adjudication process to dispense where appropriate with certain of the more formal and costly aspects of legal proceedings.

The Arbitration Procedures were also clarified to specify that hearings regarding alleged breaches of the Protocol will not be open to the media or the public, and to specify the Owners who may attend hearings involving Covered Horses when the horse is owned by multiple persons or entities.

The Arbitration Procedures were also clarified to specify that while document production requests may be permitted, discovery or other wide-ranging document requests are not permitted.

## IV. Legal Authority

This rule is proposed by the Authority for approval or disapproval by the Commission under 15 U.S.C. 3053(c)(1).

## V. Effective Date

If approved by the Commission, this proposed rule will become effective January 1, 2023.

## VI. Request for Comments

Members of the public are invited to comment on the Authority's proposed rule. The Commission requests that factual data on which the comments are based be submitted with the comments. The supporting documentation referred to in the Authority's filing, as well as the written comments it received before submitting the proposed rule to the Commission, are available for public inspection at *https://www.regulations.gov.*

The Commission seeks comments that address the decisional criteria provided by the Act. The Act gives the Commission two criteria against which to measure proposed rules and rule modifications: ''The Commission shall approve a proposed rule or modification if the Commission finds that the proposed rule or modification is consistent with—(A) this chapter; and (B) applicable rules approved by the Commission.'' [7] In other words, the Commission will evaluate the proposed rule for its consistency with the specific requirements, factors, standards, or considerations in the text of the Act as well as the Commission's procedural rule.

Although the Commission must approve the proposed rule if the Commission finds that the proposed rule is consistent with the Act and the Commission's procedural rule, the Commission may consider broader questions about the health and safety of horses or the integrity of horseraces and wagering on horseraces in another context: ''The Commission may adopt an interim final rule, to take effect immediately, . . . if the Commission finds that such a rule is necessary to protect—(1) the health and safety of covered horses; or (2) the integrity of covered horseraces and wagering on those horseraces.'' [8] The Commission may exercise its power to issue an interim final rule on its own initiative or in response to a petition from a member from the public. If members of the public wish to provide comments to the Commission that bear on protecting the health and safety of horses or the integrity of horseraces and wagering on horseraces but do not discuss whether HISA's proposed rule on Registration is consistent with the Act or the applicable rules, they should not submit a comment here. Instead, they are encouraged to submit a petition requesting that the Commission issue an interim final rule addressing the subject of interest. The petition must meet all the criteria established in the Rules of Practice (Part 1, Subpart D); [9] if it does, the petition will be published in the **Federal Register** for public comment. In particular, the petition for an interim final rule must ''identify the problem the requested action is intended to address and explain why the requested action is necessary to address the problem.'' [10] As relevant here, the petition should provide sufficient information for the public to comment on, and for the Commission to find, that the requested interim final rule is ''necessary to protect—(1) the health and safety of covered horses; or (2) the integrity of covered horseraces and wagering on those horseraces.'' [11]

## VII. Comment Submissions

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before November 14, 2022. Write ''HISA Anti-Doping and Medication Control'' on your comment. Your comment—including your name and your State—will be placed on the public record of this proceeding, including, to the extent practicable, on the website *https://www.regulations.gov.*

Because of the public health emergency in response to the COVID–19 outbreak and the Commission's heightened security screening, postal mail addressed to the Commission will be subject to delay. We strongly encourage you to submit your comments online through the *https://www.regulations.gov* website. To ensure that the Commission considers your online comment, please follow the instructions on the web-based form.

If you file your comment on paper, write ''HISA Anti-Doping and Medication Control'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex B), Washington, DC 20580.

Because your comment will be placed on the public record, you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not contain sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other State identification number or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''[t]rade secret or

[7] 15 U.S.C. 3053(c)(2).

[8] 15 U.S.C. 3053(e).

[9] 16 CFR 1.31; *see* Fed. Trade Comm'n, Procedures for Responding to Petitions for Rulemaking, 86 FR 59851 (Oct. 29, 2021).

[10] 16 CFR 1.31(b)(3).

[11] 15 U.S.C. 3053(e).

any commercial or financial information which . . . is privileged or confidential''—as provided in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule § 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule § 4.9(c), 16 CFR 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule § 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted publicly at *https://www.regulations.gov*—as legally required by FTC Rule § 4.9(b), 16 CFR 4.9(b)—we cannot redact or remove your comment, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule § 4.9(c), and the General Counsel grants that request.

Visit the FTC website to read this document and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments it receives on or before November 14, 2022. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/siteinformation/privacypolicy.*

## VIII. Communications by Outside Parties to the Commissioners or Their Advisors

Written communications and summaries or transcripts of oral communications respecting the merits of this proceeding, from any outside party to any Commissioner or Commissioner's advisor, will be placed on the public record. *See* 16 CFR 1.26(b)(5).

## IX. Self-Regulatory Organization's Proposed Rule Language

*1000. General Provisions*

Rule 1010. Rules of Interpretation

Unless specified otherwise:

(a) words in the singular include the plural, and words in the plural include the singular;

(b) references to any ''Rule'' or ''Rule Series'' are references to the rules or rule series approved by the Commission pursuant to section 3053 of the Act;

(c) any Appendices to a Rule Series form an integral part of such Rule Series;

(d) any reference to a provision in rules, protocols, policies, standards, guidelines, or similar includes any modifications or successor provisions made or issued from time to time;

(e) any reference to legislation includes any modification or re-enactment of legislation enacted in substitution of that legislation, and any regulation or other instrument from time to time issued or made under that legislation;

(f) any term defined in this Rule 1000 Series shall supersede the definition of that term in the Rule 2000 Series;

(g) a reference to ''writing,'' ''write,'' or ''written'' includes communications transmitted by email;

(h) a reference to ''may'' means ''in the sole and absolute discretion of such person or body'';

(i) a reference to a ''day'' means any day of the week and is not limited to working days;

(j) any time limits shall begin from the day after which the relevant notification is received (or the day after the relevant notification is sent, if sent by email). Official holidays and non-working days are included in the calculation of time limits. The time limits fixed under this Protocol are respected if the communications by the parties are sent before midnight (U.S. Eastern time) on the last day on which such time limits expire. If the last day of the time limit is an official holiday or a non-business day in the state or country where the notification has been made, the time limit shall expire at the end of the first subsequent business day;

(k) a reference to a ''person'' (with no initial capital letter) means a natural person; and

(l) any words following the terms ''including,'' ''include,'' ''in particular,'' ''such as,'' ''for example,'' or any similar expression, are illustrative only, and do not limit the sense of the words, description, definition, phrase, or term preceding those terms.

Rule 1020. Definitions

*Act* means the Horseracing Integrity and Safety Act of 2020 (15 U.S.C. 3051–3060), as amended from time to time.

*ADMC* means the Anti-Doping and Medication Control Standing Committee of the Authority.

*Administration* means providing, supplying, supervising, facilitating, or otherwise participating in the Use or Attempted Use in a Covered Horse of a Prohibited Substance or Prohibited Method. However, this definition shall not include the actions of bona fide veterinary personnel involving a Controlled Medication Substance or Controlled Medication Method used for genuine and legal therapeutic purposes or other acceptable justification.

*Adverse Analytical Finding (''AAF'')* means a report from a Laboratory that, consistent with the Laboratory Standards, establishes in a Sample the presence of a Prohibited Substance or its Metabolites or Markers or evidence of the Use of a Prohibited Method.

*Agency* means the anti-doping and controlled medication enforcement agency known as the Horseracing Integrity and Welfare Unit.

*Aggravating Circumstances* means circumstances involving, or actions by, a Covered Person that may justify the imposition of a period of Ineligibility or fine greater than the otherwise applicable standard sanction. Such circumstances and actions include those set forth in Rule 3227 or Rule 3327 (as applicable).

*Aliquot* means a portion of the Sample obtained from the Covered Horse.

*Analyte* means a substance, compound, or measurand that is analyzed or determined in a biological matrix using an Analytical Testing Procedure performed under controlled analytical and laboratory conditions. For anti-doping and controlled medication purposes, an Analyte may be a Prohibited Substance, a Metabolite of a Prohibited Substance, or a Marker of the Use of a Prohibited Substance or Prohibited Method.

*Analytical Method* has the same meaning as Analytical Testing Procedure.

*Analytical Testing* means the parts of the Doping Control or Medication Control process performed at the Laboratory, which includes Sample handling, analysis, and the reporting of results.

*Analytical Testing Procedure* means a Fit-for-Purpose procedure, as demonstrated through method validation, that is used to detect, identify or quantify Analytes in a

Sample in accordance with the Laboratory Standards and relevant Technical Document(s), Technical Letter(s), Technical Note(s), or Laboratory Guidelines. Unless the context otherwise requires, Analytical Testing Procedure is also referred to or known as an Analytical Method or Test Method.

*Analytical Testing Restriction (''ATR'')* means a restriction on a Laboratory's application of specified Analytical Testing Procedure(s) or on the analysis of a particular class(es) of Prohibited Substances or Prohibited Methods to Samples, as determined by the Agency.

*Anti-Doping Rule Violation (''ADRV'')* means an anti-doping rule violation under the Protocol.

*Arbitral Body* has the meaning given to it in the Rule 7000 Series.

*Arbitration Procedures* means the arbitration procedures set forth in the Rule 7000 Series.

*Assistant Trainer* means a person engaged in the training of Covered Horses, under the direct or indirect supervision of a Trainer.

*Association Veterinarian* means a Veterinarian employed by a Racetrack.

*Attempt* means purposely engaging in conduct that constitutes a substantial step in a course of conduct planned to culminate in the commission of an Anti-Doping Rule Violation or Controlled Medication Rule Violation; provided, however, that there shall be no Anti-Doping Rule Violation or Controlled Medication Rule Violation based solely on an Attempt to commit a violation if the Covered Person renounces the Attempt prior to it being discovered by a third party not involved in the Attempt.

*Attending Veterinarian* means a Veterinarian providing treatment or services to Covered Horses hired or otherwise authorized by the Trainer or Owner or his or her respective designee.

*Atypical Finding* means a report from a Laboratory that requires further investigation in accordance with the Atypical Findings Policy set out at Appendix 1 to the Protocol, prior to the determination of whether it is an Adverse Analytical Finding.

*Atypical Findings Policy* means the policy set out at Appendix 1 to the Protocol.

*Authority* means the Horseracing Integrity and Safety Authority designated by section 3052(a) of the Act.

*Banned Method* has the meaning given to it in Rule 3111.

*Banned Substance* has the meaning given to it in Rule 3111.

*Batch* means a set of Samples processed as a group.

*Bias* means deviation of a measured result from the expected or reference value when using the complete measurement procedure.

*Billing Standards* means the standards governing compensation for arbitrators and stewards under the Arbitration Procedures.

*Blood Collection Officer (''BCO'')* means a Veterinarian or a veterinary technician who has been authorized by the Agency (or its delegate) to collect blood Samples from a Covered Horse.

*Breeder* means a Person who is in the business of breeding Covered Horses.

*Certified Reference Material (''CRM'')* means Reference Material characterized by a metrologically valid procedure for one or more specified properties, which is accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability.

*Certifying Scientists* means personnel appointed by a Laboratory to review all pertinent analytical data, Analytical Method validation results, quality control results, Laboratory Documentation Packages, and to attest to the validity of the Laboratory's test results.

*Chain of Custody* means the sequence of individuals or organizations who have responsibility for the custody of a Sample from the provision of the Sample until the Sample has been delivered to the Laboratory for analysis.

*Chaperone* means a person authorized by the Agency (or its delegate) to carry out the responsibilities given to Chaperones in the Testing and Investigations Standards or by the DCO.

*Charge Letter* has the meaning given to it in (as the context requires) Rule 3248 or Rule 3348.

*Claim* means, in the context of a Claiming Race, the purchase of a Covered Horse for a designated amount.

*Claiming Race* means a Covered Horserace in which a Covered Horse after leaving the starting gate may be claimed in accordance with the rules and regulations of the applicable State Racing Commission.

*Code of Ethics* means the Code of Ethics for Laboratories set forth at Rule 6610.

*Commission* means the Federal Trade Commission.

*Confirmation Procedure (''CP'')* means an Analytical Testing Procedure that has the purpose of confirming the presence in a Sample—or, when applicable, confirming the concentration, ratio, or score, or establishing the origin (exogenous or endogenous)—of one or more specific Prohibited Substances, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method.

*Consequences* means the penalties resulting from the occurrence of one or more violations of the Protocol, as set forth in the Rule 3000 Series. The Consequences for an Anti-Doping Rule Violation or a Controlled Medication Rule Violation may include one or more of the following:

(1) Disqualification;
(2) Ineligibility;
(3) Provisional Suspension;
(4) financial penalties; and
(5) Public Disclosure.

*Contaminated Product* means a product other than feed, hay, or water, that contains a Prohibited Substance that (i) is not disclosed on the product label, and (ii) a Veterinarian or Trainer would not otherwise reasonably be aware might be included in the product.

*Controlled Medication Method* means any method so described on the Prohibited List.

*Controlled Medication Rule Violation* has the meaning given to it in Rule 3311(a).

*Controlled Medication Substance* means any substance so described on the Prohibited List or the Technical Document—Prohibited Substances.

*Corrective Action Report (''CAR'')* means a report describing the Root Cause Analysis of a nonconformity and the corrective actions implemented to rectify it. If appropriate, it shall also describe the improvements adopted to minimize the risk of recurrence of the nonconformity.

*Covered Horse* means any Thoroughbred horse, or any other horse made subject to the Act by election of the applicable State Racing Commission or the breed governing organization for such horse under section 3054(*l*), during the period: (A) beginning on the date of the horse's first Timed and Reported Workout at a Racetrack that participates in Covered Horseraces or at a training facility; and (B) ending on the date on which the horse is deemed retired pursuant to Rule 3050(b).

*Covered Horserace* means any horserace involving Covered Horses that has a substantial relation to interstate commerce, including any Thoroughbred horserace that is the subject of interstate off-track or advance deposit wagers.

*Covered Person* means all Trainers, Owners, Breeders, Jockeys, Racetracks, Veterinarians, Persons licensed by a State Racing Commission, and the agents, assigns, and employees of such Persons; any other Persons required to be registered with the Authority; and any other horse support personnel who are engaged in the care, treatment, training, or racing of Covered Horses.

*Decision Limit* means the value of the result for a Threshold Substance in a Sample, above which an Adverse Analytical Finding shall be reported.

*Designated Owner* has the meaning given to it in Rule 3020(c).

*Detection Time* means the interval after a medication is administered during which it is detectable in a specific matrix (serum, plasma, urine, or hair) from any member(s) of a group of test horses. Detection times are determined from analysis of samples collected at specific time points following an administration of a medication to group of, potentially as few as 2, test horses. A detection time is not the same as a withdrawal time. The withdrawal time for a medication must be decided upon by a Veterinarian (in consultation with the Responsible Person) and is likely to be based on the Detection Time and an added safety margin. This margin should be determined using professional judgment and discretion to take into account the variability that could be expected to normally occur in a larger population by considering individual differences between horses, such as size, metabolism, fitness, health, or recent illness or disease. The withdrawal interval used for a medication should always be longer than its Detection Time.

*Disqualification* means the results of a Covered Horse in a particular Covered Horserace are invalidated, with all resulting consequences, including forfeiture of any purses and other compensation, prizes, trophies, points, and rankings associated with such Covered Horserace.

*Doping Control* means all steps and processes from test distribution planning through to ultimate disposition of any adjudication and review process pursuant to the Protocol and the Act involving an Anti-Doping Rule Violation and the enforcement of Consequences, including all steps and processes in between, including Testing, investigations, whereabouts program, Sample collection and handling, Laboratory analysis, Results Management, hearings and reviews, and investigations and proceedings relating to Anti-Doping Rule Violations not arising from or related to Testing or violations of Rule 3229.

*Doping Control Officer (''DCO'')* means an official who has been authorized by the Agency (or its delegate) to carry out the responsibilities given to DCOs in the Testing and Investigations Standards and any related Agency procedures.

*EAD Notice* has the meaning given to it in Rule 3245.

*EAD Violations* means Anti-Doping Rule Violations arising out of the Rule 3000 Series and violations of Rule 3229.

*ECM Notice* has the meaning given to it in Rule 3345.

*ECM or Other Violations* means Controlled Medication Rule Violations arising out of the Rule 3000 Series, violations of Rule 3329, or violations of Rule 3510.

*Equibase* means the official database for Thoroughbred horseracing.

*Equine Constituencies* means, collectively, Owners, Breeders, Trainers, Racetracks, Veterinarians, State Racing Commissions, and Jockeys who are engaged in the care, training, or racing of Covered Horses.

*Equine Industry Representative* means an organization regularly and significantly engaged in the equine industry, including organizations that represent the interests of, and whose membership consists of, Owners, Breeders, Trainers, Racetracks, Veterinarians, State Racing Commissions, or Jockeys.

*Expanded Measurement Uncertainty* means the multiplication of the coverage factor (q.v.) by the Measurement Uncertainty (q.v.).

*External Quality Assessment Scheme (''EQAS'')* means a program for quality assessment of Laboratory performance, which includes the periodic distribution of urine, blood, hair, or other samples to Laboratories and probationary laboratories by the Agency, to be analyzed for the presence or absence of Prohibited Substances or their Metabolite(s), or Marker(s) of Use of Prohibited Substances or Prohibited Methods. EQAS samples may be open (*i.e.,* educational; in such cases the content may be indicated), blind or double-blind (in such cases the content is unknown to the Laboratories).

*Fault* means any breach of duty or any lack of care appropriate to a particular situation. Factors to be taken into consideration in assessing a Covered Person's degree of Fault include (but are not limited to) the Covered Person's experience and special considerations such as impairment, the degree of risk that should have been perceived by the Covered Person, and the level of care and investigation exercised by the Covered Person in relation to what should have been the perceived level of risk. With respect to supervision, factors to be taken into consideration are the degree to which the Covered Person conducted appropriate due diligence, educated, supervised, and monitored Covered Persons (including Veterinarians), employees, personnel, agents, and other Persons involved in any way with the care, treatment, training, or racing of his or her Covered Horses, and created and maintained systems to ensure compliance with the Protocol. In assessing the Covered Person's degree of Fault, the circumstances considered must be specific and relevant to explain the Covered Person's departure from the expected standard of behavior. Thus, for example, the fact that the Covered Person would lose the opportunity to earn large sums of money during a period of Ineligibility, or the fact that the Covered Person or Covered Horse only has a short time left in a career, or the timing of the horseracing calendar, would not be relevant factors to be considered in reducing the period of Ineligibility based on degree of Fault.

*Fit(ness)-for-Purpose* means suitable for the intended purpose and in conformity with the ISO/IEC 17025, ILAC–G7, the Laboratory Standards, and relevant Technical Document(s) and Technical Letter(s).

*Further Analysis* means additional analysis conducted by a Laboratory on an A Sample or a B Sample after it has reported an analytical result for that A Sample or that B Sample, save that it excludes (and, therefore, there is no limitation on a Laboratory's authority to conduct) repeat or confirmation analysis, and analysis with additional or different Analytical Methods.

*IAP* member means a member of the Internal Adjudication Panel.

*Immediate Family Member* means a spouse, domestic partner, mother, father, aunt, uncle, sibling, or child.

*Ineligibility* means the Covered Horse or Covered Person is barred for a specified period of time from participating in specified activities, as further particularized in the provisions of the Protocol relating to Ineligibility.

*Initial Testing Procedure (''ITP'')* means an Analytical Testing Procedure whose purpose is to identify those Samples that may contain a Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method or an elevated quantity of a Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method.

*Interested Party* means the Authority, the Owner of the Covered Horse, the Trainer of the Covered Horse, and the relevant State Racing Commission (provided that such State Racing Commission has entered into an agreement incorporating required confidentiality provisions).

*Intermediate Precision* (sw) means variation in results observed when one or more factors, such as time,

equipment, or operator, are varied within a Laboratory, and may also be referred to as inter-batch or inter-run precision.

*Internal Adjudication Panel* has the meaning given to it in the Rule 7000 Series. The Internal Adjudication Panel shall have the same meaning as the National Stewards Panel in any other rules approved by the Commission.

*Jockey* means a rider or driver of a Covered Horse in Covered Horseraces.

*Laboratory* means a laboratory approved by the Agency, applying Test Methods and processes to provide evidentiary data for the detection or identification of Prohibited Substances, Metabolites, Markers, or Prohibited Methods, and, if applicable, quantification of a Threshold Substance in Samples of urine, blood, hair, and other biological matrices in the context of Doping Control or Medication Control activities.

*Laboratory Director* means a person appointed by a Laboratory to be responsible for overseeing the professional, organizational, educational, operational, and administrative responsibilities of the Laboratory's operations in accordance with the Laboratory Standards.

*Laboratory Documentation Package (''LDP'')* means the physical or electronic material produced by a Laboratory upon reporting of an Adverse Analytical Finding or as requested by the Agency to support an analytical result such as an Adverse Analytical Finding or an Atypical Finding.

*Laboratory Expert Group (''LabEG'')* means the group of laboratory experts responsible for providing advice, recommendations, and guidance to the Agency with respect to the overall management of Laboratory accreditation, disciplinary action, re-accreditation, approval processes, and monitoring activities.

*Laboratory Guidelines (''LGs'')* means recommendations of Laboratory best practices that may be provided by the Agency to address specific Laboratory operations or to provide technical requirements and guidance on interpretation and reporting of results for the analysis of specific Prohibited Substance(s), Metabolites, or Markers, or Prohibited Method(s), or on the application of specific Laboratory procedures.

*Laboratory Internal Chain of Custody* means documentation maintained within the Laboratory to record the chronological traceability of custody and actions performed on the Sample and any Aliquot of the Sample taken for Analytical Testing. Laboratory Internal Chain of Custody is generally documented by a written or electronic record of the date, location, action taken, and the person performing an action with a Sample or Aliquot.

*Laboratory Standards* means the Equine Standards for Laboratories and Accreditation set forth in the Rule 6000 Series.

*Laboratory Supervisory Personnel* means personnel appointed by a Laboratory to serve as Laboratory supervisors.

*Limit of Detection (''LOD'')* means the analytical parameters of assay technical performance. Lowest concentration of an Analyte in a Sample that can be routinely detected, but not necessarily identified or quantified, under the stated Test Method conditions used.

*Limit of Identification (''LOI'')* means analytical parameter of technical performance for chromatographic-mass spectrometric Confirmation Procedures. The LOI is estimated during method validation to evaluate the rate of false negative results at a certain concentration level. The LOI of a Test Method, at 5% false negative rate, for an Analyte (for which a Reference Material is available) shall be less than the MRPL. Since the LOI is an estimation of the false negative rate, Laboratories may report findings below the estimated LOI as Adverse Analytical Findings or Atypical Findings, as applicable, when the Analyte is identified in the Sample according to the criteria established in a Technical Document.

*Limit of Quantification (''LOQ'')* means the analytical parameter of assay technical performance. Lowest concentration of an Analyte in a Sample that can be quantitatively determined with acceptable precision and accuracy (*i.e.,* acceptable Measurement Uncertainty) under the stated Test Method conditions.

*Management System* refers to the Laboratory's quality system to deal with control of management system documents and records and with actions to address risk, test improvements, corrective actions, and ongoing management reviews.

*Managing Owner* has the meaning given to it in Rule 3020(c).

*Marker* means a compound, group of compounds, or biological variable(s) that indicates the Use of a Prohibited Substance or Prohibited Method.

*Measurement Uncertainty (''MU'')* means the parameter associated with a measurement result that characterizes the dispersion of quantity values attributed to the measure and provides confidence in the validity of the measured result.

*Medication Control* means all steps and processes from test distribution planning through to ultimate disposition of any adjudication and review process pursuant to the Protocol and the Act involving a Controlled Medication Rule Violation and to enforcement of Consequences, including all steps and processes in between, including Testing, investigations, whereabouts program, Sample collection and handling, Laboratory analysis, Results Management, hearings and reviews, and investigations and proceedings relating to Controlled Medication Rule Violations not arising from or related to Testing or violations of Rule 3329.

*Metabolite* means any substance produced from a Prohibited Substance by a biotransformation process.

*Minimum Reporting Level* means the estimated concentration of a Prohibited Substance or its Metabolite(s) or Marker(s) in a Sample below which Laboratories will not report that Sample as an Adverse Analytical Finding.

*Minimum Required Performance Level (''MRPL'')* means minimum analytical criterion of Laboratory technical performance established by the Agency, including the minimum concentration at which a Laboratory is expected to consistently detect and confirm a Prohibited Substance, Metabolite of a Prohibited Substance, or Marker of a Prohibited Substance or Prohibited Method in the routine daily operation of the Laboratory.

*Minor* means a natural person who has not reached the age of 18 years.

*National Stewards Panel* means the Internal Adjudication Panel.

*Negative Finding* means a test result from a Laboratory that, in accordance with the Laboratory Standards and any relevant Technical Document(s) and Technical Letter(s), concludes that no Prohibited Substance(s) or its Metabolite(s) or Marker(s) or evidence of the Use of a Prohibited Method(s), included in the requested Analytical Testing menu, were found in a Sample based on the applied Initial Testing Procedure(s) or Confirmation Procedure(s).

*No Fault or Negligence* means the Covered Person establishing that he or she did not know or suspect, and could not reasonably have known or suspected, even with the exercise of utmost caution, that he or she had administered to the Covered Horse (or that the Covered Horse's system otherwise contained) a Banned Substance or a Controlled Medication Substance, or that he or she had Used on the Covered Horse a Banned Method or a Controlled Medication Method, or

otherwise committed an Anti-Doping Rule Violation or Controlled Medication Rule Violation. For any violation of Rule 3212 or Rule 3312, the Covered Person must also establish how the Prohibited Substance entered the Covered Horse's system in order to establish No Fault or Negligence.

*No Significant Fault or Negligence* means the Covered Person establishing that his or her fault or negligence, when viewed in the totality of the circumstances and taking into account the criteria for No Fault or Negligence, was not significant in relationship to the Anti-Doping Rule Violation or Controlled Medication Rule Violation in question. For any violation of Rule 3212 or 3312, the Covered Person must also establish how the Prohibited Substance entered the Covered Horse's system in order to establish No Significant Fault or Negligence.

*Nominated Person* means a person nominated by a Responsible Person at the time of notification or through a whereabouts filing to assist, consent to, and witness Sample collection from a Covered Horse. If the Responsible Person is not present to nominate a person, or the designated Nominated Person is not present or willing to assist with Sample collection, anyone employed by the Responsible Person or Owner at the stable where the Covered Horse is located shall be the Nominated Person for that Sample collection. If no Nominated Person is promptly identified as described above, the person who has custody or control of the Covered Horse or granted the DCO, BCO, or Chaperone access to the Covered Horse shall be the Nominated Person for that Sample collection. In each case, the Nominated Person shall be 18 years or older.

*Non-Threshold Substance* means a Prohibited Substance for which the identification, in compliance with any applicable Technical Document(s), constitutes an Adverse Analytical Finding.

*Owner* means a person who holds an ownership interest in one or more Covered Horses.

*Person* means a natural person or an organization or other entity.

*Possession* means actual, physical possession, or constructive possession (which shall be found only if the Covered Person has exclusive control or intends to exercise exclusive control over the Prohibited Substance or Prohibited Method or the premises in which a Prohibited Substance or Prohibited Method exists). If the Covered Person does not have exclusive control over the Prohibited Substance or Prohibited Method or the premises in which a Prohibited Substance or Prohibited Method exists, constructive Possession shall only be found if the Covered Person knew about the presence of the Prohibited Substance or Prohibited Method and intended to exercise control over it. There shall be no Anti-Doping or Controlled Medication Rule violation based solely on Possession if, prior to receiving notification of any kind of any violation, the Covered Person has taken concrete action demonstrating that the Covered Person never intended to have possession and has renounced possession by explicitly declaring it to the Agency. Notwithstanding anything to the contrary in this definition, the act of purchasing (including by any electronic or other means) a Banned Substance or Banned Method constitutes Possession by the Covered Person who makes the purchase, whether or not the Banned Substance or Banned Method purchased is ever delivered to the Covered Person.

*Post-Race Sample* means a Sample collected by or on behalf of the Agency from a Covered Horse where notification of such Sample collection takes place no more than 1 hour after the end of a Covered Horserace in which a Covered Horse participates or is entered, or the end of a Vets' List Workout in which a Covered Horse participates. All Banned Substances and all Controlled Medication Substances are prohibited from being present in a Post-Race Sample.

*Post-Time* means the start time of a Covered Horserace in which a Covered Horse participates or is entered, or the start time of a Vets' List Workout in which a Covered Horse participates.

*Post-Work Sample* means a Sample collected by or on behalf of the Agency from a Covered Horse where notification of such Sample collection takes place no more than 1 hour after the end of a Timed and Reported Workout. All Banned Substances and any Controlled Medication Substances specifically identified on the Prohibited List as prohibited during Timed and Reported Workouts are prohibited from being present in a Post-Work Sample.

*Presumptive Adverse Analytical Finding (''PAAF'')* means the status of a Sample test result from the Initial Testing Procedure which represents a suspicious finding, but for which a Confirmation Procedure to render a conclusive test result has not yet been performed.

*Program* means the anti-doping and medication control program established under section 3055(a) of the Act.

*Program Effective Date* means January 1, 2023.

*Prohibited List* means the list identifying Prohibited Substances and Prohibited Methods set forth in the Rule 4000 Series.

*Prohibited Method* means any method so described on the Prohibited List.

*Prohibited Substance* means any substance or class of substances so described on the Prohibited List or the Technical Document–Prohibited Substances.

*Protocol* means the Rule 3000 Series (Equine Anti-Doping and Controlled Medication Protocol), as amended from time to time.

*Provisional Hearing* means an expedited abbreviated hearing to resolve a challenge to a Provisional Suspension, occurring prior to the adjudication of the violation in issue.

*Provisional Suspension* means the Covered Horse or Covered Person is barred temporarily from participating in any Timed and Reported Workout or Covered Horserace in accordance with Rules 3229 or 3329 (as applicable).

*Public Disclosure* means the dissemination or distribution of information by the Authority or the Agency to the general public.

*Quality Manager* means the staff member appointed by a Laboratory to perform that role in accordance with the Laboratory Standards.

*Race Day* means the period commencing at 12:01 a.m. on the day of a Vets' List Workout or Covered Horserace and ending (i) 1 hour after the end of such Vets' List Workout or Covered Horserace or (ii) at the end of any Sample Collection Session conducted at that Vets' List Workout or Covered Horserace when the Covered Horse is released from the Test Barn, whichever is later.

*Race Organizer* means any Person that arranges, organizes, and has administrative responsibility for a Covered Horserace.

*Race Period* means the period:

(a) commencing 48 hours prior to the Post-Time of either (i) any Vets' List Workout in which the Covered Horse participates or (ii) any Covered Horserace that the Covered Horse has been entered in, whether or not the Covered Horse actually starts; and

(b) ending (i) 1 hour after the end of such Vets' List Workout or Covered Horserace or (ii) at the end of any Sample collection process conducted at that Vets' List Workout or Covered Horserace when the Covered Horse is released from the Test Barn, whichever is later.

However, the Prohibited List may specify a Race Period that is shorter or longer in duration than the above period for certain Controlled Medication

Substances or Controlled Medication Methods.

*Racetrack* means an organization licensed by a State Racing Commission to conduct Covered Horseraces.

*Racetrack Safety Program* means the program set forth in Rule 2000 Series, established pursuant to section 3056(a) of the Act.

*Reference Collection (''RC'')* means a collection of samples or isolates of known origin that may be used in the determination of the identity of an unknown substance. For example, a well-characterized sample obtained from a controlled administration or from in vitro studies in which the presence of the substance of interest has been established.

*Reference Material (''RM'')* means a Reference Substance or Reference Standard that is sufficiently characterized, homogeneous, and stable with respect to one or more specified properties and that has been established to be fit for its intended use in an Analytical Testing Procedure.

*Regulatory Veterinarian* means a Veterinarian who is employed, contracted, or appointed by a State Racing Commission, Racetrack, the Authority, or the Agency to monitor the health and welfare of Covered Horses, in addition to any other duties assigned to him or her by the Authority or the Agency.

*Repeatability* (sr) means variability of results obtained within a laboratory using the same method, over a short time, using a single operator, item of equipment, etc. It is also referred to as intra-batch/intra-run precision.

*Reproducibility* (sR) means variability of results obtained when different laboratories analyze Aliquots of the same Sample. Reproducibility is a property of the results obtained and represents a measurable agreement of analytical results between different laboratories.

*Responsible Person* has the meaning given to it in Rule 3030.

*Results Management* means the process encompassing the timeframe from provision of an EAD Notice or ECM Notice through the charge until the final resolution of the matter, including the end of any adjudication and review process pursuant to the Protocol and the Act.

*Revocation* means the permanent withdrawal of a Laboratory's Equine Analytical Laboratory accreditation by the Agency.

*Risk Assessment* means the assessment of risk of doping and controlled medication misuse conducted by the Agency and used to effectively conduct test distribution planning or Target Testing.

*RMTC* has the meaning given to it in Rule 6070(a).

*Root Cause Analysis (''RCA'')* means an investigation to identify one or more fundamental causes of a nonconformity based on the collection of objective evidence from an assessment of the likely factors that led to the nonconformity. The removal of a root cause factor prevents the recurrence of the nonconformity; in contrast, removing a causal factor can improve the outcome, but it does not prevent the recurrence of the problem with certainty.

*Sample* means any biological material collected for the purposes of Doping Control or Medication Control, including urine, blood, and hair.

*Sample Collection Equipment* means A and B bottles, kits, containers, collection vessels, tubes, or other apparatus used to collect, hold, or store a Sample at any time during or after a Sample Collection Session.

*Sample Collection Personnel* means all qualified officials authorized by the Agency to carry out or assist with duties during Doping Control or Medication Control, including, but not limited to, Blood Collection Officers, Doping Control Officers, and Chaperones. An individual may be authorized by the Agency to carry out one or more roles during Doping Control or Medication Control.

*Sample Collection Session* means all of the sequential activities that directly involve the collection of a Sample from a Covered Horse from the point that initial contact is made with the Responsible Person or Nominated Person until the Covered Horse provides a Sample and is discharged from Sample collection obligations.

*Screening Limit* means a concentration to be used by Laboratories when screening for certain Non-Threshold Substances during the Initial Testing Procedure, below which a Laboratory will not pursue the possible presence of a Prohibited Substance. When the concentration of an Analyte subject to a Screening Limit exceeds the Screening Limit as determined by the Initial Testing Procedure, qualitative confirmatory analysis by mass spectrometry Confirmation Procedure is required to confirm the presence or absence of the Prohibited Substance. Quantification is not required. A Screening Limit is not a Limit of Detection, a Limit of Identification, or a Limit of Quantification.

*Selectivity* means the ability of the Analytical Testing Procedure to detect or identify (as applicable) the substance of interest in the Sample.

*Specified Substance* has the meaning given to it in Rule 3111(c).

*Stacking Violation* has the meaning given to it in Rule 3312(e).

*Stakes Race* means any race so designated by the Racetrack at which such race is run, including, without limitation, the races the Breeders' Cup World Championships comprises and the races designated as graded stakes by the American Graded Stakes Committee of the Thoroughbred Owners and Breeders Association.

*Standard Operating Procedure* means a document setting out prescribed methods or procedures to be followed when performing certain routine operations.

*Standards* means the Testing and Investigations Standards and the Laboratory Standards. Compliance with a Standard (as opposed to another alternative standard, practice, or procedure) shall be sufficient to conclude that the procedures addressed by the Standard were performed properly. Standards shall include any Technical Documents issued pursuant to the Standards.

*State Racing Commission* means an entity designated by State law or regulation that has jurisdiction over the conduct of horseracing within the applicable state.

*Substantial Assistance* means, for purposes of Rule 3226(a) and Rule 3326(a), a Covered Person providing the following assistance:

(1) fully disclosing in a signed written statement or recorded interview all information the Covered Person possesses in relation to violations of the Protocol; and

(2) fully cooperating with the investigation and adjudication of any case or matter related to that information, including, for example, by providing an affidavit and presenting testimony at a hearing if requested to do so by the Agency or adjudication body.

Further, the information provided must be credible and must comprise an important part of any case or proceeding which is initiated or, if no case or proceeding is initiated, must have provided a sufficient basis on which a case or proceeding could have been brought.

*Tamper Evident* means to have one or more indicators or barriers to entry included with or incorporated into the Sample Collection Equipment, which, if breached, missing, or otherwise compromised, can provide visible evidence that Tampering or Attempted Tampering of Sample Collection Equipment has occurred.

*Tampering* means intentional conduct that subverts the Doping Control or Medication Control process, but that would not otherwise be included in the definition of Prohibited Methods. Tampering includes offering or accepting a bribe to perform or fail to perform an act, preventing the collection of a Sample, affecting or making impossible the analysis of a Sample, falsifying documents submitted to the Agency (or a committee or adjudication body), procuring false testimony from witnesses, committing any other fraudulent act upon the Agency (or committee or adjudication body) to affect Results Management or the imposition of Consequences, and any other similar interference or attempted interference with any aspect of Doping Control or Medication Control. However, this definition shall not include the actions of bona fide veterinary personnel involving a Controlled Medication Substance or Controlled Medication Method used for genuine and legal therapeutic purposes or other acceptable justification.

*Target Testing* means selection of specific Covered Horses for Sample collection based on criteria set forth in the Testing and Investigations Standards.

*Technical Document (''TD'')* means a document adopted and published by the Authority from time to time containing requirements or guidance on specific anti-doping or medication control topics.

*Technical Letter (''TL'')* means a document published containing mandatory technical requirements provided by the Agency from time to time to address particular issues on the analysis, interpretation, and reporting of specific Prohibited Substance(s), Metabolites, Markers, or Prohibited Method(s), or on the application of specific Laboratory procedures.

*Technical Note (''TN'')* means technical guidance provided by the Agency to Laboratories on the performance of specific Laboratory methods or procedures.

*Test Barn* means the location where Sample collection is conducted on Race Day.

*Test Barn Veterinarian* means a Veterinarian who is employed, contracted, or appointed by a State Racing Commission, Racetrack, the Authority, or the Agency to monitor the health and welfare of Covered Horses subject to Sample collection in the Test Barn.

*Testing* means the parts of the Doping Control or Medication Control process involving Sample collection, Sample handling, and Sample transport to the Laboratory.

*Testing and Investigations Standards* means the Equine Testing and Investigations Standards set forth in the Rule 5000 Series.

*Test Method* has the same meaning as Analytical Testing Procedure.

*Thoroughbred* means a horse that is registered in The American Stud Book or in a foreign stud book approved by the Jockey Club or the International Stud Book Committee.

*Threshold* means the maximum permissible level of the concentration, ratio, or score for a Threshold Substance in a Sample. The Threshold is used to establish the Decision Limit for reporting an Adverse Analytical Finding or Atypical Finding for a Threshold Substance. Thresholds may only be adopted for (i) substances endogenous to the horse or (ii) substances arising from plants traditionally grazed or harvested as equine feed.

*Threshold Substance* means a Prohibited Substance, or Metabolite or Marker of a Prohibited Substance, for which the identification and quantitative determination, including, for example, concentration, ratio, or score, in excess of a pre-determined Decision Limit, or, when applicable, the establishment of an exogenous origin, constitutes an Adverse Analytical Finding.

*Timed and Reported Workout* means an officially timed and published running of a Thoroughbred horse over a predetermined distance that is not a horserace, as reported by Equibase or any official supplier of racing information and statistics recognized by the Authority. Official timed workouts shall have the same meaning as Timed and Reported Workouts. Any official timed workout by a Thoroughbred horse in any other jurisdiction shall be deemed a Timed and Reported Workout upon the earliest to occur of the following: (i) the horse is brought to the United States for purposes of participating in any Covered Horserace; or (ii) the horse is nominated for a Covered Horserace.

*Trafficking* means a Covered Person selling, giving, transporting, sending, delivering, or distributing by any means a Banned Substance or Banned Method to any other Person, or Possessing a Banned Substance or Banned Method for any such purpose; provided, however, that Trafficking shall not include the actions of Veterinarians or other licensed medical personnel involving a Prohibited Substance used for genuine and legal therapeutic purposes or other acceptable justification.

*Trainer* means an individual engaged in the training of Covered Horses.

*Training Facility* means a location that is not a Racetrack licensed by a State Racing Commission that operates primarily to house Covered Horses and conduct Timed and Reported Workouts.

*Use* means the utilization, application, ingestion, injection, or consumption by any means whatsoever of any Prohibited Substance or Prohibited Method in relation to a Covered Horse.

*Veterinarian* means a licensed veterinarian who provides veterinary services to Covered Horses.

*Veterinarians' List* has the meaning given to it in Rule 2000 Series (Racetrack Safety Program).

*Vets' List Workout* means an officially timed running of a Covered Horse over a predetermined distance that is not a Covered Horserace but is overseen by a Regulatory Veterinarian or Racetrack steward.

*Whereabouts Failure* means a failure by the Responsible Person to do any of the following: (i) provide notice to the Agency that his or her Covered Horse has been moved from a Racetrack or Training Facility to a private facility (*i.e.,* a facility not under the jurisdiction of the Authority/Agency) before such move occurs; (ii) provide whereabouts information about his or her Covered Horse(s) upon request by the Agency; (iii) provide sufficient information about the Covered Horse's whereabouts to enable the Agency to Test the Covered Horse at any time; or (iv) update any whereabouts information provided to the Agency if it changes.

*Without Prejudice Agreement* means a written agreement between the Agency and a Covered Person that allows the Covered Person to provide information to the Agency in a defined time-limited setting with the understanding that, if an agreement for Substantial Assistance or a case resolution agreement is not finalized, the information provided by either party may not be used by the other party in any Results Management proceeding under this Protocol. Such an agreement shall not preclude the parties from using any information or evidence gathered from any source.

*Workout* means a timed running of a horse over a predetermined distance not associated with a race or its first qualifying race, if such race is made subject to the Act by election under section 3054(*l*) of the Act of the horse's breed governing organization or the applicable State Racing Commission.

*3000. Equine Anti-Doping and Controlled Medication Protocol*

*3000. General Provisions*

Rule 3010. Introduction

(a) The Horseracing Integrity and Safety Act of 2020 (''Act'') mandates and empowers the Horseracing Integrity and Safety Authority (''Authority'') to establish a uniform anti-doping and controlled medication program to improve the integrity and safety of horseracing in the United States (''Program'').

(b) This Equine Anti-Doping and Controlled Medication Protocol (''Protocol'') has been developed and issued by the Authority as part of that mandate. It contains or incorporates by reference rules, standards, and procedures to improve and protect the integrity and safety of horseracing in the United States by deterring and penalizing the improper administration or application of Prohibited Substances and Prohibited Methods to Covered Horses. The Protocol is split into five chapters:

(1) the purpose, scope, and organization of the Protocol;

(2) the Prohibited List, rules of proof, and testing and investigations;

(3) the Equine Anti-Doping Rules;

(4) the Equine Controlled Medication Rules; and

(5) other violations and general procedure/administration.

(c) The Protocol has intentionally divided the regulation of Anti-Doping Rule Violations and Controlled Medication Rule Violations into separate chapters to reflect the Authority's view that the treatment of such violations should be separate and distinct from each other. Anti-Doping Rule Violations involve Banned Substances or Banned Methods, which are substances/methods that should never be in a horse's system or used on a horse as they serve no legitimate treatment purpose. Conversely, Controlled Medication Rule Violations involve Controlled Medication Substances or Controlled Medication Methods, which are substances/methods that have been determined to have appropriate and therapeutic purposes, and so may be used outside the Race Period, except as otherwise provided in the Prohibited List. For the avoidance of doubt, the Protocol does not regulate the use of drugs or medications by human participants in Covered Horseraces.

(d) The Protocol reflects and implements the following principles set out in section 3055(b) of the Act that:

(1) Covered Horses should compete only when they are free from the influence of medications, other foreign substances, and treatment methods that affect their performance;

(2) Covered Horses that are injured or unsound should not train or participate in Covered Horseraces, and that medications, other foreign substances, and treatment methods that mask or deaden pain in order to allow injured or unsound horses to train or race should be prohibited;

(3) rules, standards, procedures, and protocols regulating medication and treatment methods for Covered Horses and Covered Horseraces should be uniform and uniformly administered throughout the United States;

(4) to the extent consistent with the Act, consideration should be given to international anti-doping and medication control standards of the International Federation of Horseracing Authorities and the Principles of Veterinary Medical Ethics of the American Veterinary Medical Association;

(5) the administration of medications and treatment methods to Covered Horses should be based upon a veterinary examination and diagnosis that identifies an issue requiring treatment for which the medication or method represents an appropriate component of treatment;

(6) the amount of therapeutic medication that a Covered Horse receives should be the minimum necessary to address the diagnosed health concerns identified during the veterinary examination and diagnostic process; and

(7) the welfare of Covered Horses, the integrity of the sport of horseracing, and the confidence of its stakeholders (including the betting public) require full disclosure to regulatory authorities regarding the administration of medications and treatments to Covered Horses.

(e) The Protocol will be implemented and enforced on behalf of the Authority by:

(1) an anti-doping and controlled medication enforcement agency known as the Horseracing Integrity and Welfare Unit (''Agency''); and

(2) where agreed in accordance with 3060 of the Act, by State Racing Commissions acting under the delegated authority of the Authority or the Agency (and references to the Authority or the Agency in the Protocol will be deemed to encompass such commissions as the context requires, subject to and consistent with the scope of their delegated authority).

(f) In accordance with section 3054(b) of the Act, the rules of the Authority promulgated in accordance with the Act shall preempt any provision of state law or regulation with respect to matters within the jurisdiction of the Authority under the Act. Among other things, the Protocol:

(1) identifies the conduct that will constitute an Anti-Doping Rule Violation (Rules 3211 to 3216), a Controlled Medication Rule Violation (Rules 3311 to 3315), or a related violation (Rules 3229, 3329, and 3510);

(2) establishes evidentiary and other rules for proving violations of the Protocol (Rules 3121 to 3122);

(3) provides for the creation, maintenance, and updating of a Prohibited List and related Technical Document that identify Prohibited Substances and Prohibited Methods (Rules 3111 to 3113);

(4) empowers the Agency to perform and manage test distribution planning and Testing of Covered Horses both in and out of competition, in accordance with the Testing and Investigations Standards (Rule 3133);

(5) empowers the Agency to gather intelligence and investigate potential violations of the Protocol, in accordance with the Testing and Investigations Standards, which incorporate uniform rules and procedures in accordance with section 3054(c) of the Act (Rule 3133);

(6) empowers the Agency to accredit testing laboratories in accordance with the Laboratory Standards and to monitor, test, and audit approved Laboratories to ensure continuing compliance with the Laboratory Standards; and provides for all samples collected pursuant to the Protocol to be analyzed at approved Laboratories in accordance with the Laboratory Standards or by other laboratories, such as international laboratories accredited by the International Federation of Horseracing Authorities, in accordance with Rule 3136(d) (Rule 3136);

(7) sets out uniform rules and procedures for the Agency's management of the results of testing and investigations, and for its prosecution of any charges that Covered Persons have violated the Protocol, including incorporating the Arbitration Procedures to ensure the fair adjudication of those charges;

(8) sets out the sanctions that may be applied in case of violations of the Protocol, including, but not limited to, Disqualification of results, forfeiture of prizes and purses, fines, payment of costs, periods of Ineligibility for Covered Horses or Covered Persons (including additional periods of Ineligibility for repeat offenders), and Public Disclosure (sections 3220 and 3320); and requires the Authority,

Racetracks, Race Organizers, Training Facilities, all Covered Persons, and all other relevant Persons to recognize, respect, enforce, and give full force and effect to final decisions issued under the Protocol within their respective spheres of authority (Rule 3710);

(9) regulates the public reporting and disclosure of cases, and permits and facilitates statistical reporting to the Authority and to the U.S. Congress, the Commission, State Racing Commissions, and other Federal or State governmental bodies or agencies having jurisdiction over the sport of horseracing in the United States (section 3600); and

(10) empowers the Agency to undertake and commission education and research activities designed to advance the integrity and safety of horseracing in the United States (Rule 3810).

(g) The Protocol comes into force on the Program Effective Date and will apply in full as from that date. In accordance with section 3054(k)(1) of the Act, the Protocol only has prospective effect, *i.e.,* it does not apply to, and does not give the Authority or Agency authority to investigate, prosecute, adjudicate, or penalize conduct that occurred before the Program Effective Date (Rule 3080).

(h) The Protocol incorporates by reference the supporting rules and documents approved by the Commission and issued by the Authority, including Rule 1000 Series (General Provisions), Rule 2000 Series (Racetrack Safety Program), Rule 4000 Series (Prohibited List), Rule 5000 Series (Testing and Investigations Standards), Rule 6000 Series (Laboratory Standards), Rule 7000 Series (Arbitration Procedures), Rule 8000 Series (Enforcement Rule), Rule 8500 Series (Methodology for Determining Assessments), and Rule 9000 Series (Registration of Covered Persons and Covered Horses).

(i) In accordance with section 3055(c)(4) of the Act, the Agency may develop further rules, protocols, policies, and guidelines for approval by the Authority to support the implementation of the Protocol. These materials will be developed in consultation with the Anti-Doping and Medication Control Standing Committee (ADMC) of the Authority and will be consistent with international best practices.

(j) Nothing in the Protocol or in any of its associated rules, protocols, policies, and guidelines:

(1) is intended to constrain or limit in any way the powers of the Authority or the Agency under the Act; or

(2) shall be interpreted or applied in a manner that has the effect of constraining or limiting those powers in any way.

(k) Unless specified otherwise, words and terms in the Protocol that are capitalized are defined terms that have the meaning given to them in Rule 1020.

(l) The rules of interpretation included at Rule 1010 and Rule 3070 shall be used as an aid to interpretation of the Protocol.

Rule 3020. Application

(a) The Protocol applies to and is binding on:

(1) any horserace involving Covered Horses that has a substantial relation to interstate commerce, including any Thoroughbred horserace that is the subject of interstate off-track or advance deposit wagers (each, a Covered Horserace);

(2) any Thoroughbred horse, or any other horse made subject to the Act by election of the applicable State Racing Commission or the breed governing organization for such horse under section 3054(*l*), during the period: (A) beginning on the date of the horse's first Timed and Reported Workout at a racetrack that participates in Covered Horseraces or at a Training Facility; and (B) ending on the date on which the horse is deemed retired pursuant to Rule 3050(b) (each, a Covered Horse); and

(3) the following persons (each, a Covered Person): all Trainers, Owners, Breeders, Jockeys, Racetracks, Veterinarians, Persons licensed by a State Racing Commission, and the agents, assigns, and employees of such Persons; any other Persons required to be registered with the Authority; and any other horse support personnel who are engaged in the care, treatment, training, or racing of Covered Horses.

(b) Pursuant to section 3054 of the Act, Covered Persons must register with the Authority. However, they are bound by the Protocol by undertaking the activity (or activities) that make(s) them a Covered Person, whether or not they register with the Authority.

(c) Owners. Covered Horses may be owned by a sole individual, multiple individuals, or one or more entities. As a consequence of the various ownership structures and property interests of Covered Horses, it is necessary to identify which Person shall be responsible as the Owner for purposes of registration, communication, personal liability, and other requirements under the Protocol and related rules. Accordingly:

(1) For purposes of mandatory registration with the Authority, any Covered Person who owns a 5% or greater ownership or property interest in a Covered Horse shall register with the Authority as an Owner.

(2) The following person shall be responsible as the Owner for any communication, notification, and reporting requirements under the Protocol:

(i) if the Covered Horse is owned by one individual, that individual; or

(ii) if the Covered Horse is owned by more than one individual or by a partnership, corporation, limited liability company, syndicate, or other association or entity, the individual designated in the Authority's database as the representative for the other owners of the Covered Horse authorized to receive communications or notifications and fulfill any reporting requirements on their behalf in respect of the Covered Horse (Designated Owner).

(3) If Rule 3030 makes the Owner the Responsible Person for a Covered Horse, that shall mean that the following person is personally liable for violations involving that Covered Horse:

(i) if the Covered Horse is owned by one individual, that individual; or

(ii) if the Covered Horse is owned by more than one individual or by a partnership, corporation, limited liability company, syndicate, or other association or entity, the individual who manages the Covered Horse as a matter of fact (Managing Owner). If an individual owns more than a 50% stake in a Covered Horse or where the entity that owns the Covered Horse has designated an individual with an ownership interest in the Covered Horse as the individual who will be personally liable under the Protocol as the Owner of the Covered Horse, that individual will be presumed to be the Managing Owner. If an individual with an ownership or property interest in the Covered Horse who is not the Managing Owner makes a relevant decision about the Covered Horse that leads to a violation of the Protocol, that person shall be jointly and severally liable with the Managing Owner for such decision as an Owner of the Covered Horse.

(4) Only the following persons may attend hearings under the Protocol as the Owner of the Covered Horse, unless otherwise agreed by the hearing panel:

(i) if the Covered Horse is owned by one individual, that individual; or

(ii) if the Covered Horse is owned by more than one individual or by a partnership, corporation, limited liability company, syndicate, or other association or entity, the Designated Owner or Managing Owner.

(5) Unless the context requires otherwise, the individual owner or Managing Owner of the Covered Horse (as applicable) shall be responsible for discharging any other requirements imposed on an Owner under the Protocol or related rules.

Rule 3030. Responsible Persons

(a) ''Responsible Person'' means the Trainer of the Covered Horse. If the Covered Horse does not have a Trainer, the Responsible Person shall be the Owner of the Covered Horse. The Responsible Person shall be personally liable for his or her Covered Horse(s) as set out under the Protocol. Other Covered Persons who make a relevant decision about the Covered Horse may also be liable depending on the facts and circumstances.

(b) If a Covered Horse is claimed in a Claiming Race, the person designated as the Responsible Person prior to that Claiming Race shall be liable for any violation resulting from a Sample collected on Race Day. The person who claims the Covered Horse in the Claiming Race shall not be liable for such violation, unless he or she was complicit in the violation.

(c) The Responsible Person shall register their designation as the Responsible Person for a Covered Horse with the Authority and shall keep such designation and registration up-to-date. Any transfer of the Responsible Person designation to another Covered Person shall be done with the Authority in accordance with its procedures prior to the effective date of the transfer, except that if a Covered Horse is claimed in a Claiming Race, the transfer shall be done on the day of the Claiming Race.

(d) The Responsible Person for a Covered Horse shall be the sole representative for the interests of that Covered Horse in any matter arising under the Protocol. The Owner (if not the Responsible Person) may attend any hearing concerning a violation of the Protocol involving his or her Covered Horse(s) in accordance with the Arbitration Procedures.

Rule 3040. Core responsibilities of Covered Persons

(a) Responsibilities of All Covered Persons

It is the personal responsibility of each Covered Person:

(1) to be knowledgeable of and to comply with the Protocol and related rules at all times. All Covered Persons shall be bound by the Protocol and related rules, and any revisions thereto, from the date they go into effect, without further formality. It is the responsibility of all Covered Persons to familiarize themselves with the most up-to-date version of the Protocol and related rules and all revisions thereto;

(2) to cooperate promptly and completely with the Authority and the Agency in the exercise of their respective powers under the Act and the Protocol and related rules, including:

(i) in relation to the Testing program and in relation to the investigation of potential violations of the Protocol;

(ii) by providing complete and accurate information to the Authority and the Agency in all interactions and filings; and

(iii) on request by the Agency:

(A) making available for inspection any facility, office, stall, or equipment or other relevant location that is used in the care, treatment, training, or racing of Covered Horses, or any feed, medicine, or other item given to Covered Horses;

(B) submitting to under-oath transcribed interviews about his or her dealings with or in relation to Covered Horses;

(C) providing immediate and unfettered access to any and all data, documents, and records used in the care, treatment, training or racing of any Covered Horse (including, but not limited to, data, documents and records existing in electronic form, *e.g.,* on computers, mobile phones, or other devices); and

(D) permitting the Agency to review or make and take away copies of any such data, documents, or records for analysis, investigation, and potential use as evidence of a violation of the Protocol by a Covered Person;

Failure to cooperate promptly and completely with the Agency may constitute a violation pursuant to Rule 3510(b); and

(3) not to engage in offensive conduct towards any Sample Collection Personnel or any representative of the Agency or the Authority (including engaging in improper, insulting, or obstructive conduct, or recording any Sample Collection Session contrary to Rule 5410). Failure to comply may constitute a violation pursuant to Rule 3510(a) or Tampering or Attempted Tampering, depending on the circumstances of the case.

(b) Additional Responsibilities of Responsible Persons

In addition to the duties under Rule 3040(a), it is the personal responsibility of each Responsible Person:

(1) to ensure that Covered Horses for which he or she is the Responsible Person are made available for Sample collection at any time and any place where they are located (*e.g.,* Racetrack, Training Facility, private facility) upon request by the Agency (or its delegate). In particular, without limiting the generality of the foregoing:

(i) The Responsible Person shall ensure that the Covered Horse is produced for Sample collection immediately upon notification by a duly authorized person in accordance with the Agency's procedures if the Covered Horse is present at the location where notification is attempted. If the Covered Horse is present at the location where notification is attempted, failure to produce a Covered Horse immediately upon valid notification shall constitute an Anti-Doping Rule Violation under Rule 3215.

(ii) If the Covered Horse is not present at the location where notification is attempted (including due to a Whereabouts Failure), the Responsible Person shall ensure that the Covered Horse is produced for Sample collection within 6 hours of notification by a duly authorized Person in accordance with the Agency's procedures, except that the Agency may extend the 6-hour period if it determines that extenuating circumstances justify doing so. If the Covered Horse is not present at the location where notification is attempted or if a Covered Horse cannot be located by the Agency, failure to produce a Covered Horse for Sample collection within 6 hours (or any extended period agreed by the Agency) of valid notification period shall constitute an Anti-Doping Rule Violation under Rule 3215.

(2) to either be present during a Sample collection involving his or her Covered Horse and comply with all Sample collection procedure requirements, or (if not present) to ensure that a Nominated Person who is 18 years or older is present to represent him or her and complies with all Sample collection procedure requirements;

(3) to ensure that treatments and medications administered to his or her Covered Horses:

(i) are administered only on the advice of a Veterinarian or (if a prescription is not required) following sufficient due diligence regarding the treatment or medication;

(ii) are not administered in a manner detrimental or contrary to horse welfare;

(iii) are the minimum necessary to address the diagnosed health concerns identified during the veterinary examination and diagnostic process;

(iv) do not contain a Banned Substance or involve a Banned Method; and

(v) do not otherwise violate the Protocol;

(4) to inform all Covered Persons (including Veterinarians), employees, personnel, agents, and other Persons involved in any way with the care, treatment, training, or racing of his or her Covered Horses of their respective obligations under the Protocol (including, in particular, those specified in Rule 3040(a));

(5) to adequately supervise all Covered Persons (including Veterinarians), employees, personnel, agents, and other Persons involved in any way with the care, treatment, training, or racing of his or her Covered Horses, including by (without limitation):

(i) conducting appropriate due diligence in the hiring process before engaging their services;

(ii) clearly communicating to such Persons that compliance with the Protocol is a condition of employment or continuing engagement in the care, treatment, training, or racing of his or her Covered Horses;

(iii) creating and maintaining systems to ensure that those Persons comply with the Protocol; and

(iv) adequately monitoring and overseeing the services provided by those Persons in relation to the care, treatment, training, or racing of his or her Covered Horses;

(6) to bear strict liability for any violations of the Protocol by such Covered Persons (including Veterinarians), employees, personnel, agents, and other Persons involved in the care, treatment, training, or racing of his or her Covered Horses;

(7) to file and update as necessary with the Authority information identifying what Covered Horses he or she is the Responsible Person for;

(8) to maintain accurate, complete, and up-to-date treatment records (including, without limitation, records of medical, therapeutic, and surgical treatments and procedures, including diagnostics) of his or her Covered Horses in an electronic or other form specified by the Agency, and to provide the Agency with access to those records upon request and without delay so that it may inspect and make and retain copies of them for purposes of monitoring and ensuring compliance with the requirements of the Protocol. The records must include the details required under Rule 2251(b). The Responsible Person must retain copies of such treatment records for a period of no less than 3 years, although the Responsible Person is advised to retain them for the duration of the limitation periods under Rule 3090;

(9) at the time of registering a horse with the Authority and prior to such horse competing in any Timed and Reported Workout or Covered Horserace, the Responsible Person shall declare in writing to the Agency all administrations of Banned Substances and Banned Methods to the horse since the Responsible Person first owned the horse (or, if not the Owner, since the Owner at the time of registration first owned the horse) or since the Program Effective date, whichever is earlier. On request by the Agency, the Responsible Person shall provide any related treatment records for the horse during that period. If a Banned Substance or Banned Method has been administered in that period, the Agency may impose a stand down period for the horse of up to the period of Ineligibility that would be applicable for the relevant Banned Substance or Banned Method and require that (at the Responsible Person's cost) the Covered Horse provide one or more negative Samples before subsequently being eligible to participate in a Timed and Reported Workout or a Covered Horserace. Failure by a Responsible Person to comply with this Rule 3040(b)(9) may constitute a violation of Rule 3510(b);

(10) if any Covered Horse is moved from a Racetrack or Training Facility to a private facility (*i.e.,* a facility not under the jurisdiction of the Authority or the Agency), the Responsible Person shall provide sufficient information about the Covered Horse's whereabouts so that the Agency remains able to collect Samples from the Covered Horse at any time. The Responsible Person shall also provide any further information about the whereabouts of a Covered Horse that is specifically requested by the Agency. Failure to do so may constitute a violation of Rule 3510(d);

(11) to notify the Authority in writing within 7 days of becoming aware that any of his or her Covered Horses:

(i) is pregnant;

(ii) was pregnant but has foaled or is no longer pregnant;

(iii) has been castrated or hemicastrated (including chemical castration or immunocastration); or

(iv) has suffered a fatal condition.

In each case, the Responsible Person shall state the name of the Covered Horse, the date of the event triggering the notice, and (for paragraph (iv) above) a summary explanation regarding the cause of the fatal condition.

(c) Additional Responsibilities of Owners

In addition to the duties under Rule 3040(a):

(1) each person with a 5% percent or greater ownership or property interest in a Covered Horse shall register with the Authority as an Owner of the Covered Horse, and ensure that any transfer of ownership is registered with the Authority in accordance with its procedures; and

(2) if a Covered Horse is owned by multiple Owners, they shall ensure that the Agency is notified in writing of one Designated Owner authorized to receive communications and notifications and fulfil any reporting requirements on their behalf.

(d) Additional Responsibilities of Attending Veterinarians

In addition to the duties under Rule 3040(a), and the further duties and requirements imposed under the Rule 2000 Series (Racetrack Safety Program), it is the personal responsibility of each Attending Veterinarian to act in strict compliance with the Protocol and keep updated treatment records (including, without limitation, records of medical, therapeutic, and surgical treatments and procedures, including diagnostics) in an electronic database designated by the Agency or in any other form designated by the Agency and provide access to the Agency upon request and without delay to or copies of such treatment records. The records must include the details required under Rule 2251(b) and must be submitted in an electronic format designated by the Authority within the deadline specified in that same provision. Attending Veterinarians must retain copies of such treatment records for a period of no less than 3 years, or for the retention period required by the relevant state veterinary practice act, whichever is longer.

Rule 3050. Retirement and Equine Fatalities

(a) Covered Persons.

(1) Each Responsible Person who wishes to no longer be bound by the Protocol shall give written notice to the Authority of his or her retirement from the position that made him or her a Responsible Person. In each case, the Responsible Person shall be deemed to have retired (and to be no longer subject to the Protocol) on the later of (i) the date given in the written notice of retirement and (ii) the date the notice is received.

(2) Any other Covered Person will continue to be bound by and required to comply with the Protocol and related rules unless and until he or she unregisters with the Authority.

(3) If a Covered Person ceases to be subject to the Protocol while the Agency is conducting a Results Management process in respect of that person, the Agency retains jurisdiction to complete

its Results Management process. If a Covered Person retires or ceases to be subject to the Protocol before any Results Management process has begun, and the Agency had jurisdiction over the Covered Person at the time the Anti-Doping Rule Violation or Controlled Medication Rule Violation was committed, the Agency retains jurisdiction to conduct Results Management in respect of that violation.

(4) If a Covered Person retires while subject to a period of Ineligibility, he or she must give written notice of such retirement to the Authority. The Covered Person may not return to the sport (*i.e.,* carry out any of the activities prohibited during the period of Ineligibility pursuant to Rules 3229 and 3329) unless the Covered Person has given 4 months' prior written notice (or notice equivalent to the period of Ineligibility remaining as of the date the Covered Person retired, if that period was longer than 4 months) to the Authority of his or her intent to return to the sport.

(5) The Agency may forward notifications of retirement of Covered Persons to Interested Parties or other Persons with a need to know.

(b) Covered Horses.

(1) If an Owner wishes to retire a Covered Horse such that it is no longer made available for Testing, the Owner must provide written notice of such retirement to the Agency, in accordance with its procedures.

(2) A Covered Horse that has been retired in accordance with the previous clause may not participate in a Timed and Reported Workout or be entered in a Covered Horserace until the Covered Horse has been made available for Testing at least 4 months prior to notice being given to the Agency (in accordance with its procedures) of the intention to unretire the Covered Horse.

(3) If a Covered Horse is retired from horseracing or suffers a fatal condition while the Agency is conducting a Results Management process in respect of it, the Agency retains jurisdiction to complete its Results Management process. If a Covered Horse is retired or suffers a fatal condition before any Results Management process has begun, and the Agency had jurisdiction over the Covered Horse at the time the Anti-Doping Rule Violation or Controlled Medication Rule Violation was committed, the Agency retains jurisdiction to conduct Results Management in respect of that violation. If a Covered Horse suffers a fatal condition, the Agency retains Testing authority over that horse in accordance with Rule 3132(d).

(4) If a Covered Horse is retired from horseracing while subject to a period of Ineligibility, the Owner must notify the Agency in writing of such retirement. If the Owner wishes that horse to return to participation in Covered Horseraces or Timed and Reported Workouts, the Owner must first provide the Agency with written notice and make the Covered Horse available for Testing for at least 4 months prior to such participation or for the remainder of the Covered Horse's period of Ineligibility, whichever is longer.

(5) In order to manage the number of Covered Horses registered with the Authority, the Agency may retire a Covered Horse based on inactivity (*i.e.,* where the Covered Horse does not participate in a Timed and Reported Workout or Covered Horserace for 18 months or more, excluding periods of inactivity due to a Provisional Suspension or period of Ineligibility) by sending written notice thereof to the Authority and the Owner in accordance with the Agency's procedures. If the Owner disputes that retirement, while the dispute is pending the Covered Horse may not participate in any Timed and Reported Workout or Covered Horserace but must be made available for Testing. Upon resolution of the dispute, the Authority will notify the Agency whether the horse is retired and, therefore, no longer subject to Testing. If the Owner wishes to return the Covered Horse to participation in Timed and Reported Workouts or Covered Horseraces, the Owner must first provide the Agency with written notice and make the Covered Horse available for Testing for at least 4 months prior to such participation.

(6) The Agency may reduce the 4-month notice period in Rule 3050(b) to 2 months where the Owner of the Covered Horse submits an application establishing good cause to do so, and where the Agency approves such application based on a review conducted in accordance with the objectives of the Protocol.

(7) The Agency may forward notifications of retirement of Covered Horses to Interested Parties or other Persons with a need to know.

Rule 3060. Claiming Races and Voidable Claims

(a) Subject to Rule 3132(b), a claimed horse may be subject to Sample collection at a Claiming Race if requested (and paid for) by the claimant as part of the claiming procedure on the day of the Claim. If a Sample collected from the claimed horse results in an Anti-Doping Rule Violation or Controlled Medication Rule Violation, the Claim may be voided at the option of the claimant, and the claimant shall be entitled to the return from the seller of all sums paid for the claimed horse and of all reasonable expenses incurred after the date of the Claim. While awaiting test results, a claimant shall: (i) exercise due care in maintaining and boarding a claimed horse; and (ii) not materially alter a claimed horse.

(b) Any voided claim shall be recorded in Equibase.

Rule 3070. Amendment and Interpretation of the Protocol

(a) The Authority may amend the Protocol from time to time, as necessary to ensure that it remains fit for purpose, in accordance with section 3057(e) of the Act. Unless provided otherwise, any amendments will come into force on the date specified or (if no date is specified) on the date the amendment is approved by the Commission.

(b) Subject to Rule 3070(d), the Protocol shall be interpreted as an independent and autonomous text and not by reference to existing law or statutes.

(c) The Protocol has been adopted pursuant to the Act and shall be interpreted, where applicable, in a manner that is consistent with applicable provisions of the Act and the other rules in Rule 1000–9000 Series. In the event of any conflict between the Act and the Protocol, the Act shall prevail. In the event of any conflict between the Protocol and any other rules in Rule 1000–9000 Series, the Protocol shall prevail.

(d) The World Anti-Doping Code and related International Standards, procedures, documents, and practices (WADA Code Program), the comments annotating provisions of the WADA Code Program, and any case law interpreting or applying any provisions, comments, or other aspects of the WADA Code Program, may be considered when adjudicating cases relating to the Protocol, where appropriate.

Rule 3080. Transitional Provisions

(a) The Protocol shall not apply retroactively to matters pending before the Program Effective Date.

(b) A presence violation under Rule 3212 or Rule 3312 that occurs after the Program Effective Date as a result of Use or Administration prior to the Program Effective Date shall not constitute a violation of the Protocol.

(c) The relevant State Racing Commission retains authority (including results management) in relation to any anti-doping or controlled medication

matters taking place prior to the Program Effective Date.

(d) Changes to substances or methods covered by the Prohibited List or related Technical Document-Prohibited Substances shall not, unless they specifically provide otherwise, be applied retroactively. However, a Responsible Person or other Covered Person who is serving a period of Ineligibility on account of a Prohibited Substance or Prohibited Method that is later subject to a change in status (either because it is no longer prohibited or subject to lesser sanctions) may apply to the Agency for consideration of a reduction in the period of Ineligibility in light of that change in status. The Responsible Person may also apply to the Agency for consideration of a reduction in the period of Ineligibility applicable to his or her Covered Horse(s).

Rule 3090. Statute of Limitations

(a) No charge may be brought against a Covered Person or in relation to a Covered Horse in respect of an Anti-Doping Rule Violation unless the Covered Person or Responsible Person for the Covered Horse has been given notice, or notification has been reasonably attempted, within 10 years of the date the Anti-Doping Rule Violation is asserted to have occurred. Any violation of Rule 3229 is also subject to a 10-year limitation period.

(b) No charge may be brought against a Covered Person or in relation to a Covered Horse in respect of a Controlled Medication Rule Violation unless the Covered Person or Responsible Person for the Covered Horse has been given notice, or notification has been reasonably attempted, within 2 years of the date the Controlled Medication Rule Violation is asserted to have occurred. Any violation of Rule 3329 is also subject to a 2-year limitation period.

(c) Any violation of Rule 3510 is subject to a 4-year limitation period.

*3110. The Prohibited List*

Rule 3111. Prohibited Substances and Prohibited Methods

(a) The Prohibited List identifies Prohibited Substances and Prohibited Methods that are:

(1) prohibited at all times (Banned Substances and Banned Methods) on the basis of the Agency's determination that medical, veterinary, or other scientific evidence or experience supports their actual or potential (i) ability to enhance the performance of Covered Horses, (ii) masking properties, or (iii) detrimental impact on horse welfare; or

(2) prohibited for Use or Administration in relation to a Covered Horse during the Race Period and prohibited to be present in a Post-Race Sample or Post-Work Sample, except as otherwise specified in the Prohibited List (Controlled Medication Substances and Controlled Medication Methods).

(b) Prohibited Substances and Prohibited Methods may be included in the Prohibited List by general category (*e.g.,* anabolic steroids) or by specific reference to a particular substance or method.

(c) The Prohibited List is supplemented by the ''Technical Document—Prohibited Substances,'' which provides guidance on the Prohibited Substances that fall into the general categories listed in the Prohibited List and on Screening Limits, Thresholds, or Detection Times for those Prohibited Substances (as applicable), and also designates certain Prohibited Substances as Specified Substances, which are those that pose a higher risk of being the result of contamination and, therefore, are subject to more flexible sanctions.

(d) Certain Prohibited Substances may first be reported as Atypical Findings requiring further investigation before being declared as Adverse Analytical Findings, in accordance with the Atypical Findings Policy set out at Appendix 1 to the Protocol.

Rule 3112. Review and Publication of the Prohibited List and Related Technical Documents

The Agency will publish the Prohibited List on its website at least annually, following an opportunity for stakeholder comment. The Agency will review and consider such stakeholder comment and will provide recommended revisions to the Authority. Each new version of the Prohibited List will also be sent to the State Racing Commissions. The Authority (on recommendation of the ADMC, in consultation with the Agency) may revise the Prohibited List from time to time, subject to approval by the Commission. Revisions to the Prohibited List will go into effect on the date specified in the revised Prohibited List (which will not be any earlier than 90 days following its publication). The Agency will also publish any Technical Documents supplementing the Prohibited List (including the Technical Document-Prohibited Substances) on its website at least annually, following an opportunity for public comment. Any revisions to such Technical Documents will go into effect on the date specified in the revised Technical Document. All Covered Persons shall be bound by the Prohibited List and related Technical Documents (including the Technical Document-Prohibited Substances), and any revisions thereto, from the date they go into effect, without further formality. It is the responsibility of all Covered Persons to familiarize themselves with the most up-to-date version of the Prohibited List and related Technical Documents (including the Technical Document-Prohibited Substances) and all revisions thereto.

Rule 3113. Validity of the Prohibited List and Related Technical Documents

The following decisions are final and shall not be subject to any challenge by any Covered Person or other Person on any basis, including any challenge based on an argument that the substance or method is not a masking agent or does not have the potential to enhance the performance of Covered Horses or have a detrimental impact on horse welfare:

(a) the Authority's determination of the Prohibited Substances and Prohibited Methods included on the Prohibited List or Technical Document-Prohibited Substances;

(b) the approval of the Prohibited List or Technical Document-Prohibited Substances by the Commission or the Authority;

(c) the classification of substances and methods into categories or classes on the Prohibited List or Technical Document-Prohibited Substances;

(d) the classification of a substance or method as a Banned Substance or Banned Method as opposed to a Controlled Medication Substance or Controlled Medication Method;

(e) the periods during which Prohibited Substances or Prohibited Methods are prohibited; and

(f) the classification of Prohibited Substances as either Specified Substances or non-Specified Substances.

Rule 3114. Monitoring Program

The Agency may approve a monitoring program regarding substances that are not on the Prohibited List or Technical Document-Prohibited Substances, if the Agency wishes to research or monitor such substances, including to identify potential patterns of misuse in horseracing. Laboratories will report the instances of reported Use or detected presence of monitored substances to the Agency, but the results of any such analyses shall not constitute an Anti-Doping Rule Violation or Controlled Medication Rule Violation. Nothing in this Rule 3114 or elsewhere in the Protocol prevents a Laboratory from sharing information with the Agency for any anti-doping or controlled

medication purpose or other purpose authorized by the Act. The list of substances in the monitoring program will be reviewed annually by the Agency.

*3120. Proof of Violations*

Rule 3121. Burden and Standard of Proof

(a) The Agency shall have the burden of establishing that a violation of the Protocol has occurred to the comfortable satisfaction of the hearing panel, bearing in mind the seriousness of the allegation that is made. This standard of proof in all cases is greater than a mere balance of probability (*i.e.,* a preponderance of the evidence) but less than clear and convincing evidence or proof beyond a reasonable doubt.

(b) Where the Protocol places the burden of proof on a Covered Person to rebut a presumption or to establish specified facts or circumstances, the standard of proof shall be by a balance of probability (*i.e.,* a preponderance of the evidence), except as provided in Rules 3122(c) and 3122(d).

Rule 3122. Methods of Establishing Facts and Presumptions

Facts related to violations may be established by any reliable means, including admissions. The following rules of proof shall apply:

(a) Analytical methods, Minimum Reporting Levels, Thresholds, Screening Limits, Decision Limits, and any other Laboratory reporting requirements approved by the Commission are presumed to be scientifically valid.

(b) Compliance with the Standards (as opposed to an alternative standard, practice, or procedure) will be sufficient to conclude that the procedures addressed by those Standards were performed properly.

(c) Laboratories are presumed to have conducted Sample analysis and custodial procedures in accordance with the Laboratory Standards. A Covered Person who is alleged to have committed a violation may rebut this presumption by establishing that a departure from the Laboratory Standards occurred that could reasonably have caused the Adverse Analytical Finding or other factual basis for any other violation asserted. Where the presumption is rebutted, the Agency shall have the burden of establishing that such departure did not cause the Adverse Analytical Finding or other factual basis for the violation asserted.

(d) Departures from any other Standards or any provisions of the Protocol shall not invalidate analytical results or other evidence of a violation, and shall not constitute a defense to a charge of such violation; provided, however, that if the Covered Person establishes that a departure from any other Standards or any provisions of the Protocol could reasonably have caused the Adverse Analytical Finding or other factual basis for the violation charged, the Agency shall have the burden to establish that such departure did not cause the Adverse Analytical Finding or other factual basis for the violation.

(e) Non-appealable and final factual findings of a court, arbitral tribunal, professional disciplinary body, or administrative body of competent jurisdiction shall be irrebuttable evidence against the Covered Person to whom the decision pertained of those facts, unless the Covered Person establishes that the decision did not respect due process.

(f) A hearing panel may draw an inference adverse to a Covered Person who is asserted to have committed a violation of the Protocol based on the Covered Person's refusal to cooperate with the Agency, including any refusal to respond to questions put to him or her as part of an investigation or to appear at the hearing (either in person or remotely) and to answer questions put by the Agency or the hearing panel.

*3130. Testing and Investigations*

Rule 3131. Purpose of Testing and Investigations

Testing and investigations may be undertaken to assist in the effective policing and enforcement of the Protocol, including to obtain evidence regarding potential violations of the Protocol.

Rule 3132. Authority To Test

(a) Only the Agency (and those authorized by the Agency) may initiate and direct Testing on Covered Horses. The Agency has authority to conduct Testing both in and out of competition.

(b) No other entity (including State Racing Commissions, Racetracks, Race Organizers, and Training Facilities) may initiate or direct any Testing on Covered Horses. However, a State Racing Commission, Racetrack, Race Organizer, or other third party may request that the Agency initiate and direct enhanced or additional Testing (*e.g.,* in relation to a particular Covered Horserace). The Agency may accept or decline such request at its absolute discretion. Where the Agency accepts the request, the costs of Sample collection and analysis shall be borne by the entity requesting the additional or enhanced Testing. The Agency may conduct the Testing itself or delegate Testing (or aspects thereof) to the relevant State Racing Commission, subject to the applicable State Racing Commission electing to enter into an agreement with the Agency.

(c) Covered Horses may be subject to Testing at any time and any place where they are located by or on behalf of the Agency.

(d) A Covered Horse that is subject to a Provisional Suspension or period of Ineligibility, or that sustains a fatal condition, remains subject to Testing.

(e) In accordance with the Racetrack Safety Program, a Covered Horse may be required to submit to Sample collection (at the Owner's cost) following a Vets' List Workout in order to be released from the Veterinarians' List. Any Sample collected following a Vets' List Workout constitutes a Post-Race Sample, and, as a result, is subject to all of the same requirements that apply to Sample collection at Covered Horseraces. To schedule a Vets' List Workout, the Responsible Person or the Owner of the Covered Horse shall make a request to a Regulatory Veterinarian who shall, in turn, notify the Agency in order to make any necessary arrangements. The Agency must be given a minimum of 48 hours' notice of any Vets' List Workout.

Rule 3133. Requirements

(a) Testing. The Agency shall conduct test distribution planning and Testing in accordance with the Testing and Investigations Standards. The Agency may delegate authority to third parties, including State Racing Commissions (see Rule 3132), to conduct Testing (or aspects thereof) in accordance with the Testing and Investigations Standards under its supervision.

(b) Investigations and intelligence gathering. The Agency shall gather intelligence and conduct investigations, or delegate to third parties to do so under its supervision, in accordance with the Testing and Investigations Standards, which incorporate uniform rules and procedures in accordance with section 3054 of the Act providing for:

(1) access for the Agency to books, records, offices, racetrack facilities, and other places of business of Covered Persons that are used in the care, treatment, training, or racing of Covered Horses;

(2) the issuance and enforcement of subpoenas and subpoenas duces tecum by the Authority at the request of the Agency;

(3) the exercise of other investigatory powers similar in nature and scope to those exercised by State Racing

Commissions before the Program Effective Date; and

(4) the coordination and sharing of intelligence and information with the Authority, law enforcement (authorized by any government, including Federal, State, or international), State Racing Commissions, Racetracks, Race Organizers, Training Facilities, Laboratories, anti-doping organizations, equine regulatory bodies, or other relevant regulatory or disciplinary authorities.

Rule 3134. Sample Analysis

Samples shall be analyzed in accordance with the principles set forth in Rules 3135 through 3139.

Rule 3135. Ownership of Samples

Samples collected under the Protocol are the property of the Authority, and the Authority is entitled (subject to Rule 3138(b)) to determine all matters regarding access to and the analysis and disposal of such Samples.

Rule 3136. Use of Approved Laboratories and Other Laboratories

(a) The Agency will publish a list of approved Laboratories, which may be revised from time to time.

(b) Subject to paragraph (d) below, Samples collected by or on behalf of the Agency pursuant to the Protocol will be analyzed by approved Laboratories. Only approved Laboratories may declare an Adverse Analytical Finding.

(c) Selection of Laboratories.

(1) Subject to paragraph (2) below, a State Racing Commission may select a Laboratory to analyze A Samples or TCO2 Samples collected in its State. If a State Racing Commission does not select a Laboratory, the selection of the Laboratory to analyze such Samples shall be determined exclusively by the Agency.

(2) The Agency shall have the authority to require specific Samples to be directed to and analyzed by Laboratories having special expertise in the required analysis.

(3) The selection of the Laboratory for any B Sample analysis shall be determined exclusively by the Agency. The B Sample analysis (if applicable) will be performed in a different Laboratory from the A Sample analysis, except if provided otherwise in the Laboratory Standards.

(d) In accordance with Rule 3122, facts related to violations of the Protocol may be established by any reliable means. This would include, for example, laboratory analysis or other forensic testing conducted reliably outside of Agency-approved laboratories.

Rule 3137. Purpose of Sample Analysis

(a) General. Samples, related analytical data, Doping Control information, and Medication Control information shall be analyzed (1) to detect the presence of Prohibited Substances and Prohibited Methods identified on the Prohibited List (or Technical Document—Prohibited Substances) and other substances as may be directed pursuant to Rule 3114, (2) to assist the Agency in profiling relevant parameters in a Covered Horse's urine, blood, hair, or other matrix, including for DNA or genomic profiling, or (3) for any other legitimate purpose.

(b) Research on Samples and Data. Samples, related analytical data, Doping Control information, and Medication Control information may be used for anti-doping or medication control research purposes. However, the results of any analyses performed for such research purposes may not be used as the basis for pursuing an Anti-Doping Rule Violation or Controlled Medication Rule Violation.

Rule 3138. Standards for Sample Analysis and Reporting

(a) General. Laboratories may not accept or analyze any Samples from Covered Horses that were not collected by or on behalf of the Agency or otherwise authorized by the Agency. Laboratories shall analyze Samples and report results in accordance with the Laboratory Standards. The results of all Sample analyses must be sent exclusively to the Agency via secure transmission in a form designated by the Agency. All communications must be conducted in such a way that the results of the Sample analyses are kept confidential.

(b) Further Analysis of a Sample prior to or during Results Management. Further Analyses may be conducted, without limitation, on a Sample prior to the time that it is reported as negative or prior to the time that the Agency notifies a Covered Person that the Sample is the basis for an Anti-Doping Rule Violation or Controlled Medication Rule Violation. If the Agency notifies a Covered Person that the Sample is the basis for an Anti-Doping Rule Violation or Controlled Medication Rule Violation, and the Agency wishes to conduct Further Analyses on that Sample after such notification, it may do so only with the consent of the Covered Person or the approval of the hearing panel adjudicating the case against the Covered Person.

(c) Further Analysis of a Sample after it has been reported as negative or has otherwise not resulted in an Anti-Doping Rule Violation or Controlled Medication Rule Violation. A Sample that has been reported as negative or has otherwise not resulted in a charge may be stored and subjected to Further Analyses for the purpose described in Rule 3137 at any time exclusively at the direction of the Agency. Any Sample storage and Further Analysis initiated by the Agency shall be at the Agency's expense. Further Analysis of Samples shall be conducted in accordance with the Laboratory Standards.

(d) Split of A or B Sample. Where, in exceptional circumstances, the Laboratory (on instruction from the Agency) is required to further split an A or B Sample for the purpose of using the first part of the resulting split Sample for an A Sample analysis and the second part of the resulting split Sample for B confirmation, the procedures and analysis shall be conducted in accordance with the Laboratory Standards.

Rule 3139. The Agency's Right To Take Possession of Samples and Related Data

The Agency may at any time, with or without prior notice, take physical possession of any Sample collected by or on behalf of the Agency and any related analytical data or information in the possession of a Laboratory. Upon request by the Agency, the Laboratory in possession of the Sample or related data shall grant access to and enable the Agency to take physical possession of the Sample or data as soon as possible.

Rule 3140. Clearance Testing

Clearance testing for a Covered Horse at the request of a Covered Person (*i.e.,* testing to determine if Controlled Medications Substances have cleared the horse's system) may be performed by a Laboratory only if in advance of such testing (1) the Agency approves such request (which approval may be subject to conditions determined by the Agency), and (2) the Covered Person pays for all of the costs of Sample collection and analysis. The Agency may pursue any violation of the Protocol that is evidenced by the results of the clearance testing.

*3210. Anti-Doping Rule Violations*

Rule 3211. Definition of Anti-Doping Rule Violation and Responsibility for Violations

(a) Doping cases will be initiated based on the assertion that one or more of Rules 3212 through 3216 has been violated (each, an Anti-Doping Rule Violation).

(b) The Anti-Doping Rule Violations described below may only be committed

by Covered Persons, but the Consequences for Anti-Doping Rule Violations may apply to both the Covered Person(s) who commit(s) the violation and any Covered Horse(s) implicated by the violation.

(c) All Covered Persons are responsible for knowing what constitutes an Anti-Doping Rule Violation and what Banned Substances and what Banned Methods are included on the Prohibited List and Technical Document–Prohibited Substances.

Rule 3212. Presence of a Banned Substance

(a) It is the personal and non-delegable duty of the Responsible Person to ensure that no Banned Substance is present in the body of his or her Covered Horse(s). The Responsible Person is therefore strictly liable for any Banned Substance or its Metabolites or Markers found to be present in a Sample collected from his or her Covered Horse(s). Accordingly, it is not necessary to demonstrate intent, Fault, negligence, or knowing Use on the part of the Responsible Person in order to establish that the Responsible Person has committed a Rule 3212 Anti-Doping Rule Violation.

(b) Sufficient proof of a Rule 3212 Anti-Doping Rule Violation is established by any of the following:

(1) the presence of a Banned Substance or its Metabolites or Markers in the Covered Horse's A Sample where the Responsible Person waives analysis of the B Sample and the B Sample is not analyzed;

(2) the Covered Horse's B Sample is analyzed and the analysis of the B Sample confirms the presence of the Banned Substance or its Metabolites or Markers found in the A Sample; or

(3) where, in exceptional circumstances, the Laboratory (on instruction from the Agency) further splits the A or B Sample into two parts in accordance with the Laboratory Standards, the analysis of the second part of the resulting split Sample confirms the presence of the same Banned Substance or its Metabolites or Markers as were found in the first part of the split Sample, or the Responsible Person waives analysis of the second part of the split Sample.

(c) The general rule is that the presence of any amount of a Banned Substance or its Metabolites or Markers in a Sample collected from a Covered Horse constitutes an Anti-Doping Rule Violation by the Responsible Person of that Covered Horse.

(d) As an exception to the general rule of Rule 3212(c), the Prohibited List, Standards, or Technical Documents may establish special criteria for the reporting or the evaluation of certain Banned Substances, including a Minimum Reporting Level, Screening Limit, Threshold, or Decision Limit.

Rule 3213. Use or Attempted Use of a Banned Substance or a Banned Method

(a) Subject to Rule 3213(c), the Use or Attempted Use of a Banned Substance or Banned Method in relation to a Covered Horse constitutes an Anti-Doping Rule Violation. The success or failure of that Use or Attempted Use is not material. For a Rule 3213 violation to be committed, it is sufficient that the Banned Substance or Banned Method was Used or Attempted to be Used.

(b) It is the personal and non-delegable duty of the Responsible Person to ensure that no Banned Substance or Banned Method is Used in relation to his or her Covered Horse. The Responsible Person is therefore strictly liable for any Use of a Banned Substance or Banned Method in relation to his or her Covered Horse(s). Accordingly, it is not necessary to demonstrate intent, Fault, negligence, or knowing Use on the part of the Responsible Person in order to establish that the Responsible Person has committed a Rule 3213 Anti-Doping Rule Violation of Use. However, in accordance with the definition of Attempt, it is necessary to show intent on the part of the Responsible Person in order to establish that the Responsible Person has committed a Rule 3213 Anti-Doping Rule Violation of Attempted Use.

(c) The presence of a Prohibited Substance or of evidence of Use of a Prohibited Method in the Covered Horse's Sample or other evidence of Use of such Prohibited Substance or Prohibited Method shall not be considered an Anti-Doping Rule Violation if it is determined to have resulted from Use of the Banned Substance or Banned Method prior to the horse becoming a Covered Horse. However, any such Use is subject to Rule 3040(b)(9) and may be reported to the relevant State Racing Commission.

Rule 3214. Other Anti-Doping Rule Violations Involving Banned Substances or Banned Methods

The following acts and omissions constitute Anti-Doping Rule Violations by the Covered Person(s) in question:

(a) Possession of a Banned Substance or a Banned Method, unless there is compelling justification for such Possession.

(b) Trafficking or Attempted Trafficking in any Banned Substance or Banned Method.

(c) Administration or Attempted Administration to a Covered Horse of any Banned Substance or any Banned Method.

Rule 3215. Evading Collection of a Sample From a Covered Horse; Refusing or Failing Without Compelling Justification To Submit a Covered Horse To Sample Collection; or Refusing or Failing To Comply With All Sample Collection Procedure Requirements

(a) Except as provided in Rule 3215(d), each of the following constitutes an Anti-Doping Rule Violation: (1) evading collection of a Sample from a Covered Horse, (2) refusing or failing without compelling justification to submit a Covered Horse to Sample collection after notification by a duly authorized person, or (3) refusing or failing to comply with all Sample collection procedure requirements.

(b) Responsible Persons are responsible for ensuring compliance with Rules 3040(b)(1) and 3040(b)(2). A Responsible Person may delegate the submission and supervision of the Covered Horse to a third party, but the Responsible Person remains responsible for the Covered Horse throughout the Sample collection process and for the acts and omissions of his or her delegate. Therefore, the Responsible Person shall be deemed liable for any evasion by his or her delegate of Sample collection, any refusal or failure by his or her delegate without compelling justification to submit the Covered Horse to Sample collection, or any refusal or failure by his or her delegate to comply with all Sample collection procedure requirements.

(c) Sample collection shall ordinarily be conducted where the Covered Horse is located (*e.g.,* Racetrack, Training Facility, or private facility), unless the Agency agrees that the Covered Horse may be transported to another agreed location (*e.g.,* a nearby Racetrack).

(d) No violation occurs where a Covered Horse is made available for Sample collection, but a Sample is not collected because the Covered Horse is intractable.

Rule 3216. Other Anti-Doping Rule Violations

The following acts and omissions constitute Anti-Doping Rule Violations by the Covered Person(s) in question:

(a) Tampering or Attempted Tampering by a Covered Person with any part of Doping Control or Medication Control;

(b) a Covered Person assisting, encouraging, aiding, abetting, conspiring, covering up, or engaging in

any other type of intentional complicity or Attempted complicity involving (1) an Anti-Doping Rule Violation or Attempted Anti-Doping Rule Violation, or (2) a violation of Rule 3229 by another Covered Person.

(c) Prohibited Association:

(1) Association by a Covered Person in a professional or sport-related capacity with any Person who:

(i) is serving a period of Ineligibility imposed pursuant to the Protocol or is serving a period of ineligibility imposed pursuant to anti-doping rules administered by any other equine regulatory body or anti-doping organization; or

(ii) has been found in a criminal, disciplinary, or professional proceeding to have engaged in conduct that would have constituted a violation of the Protocol if it had been applicable to such Person at the relevant time. The disqualifying status of such Person shall last for the longer of:

(A) 6 years from the criminal, professional, or disciplinary decision; and (B) the duration of the criminal, disciplinary, or professional sanction imposed; or

(iii) is serving as a front or intermediary for an individual falling within paragraph (i) or (ii) above.

(2) To establish a violation of Rule 3216(c), the Agency must establish that the Covered Person knew at the relevant time of the Person's disqualifying status. It is presumed that any association with the Person described in Rules 3216(c)(1)(i) and (ii) is in a professional or sport-related capacity, and the burden shall be on the Covered Person to rebut that presumption.

(3) It shall be a defense to a charge of violation of Rule 3216 if the Covered Person establishes that the association with the Person could not have been reasonably avoided.

(d) Acts by a Covered Person to discourage or retaliate against reporting to authorities.

(1) Where such conduct does not otherwise constitute a violation under Rule 3216(a) (Tampering or Attempted Tampering), each of the following constitutes an Anti-Doping Rule Violation under this Rule 3216(d):

(i) any act that threatens or seeks to intimidate another Person with the intent of discouraging that Person from the good faith reporting of information that relates to an alleged Anti-Doping Rule Violation or other alleged non-compliance with the Protocol to the Agency or other appropriate Person; and

(ii) retaliation against a Person who, in good faith, has provided evidence or information that relates to an alleged Anti-Doping Rule Violation or other alleged non-compliance with the Protocol to the Agency or other appropriate entity or Person.

(2) For purposes of Rule 3216(d), threatening or seeking to intimidate a Person, and retaliation against a Person, include an act taken against such Person that lacks a good faith basis or is a disproportionate response.

*3220. Sanctions*

Rule 3221. Disqualification of the Covered Horse's Results

(a) Automatic Disqualification of results.

(1) An Anti-Doping Rule Violation that arises from a Post-Race Sample, or that occurs during the Race Period, automatically leads to Disqualification of the results of the Covered Horse obtained on the Race Day(s) that fall(s) within the Race Period, even if any other sanction for the violation is eliminated or reduced under Rules 3224, 3325, or 3226.

(2) In circumstances where an EAD Notice has been sent as required under Rule 3245, and the B Sample analysis confirms the A Sample analysis, or the right to request the analysis of the B Sample is waived, the Agency, the Responsible Person, and the Owner of the Covered Horse in question may agree to apply Rule 3221 immediately, *i.e.,* prior to adjudication of any other issue, or (in the absence of such agreement) any one of them may request that the Arbitral Body apply Rule 3221 immediately.

(b) Disqualification of subsequent results.

(1) Subject to paragraph (2), in addition to the automatic Disqualification of results under Rule 3221(a), any other results that the Covered Horse obtained from the date the Anti-Doping Rule Violation first occurred, as well as during any period of retroactive Ineligibility, shall be Disqualified, unless it is established by the Responsible Person that fairness requires otherwise.

(2) If the Anti-Doping Rule Violation occurs in relation to a Claiming Race in which the Covered Horse is claimed, Rule 3221(b)(1) shall not apply to any results obtained by the Covered Horse under the new ownership.

(c) Consequence of Disqualification of results:

(1) If a Covered Horse has results Disqualified under the Protocol, all purses and other compensation, prizes, trophies, points, and rankings are forfeited and must be repaid or surrendered (as applicable) to the Race Organizer, and the results of the other Covered Horses in the race(s) in question must be adjusted accordingly and the purses, prizes, and trophies redistributed. Purses, prizes, trophies, and other compensation shall (where possible) be withheld for the Covered Horse in issue pending resolution of the relevant charge.

(2) The Covered Horses that participated in a Covered Horserace involving an alleged Anti-Doping Rule Violation are often entered in other Covered Horseraces prior to the final adjudication of the violation. The ultimate Disqualification of a Covered Horse in connection with final adjudication of a violation shall only impact that horse's conditions for eligibility. By way of example, a maiden that is Disqualified after finishing first in a maiden race shall remain a maiden until it has won another race, but the runner-up in the disputed Covered Horserace shall not be considered the winner for purposes of its future condition eligibility. The adjustment to the Disqualified horse's condition eligibility shall only occur once the violation has been finally adjudicated.

Rule 3222. Ineligibility for Covered Horses

(a) For a violation of Rule 3212 (presence), 3213 (Use or Attempted Use), or Rule 3214(c) (Administration or Attempted Administration), the Covered Horse involved shall be Ineligible for the period designated in the Prohibited List for the Banned Substance or Banned Method in issue.

(b) For a violation of Rule 3215 involving evasion of Sample collection, the Covered Horse shall be Ineligible for 18 months. For a violation of Rule 3215 involving refusal or failure to submit to Sample collection, or refusal or failure to comply with all Sample collection procedure requirements, the Covered Horse shall be Ineligible for 18 months, unless it is established by the Responsible Person that fairness requires otherwise, in which case the period of Ineligibility may be reduced, depending on the specific circumstances of the case and considerations of horse welfare.

(c) Rule 3228 on increased periods of Ineligibility for repeat offenders does not apply to Covered Horses.

(d) The period of Ineligibility for a Covered Horse shall be deemed to commence on the date that the violation occurred (which, in the case of a Rule 3212 violation, shall be the date that the positive Sample was collected, even if the Covered Horse has participated in Timed and Reported Workouts or Covered Races after that date).

Rule 3223. Ineligibility and Financial Penalties for Covered Persons

(a) General.

(1) The periods of Ineligibility and financial penalties set out in this Rule 3223 apply to the Covered Person's first doping offense. Where an offense is not the Covered Person's first doping offense, Rule 3228 applies.

(2) Unless specified otherwise, the periods of Ineligibility set out in this Rule 3223 are subject to potential elimination, reduction, or suspension pursuant to Rules 3224 to 3226 or potential increase pursuant to Rule 3227.

(3) In accordance with Rule 3247(i), any period of Provisional Suspension served by the Covered Person shall be credited against the period of Ineligibility ultimately imposed on that Covered Person for the violation in question.

(b) Consequences.

Subject to Rule 3223(a), and in addition to any other Consequences that apply under the Protocol (including Disqualification), the periods of Ineligibility and financial penalties specified below shall apply to a Covered Person for his or her first Anti-Doping Rule Violation:

| Anti-doping rule violation (first offense in ten (10) year period) | Period of ineligibility | Financial penalties |
|---|---|---|
| Presence (Rule 3212); Use or Attempted Use (Rule 3213); Possession (Rule 3214(a)); or Administration or Attempted Administration (Rule 3214(c)). | 2 years | Fine of up to $25,000 or 25% of the total purse (whichever is greater); and<br>Payment of some or all of the adjudication costs and the Agency's legal costs. |
| Trafficking or Attempted Trafficking (Rule 3214(b)). | Minimum of 4 years up to lifetime Ineligibility, depending on the seriousness of the violation.<br>A violation involving a Minor shall be considered a particularly serious violation and shall result in lifetime Ineligibility for the Covered Person who commits it.<br>A violation that may also violate non-sporting laws and regulations shall be reported to the competent administrative, professional, or judicial authorities. | Fine of up to $50,000 or 50% of the total purse (whichever is greater); and<br>Payment of some or all of the adjudication costs and the Agency's legal costs. |
| Evading collection of a Sample from a Covered Horse; refusing or failing without compelling justification to submit a Covered Horse to Sample collection; or refusing or failing to comply with all Sample collection procedure requirements (Rule 3215); or<br>Tampering or Attempted Tampering (Rule 3216(a)). | 4 years, except:<br>in the case of failing to submit to Sample collection, if the Covered Person can establish that the failure was not intentional, the period of Ineligibility shall be in a range between 3 months to 2 years, depending on his or her degree of Fault; and.<br>in all other cases, if the Covered Person can establish exceptional circumstances that justify a reduction of the period of Ineligibility, the period of Ineligibility shall be in a range from 3 months to 4 years, depending on his or her degree of Fault. | Fine up to $50,000 or 50% of the total purse (whichever is greater); and<br>Payment of some or all of the adjudication costs and the Agency's legal costs. |
| Complicity or Attempted complicity (Rule 3216(b)). | Same Consequences that apply to the principal actor, absent mitigating or aggravating circumstances. | |
| Prohibited Association (Rule 3216(c)) | 2 years, subject to a reduction down to a minimum of 1 year, depending on the Covered Person's degree of Fault and other circumstances of the case. | Fine up to $25,000 or 25% of the total purse (whichever is greater); and<br>Payment of some or all of the adjudication costs and the Agency's legal costs. |
| Acts to discourage or retaliate against reporting (Rule 3216(d)). | 2 years up to lifetime Ineligibility, depending on the seriousness of the violation. | Fine of up to $50,000 or 50% of the total purse (whichever is greater); andLI≤Payment of some or all of the adjudication costs and the Agency's legal costs. |

(c) Commencement of the period of Ineligibility for a Covered Person.

(1) Except as otherwise provided in this Rule 3223, the period of Ineligibility imposed on any Covered Person shall start on the date the period of Ineligibility is accepted or otherwise imposed in accordance with the Protocol.

(2) Where a Covered Person is already serving a period of Ineligibility for another violation of the Protocol, any new period of Ineligibility shall start to run the day after the original period of Ineligibility ends.

(3) Where there have been substantial delays in the adjudication process or other aspects of Doping Control that go well beyond the standard timeframes for Laboratory analyses and Results Management, and the Covered Person can establish that such delays are not attributable to him or her, the start date of the period of Ineligibility may be deemed back-dated to reflect such delays, but in no event may it be deemed back-dated to a date before the Anti-Doping Rule Violation last occurred. All competitive results achieved during the period of Ineligibility by the Covered Person or Covered Horse in issue, including retroactive Ineligibility, shall be Disqualified, unless it is established by the Covered Person that fairness requires otherwise.

Rule 3224. Elimination of the Period of Ineligibility Where There Is No Fault or Negligence

(a) If a Covered Person establishes in an individual case that he or she bears No Fault or Negligence for the Anti-Doping Rule Violation(s) charged, the otherwise applicable period of

Ineligibility and other Consequences for such Covered Person shall be eliminated (except for those set out in Rule 3221(a) and Rule 3620). When the violation is of Rule 3212 (presence of a Banned Substance), the Covered Person must also establish how the Banned Substance entered the Covered Horse's system as a pre-condition to application of this Rule 3224(a). In the event the period of Ineligibility otherwise applicable is eliminated pursuant to this Rule 3224, the Anti-Doping Rule Violation shall not be considered a prior violation for the purpose of Rule 3228.

(b) Rule 3224 only applies in exceptional circumstances. In particular, it will not apply where the Banned Substance found to be present in a Sample: (1) came from a mislabeled or contaminated supplement; or (2) was administered to the Covered Horse by veterinary or other support personnel without the knowledge of the Responsible Person.

(c) A finding that the Covered Person bears No Fault or Negligence for an Anti-Doping Rule Violation shall not affect the Consequences of that violation that apply to the Covered Horse (*i.e.,* Ineligibility in accordance with Rule 3222(a) and Disqualification of results in accordance with Rule 3221).

Rule 3225. Reduction of the Period of Ineligibility Where There Is No Significant Fault or Negligence

Reductions under this Rule 3225 are mutually exclusive and not cumulative, *i.e.,* no more than one of them may be applied in a particular case.

(a) General rule.

Where the Covered Person establishes that he or she bears No Significant Fault or Negligence for the Anti-Doping Rule Violation in question, then (unless Rule 3225(b) or 3225(c) applies) the period of Ineligibility shall be fixed between 3 months and 2 years, depending on the Covered Person's degree of Fault.

(b) Specified Substances.

Where the Covered Person establishes that he or she bears No Significant Fault or Negligence for the Anti-Doping Rule Violation in question, and the violation involves only a Specified Substance, the period of Ineligibility shall be, at a minimum, a reprimand and no period of Ineligibility, and, at a maximum, 2 years of Ineligibility, depending on the Covered Person's degree of Fault.

(c) Contaminated Products or other contamination.

Where the Covered Person establishes that he or she bears No Significant Fault or Negligence for the Anti-Doping Rule Violation in question and that the Banned Substance in question came from a Contaminated Product or from another form of contamination, the period of Ineligibility shall be, at a minimum, a reprimand and no period of Ineligibility, and, at a maximum, 2 years of Ineligibility, depending on the Covered Person's degree of Fault.

Rule 3226. Elimination, Reduction, or Suspension of Period of Ineligibility or Other Consequences for Reasons Unrelated to Degree of Fault

(a) Substantial Assistance. The Agency may suspend all or part of the Consequences imposed on a Covered Person in an individual doping case—other than Disqualification of results pursuant to Rule 3221—based on the following:

(1) The Covered Person provides Substantial Assistance to the Agency, the Authority, or a State Racing Commission, a criminal authority, or a professional disciplinary body that results in:

(i) the Agency discovering or bringing forward an Anti-Doping Rule Violation or a Controlled Medication Rule Violation by another Covered Person; or

(ii) a criminal or disciplinary body discovering or bringing forward a sport-related criminal offense or the breach of professional or sports rules by another Person, including offenses arising out of a sport integrity violation or sport safety violation, or the violation of any rule or requirement in the Act, and the information provided by the Covered Person providing Substantial Assistance is also made available to the Agency.

(2) The extent to which the otherwise applicable period of Ineligibility may be suspended shall be based on the seriousness of the Anti-Doping Rule Violation committed by the Covered Person and the degree to which the Substantial Assistance provided by the Covered Person assists the effort to promote doping-free racing, compliance with the Protocol, or the integrity of racing. In any event, no more than three-quarters of the otherwise applicable period of Ineligibility may be suspended. If the otherwise applicable period of Ineligibility is a lifetime, the non-suspended period under this section must be no less than 8 years. For purposes of this Rule 3226, the otherwise applicable period of Ineligibility shall not include any period of Ineligibility that could be added under Rule 3228(c)(2).

(3) If so requested, the Agency shall allow the Covered Person who seeks to provide Substantial Assistance to provide the information to the Agency subject to a Without Prejudice Agreement.

(4) If the Covered Person fails to continue to cooperate or fails to provide the complete, accurate, and credible Substantial Assistance promised, the Agency shall reinstate the original Consequences. That decision is not subject to review.

(b) Voluntary Admission of an Anti-Doping Rule Violation in the absence of other evidence. If (1) the Covered Person voluntarily admits the commission of an Anti-Doping Rule Violation before receiving the EAD Notice or (in the case of a Rule 3212 violation) before having received notice of a Sample collection that could establish the Anti-Doping Rule Violation, and (2) that admission is the only reliable evidence of the violation at the time the admission is made, the otherwise applicable period of Ineligibility may be reduced by up to one-half.

(c) Application of multiple grounds for reduction of a sanction. If the Covered Person establishes entitlement to a reduction or suspension of the period of Ineligibility under 2 or more of Rules 3224, 3225, or 3226, the otherwise applicable period of Ineligibility shall be determined in accordance with Rules 3223, 3224, and 3225 before applying any reduction or suspension under Rule 3226. If the Covered Person establishes entitlement to a reduction or suspension of the period of Ineligibility under Rule 3226, up to three-quarters of the otherwise applicable period of Ineligibility may be reduced or suspended.

(d) Reductions for certain Anti-Doping Rule Violations based on early admission and acceptance of sanction.

(1) If the Agency notifies a Covered Person of a potential Anti-Doping Rule Violation that carries an asserted period of Ineligibility of 4 or more years (including any period of Ineligibility asserted under Rule 3227), if the Covered Person admits the violation and accepts the asserted period of Ineligibility no more than 7 days after receiving the Charge Letter, the period of Ineligibility to be served will be automatically reduced by 1 year (but no further reduction shall be allowed under any other Rule).

(2) If the Agency notifies a Covered Person of a potential Anti-Doping Rule Violation that carries an asserted period of Ineligibility of 2 years or more years, but less than 4 years (including any period of Ineligibility asserted under Rule 3227), if the Covered Person admits the violation and accepts the asserted period of Ineligibility no more than 7 days after receiving the Charge Letter, the period of Ineligibility to be served will be automatically reduced by 6 months (but no further reduction shall be allowed under any other Rule).

Rule 3227. Aggravating Circumstances

(a) In an individual case involving an Anti-Doping Rule Violation that is not a Rule 3214(b) violation (Trafficking or Attempted Trafficking) or a Rule 3216(d) violation (acts to discourage or retaliate against reporting), if the Agency establishes that Aggravating Circumstances are present, the period of Ineligibility otherwise applicable shall be increased by up to 2 years, depending on the seriousness of the Aggravating Circumstances, unless the Covered Person establishes that he or she did not knowingly commit the Anti-Doping Rule Violation. Where the period of Ineligibility is increased pursuant to this Rule, an additional fine of up to $10,000 or an additional 10% of the total purse (whichever is greater) may also be imposed.

(b) Actions and circumstances constituting Aggravating Circumstances include:

(1) Administration of a Banned Substance or Use of a Banned Method that is detrimental to the health and welfare of the horse or is designed to deceive the betting public;

(2) the presence in the Covered Horse's Sample of a combination of Banned Substance(s) and Controlled Medication Substance(s);

(3) prior violations under the Protocol; or

(4) the Covered Person engaged in deceptive or obstructive conduct to avoid the detection or adjudication of an Anti-Doping Rule Violation or a Controlled Medication Rule Violation, for which the Covered Person has not been separately sanctioned for Tampering.

(c) For the avoidance of doubt, the examples set out in Rule 3227(b) are not exhaustive and other similar circumstances or conduct may also be deemed to amount to Aggravating Circumstances that justify the imposition of a longer period of Ineligibility.

Rule 3228. Increased Sanctions for Repeat Offenders

(a) For purposes of this Rule 3228, the following prior Anti-Doping Rule Violations shall be disregarded: (1) violations that occurred more than 10 years prior to the violation now being sanctioned; and (2) violations for which the Covered Person was found to bear No Fault or Negligence.

(b) Subject to Rule 3228(a), and in addition to any other Consequences that apply under the Protocol (including Disqualification), the periods of Ineligibility and financial penalties specified below shall apply to any Covered Person who commits a second or subsequent Anti-Doping Rule Violation:

| Number of anti-doping rule violations (in 10-year period) | Period of ineligibility | Financial penalties |
|---|---|---|
| Second Anti-Doping Rule Violation | The period of Ineligibility shall be the greater of:<br>(a) a 6-month period of Ineligibility; or<br>(b) a period of Ineligibility in the following range, taking into account the entirety of the circumstances and the Covered Person's degree of Fault with respect to the second violation:<br>(i) the sum of the period of Ineligibility imposed for the first Anti-Doping Rule Violation, plus the period of Ineligibility otherwise applicable to the second Anti-Doping Rule Violation treated as if it were a first violation; and<br>(ii) twice the period of Ineligibility otherwise applicable to the second Anti-Doping Rule Violation treated as if it were a first violation. | Fine of up to $50,000 or 50% of the total purse (whichever is greater); and<br>Payment of some or all of the adjudication costs and the Agency's legal costs. |
| Third (or subsequent) Anti-Doping Rule Violation. | Lifetime Ineligibility, except if the third violation satisfies the conditions for elimination or reduction of the period of Ineligibility under Rule 3224 or Rule 3225, in which case the period of Ineligibility shall be from 8 years to lifetime Ineligibility.<br>If the above exception applies, the same rule shall apply to any subsequent violation. | Fine of up to $100,000 or 100% of the total purse (whichever is greater); and<br>Payment of some or all of the adjudication costs and the Agency's legal costs. |

(c) Additional rules for certain multiple violations.

(1) Multiple violations for the same Banned Substance/Method incurred by a Covered Person in relation to the same Covered Horse prior to delivery of an EAD Notice may (at the Agency's discretion) be treated together as a single Anti-Doping Rule Violation, unless the facts demonstrate that there was more than one administration. Multiple violations for the same Banned Substance/Method incurred by a Covered Person in relation to different Covered Horses prior to delivery of an EAD Notice may (at the Agency's discretion) each be treated as a first Anti-Doping Rule Violation. Where multiple Banned Substances are detected in a single Post-Race Sample or Post-Work Sample, each Banned Substance may (at the Agency's discretion) be treated as a separate violation.

(2) If the Agency establishes that, prior to receiving an EAD Notice in respect of one Anti-Doping Rule Violation, the Covered Person committed an additional Anti-Doping Rule Violation that occurred 12 months or more before or after the violation asserted in that EAD Notice, the period of Ineligibility for the additional violation shall be calculated as if the additional violation were a stand-alone first violation, and that period of Ineligibility will run consecutively to (rather than concurrently with) the period of Ineligibility imposed for the first-notified violation. Where this Rule applies, the violations taken together will constitute a single violation for purposes of Rule 3228.

(3) If a Doping Control process results in the assertion of an Anti-Doping Rule

Violation, and the Agency establishes that the Covered Person committed an independent violation of Rule 3216(a) (Tampering) in connection with that Doping Control process, the Rule 3216(a) (Tampering) violation shall be treated as a stand-alone violation and the period of Ineligibility for such violation shall be served consecutively to, rather than concurrently with, the period of Ineligibility imposed for the other Anti-Doping Rule Violation. Where this Rule 3228(c)(3) is applied, the violations taken together shall constitute a single violation for purposes of Rule 3228.

(4) If the Agency establishes that the Covered Person has committed a further violation of the Protocol during a period of Ineligibility, any new period of Ineligibility shall start to run the day after the original period of Ineligibility ends.

(d) Violations involving both a Banned Substance or Method and a Controlled Medication Substance or Method.

Where a Covered Person is found, based on a common set of facts, to have committed a (1) violation involving one or more Banned Substance(s) or Banned Method(s), and (2) a violation involving one or more Controlled Medication Substance(s) or Controlled Medication Method(s), they shall be treated as separate violations, but shall be adjudicated together in consolidated proceedings pursuant to the procedure that applies to Anti-Doping Rule Violations under the Arbitration Procedures.

Rule 3229. Status During Provisional Suspension or Ineligibility

(a) While serving a Provisional Suspension or period of Ineligibility for an Anti-Doping Rule Violation:

(1) a Covered Horse may not participate in any Timed and Reported Workout or Covered Horserace, but shall remain subject to Testing;

(2) a Covered Person may not participate in any capacity in any activity involving Covered Horses, or in any other activity (other than authorized anti-doping education or rehabilitation programs) taking place at a Racetrack or Training Facility; nor shall he or she permit anyone to participate in any capacity on his or her behalf in any such activities, except to the extent that the Covered Person is an Owner and the activity is necessary to ensure the safekeeping and wellbeing of the horse during the period of such Owner's Provisional Suspension or Ineligibility.

(b) The Covered Horse(s) of an Owner or Trainer who is subject to a Provisional Suspension or period of Ineligibility shall be subject to the following restrictions:

(1) The Covered Horse(s) of a Trainer who is subject to a Provisional Suspension or period of Ineligibility may not participate in any Timed and Reported Workout or Covered Horserace unless and until they have been transferred to another Covered Person. For the ''transfer'' to be valid, (i) the transfer must be registered with the Authority in accordance with its procedures, and (ii) the Covered Horses must also be physically relocated to facilities under the care or control of a Covered Person who is not affiliated with the suspended Trainer (and failure to comply may constitute an Anti-Doping Rule Violation under Rule 3216(c), *i.e.,* Prohibited Association).

(2) The Covered Horse(s) of an Owner who is subject to a Provisional Suspension or period of Ineligibility may not participate in any Timed and Reported Workout or Covered Horserace unless and until they have been transferred in a bona fide transaction to a different Owner. If an Immediate Family Member has any ownership or property interest in the Covered Horse(s) following such transfer, the transfer shall not constitute a bona fide transaction to a different Owner.

Rule 3230. Consequences for Violation of the Prohibition on Participation During Ineligibility or Provisional Suspension Under Rule 3229

(a) Consequences for violation of the prohibition on participation during Ineligibility.

(1) If a Covered Person violates the prohibition against participation during Ineligibility described in Rule 3229, any results obtained from such participation shall be Disqualified and a new period of Ineligibility equal in length to the original period of Ineligibility shall be added to the end of the Covered Person's original period of Ineligibility.

(2) If a Covered Horse participates in any Timed and Reported Workout or Covered Horserace in violation of the prohibition against participation during Ineligibility described in Rule 3229, any results obtained from such participation shall be Disqualified and the Responsible Person for that Covered Horse shall receive the following period of Ineligibility:

(i) if the Responsible Person was subject to an original period of Ineligibility, a new period of Ineligibility equal in length to the original period of Ineligibility shall be added to the end of the original period of Ineligibility. If the original period of Ineligibility has already expired, the new period of Ineligibility shall start on the date that it is accepted or imposed; or

(ii) if the Responsible Person was not subject to an original period of Ineligibility, the period of Ineligibility for violating Rule 3229 shall be from a reprimand to 1 year, depending on the Covered Person's degree of Fault.

(b) Consequences for violation of the prohibition on participation during Provisional Suspension.

(1) A Covered Person who violates the prohibition against participation during a Provisional Suspension shall receive no credit for any period of Provisional Suspension served and the results of such participation shall be Disqualified.

(2) If a Covered Horse participates in any Timed and Reported Workout or Covered Horserace in violation of the prohibition against participation during a Provisional Suspension described in Rule 3229, the Responsible Person for that Covered Horse and the Covered Horse shall receive no credit for any period of Provisional Suspension served and the results of such participation shall be Disqualified.

(c) The consequence of Disqualification under this Rule 3230 shall be the same as set out in Rule 3221(c).

(d) The Arbitral Body (or the Agency, if the Covered Person admits the violation and accepts the consequences) shall determine whether there has been a violation of the prohibition against participation during Provisional Suspension or Ineligibility and apply the appropriate consequences pursuant to Rule 3261.

Rule 3231. Automatic Public Disclosure

A mandatory part of each sanction shall include automatic Public Disclosure in accordance with Rule 3620.

Rule 3232. Conditions Precedent to Reinstatement for Covered Persons

(a) To be reinstated after commission of an Anti-Doping Rule Violation, the Covered Person must have respected his or her period of Ineligibility (Rule 3229); and repaid or surrendered any purses and other compensation, prizes, trophies, points, and rankings forfeited pursuant to Rule 3221, and paid any fines and reimbursed any costs imposed or accepted to the Agency, unless an installment plan was established pursuant to Rule 3232(b), in which case the Covered Person must have made all payments due under that plan. If any installment(s) subsequently become(s) overdue under that plan (*i.e.,* after reinstatement), the Covered Person and the Covered Horses under his or her ownership or training may not

participate in any Timed and Reported Workout or Covered Horserace until such overdue installment(s) is/are paid in full.

(b) Where fairness requires, the Agency or the Arbitral Body may establish an installment plan for repayment of amounts due to be paid or reimbursed under the Protocol. The payment schedule may extend beyond any period of Ineligibility imposed upon the Covered Person.

Rule 3233. Conditions Precedent to Reinstatement for Covered Horses

(a) A Covered Horse shall be reinstated once its period of Ineligibility ends, provided that (1) the Ineligibility has been respected in full throughout that period in accordance with Rule 3229, (2) the Covered Horse has been made available for Testing during that period in accordance with Rule 3132(d), and (3) the Covered Horse has completed any Vets' List Workout(s) required by the Racetrack Safety Program or the Agency (for the avoidance of doubt, such workouts may be scheduled prior to the expiry of the period of Ineligibility and will not constitute a violation of Rule 3229).

(b) Any reinstatement pursuant to this Rule 3233 is without prejudice to any rest or stand down period that may be imposed on the Covered Horse (*e.g.,* due to injuries), and any requirements for release from the Veterinarians' List, pursuant to the Racetrack Safety Program.

*3240. Results Management*

Rule 3241. General

Where there is evidence of a potential Anti-Doping Rule Violation(s), the Agency will conduct Results Management in accordance with this section 3240 and the Testing and Investigations Standards.

Rule 3242. Review of Adverse Analytical Findings

(a) Upon receipt of an Adverse Analytical Finding in relation to an A Sample, the Agency will conduct a review of the Laboratory certificate of analysis supporting the Adverse Analytical Finding and the relevant Sample collection documentation and Testing documents to determine whether the Adverse Analytical Finding was caused by any apparent departure from the Testing and Investigations Standards, the Laboratory Standards, or any provision of the Protocol. Subject to Rule 3242(b), the Agency may, but does not have to, communicate with the Responsible Person and Owner during such review.

(b) If the review under Rule 3242(a) reveals an apparent departure that caused the Adverse Analytical Finding, the entire test shall be considered negative, and the Agency shall promptly inform the Responsible Person and each Interested Party of that fact.

(c) If the initial review of an Adverse Analytical Finding under Rule 3242(a) does not reveal an apparent departure that caused the Adverse Analytical Finding, the Agency shall promptly send an EAD Notice to the Responsible Person and each Interested Party in accordance with Rule 3245.

Rule 3243. Review of Atypical Findings Relating to Banned Substances

(a) In certain circumstances, Laboratories may report the presence of certain Banned Substances as ''Atypical Findings'' in accordance with the Atypical Findings Policy set out at Appendix 1. Upon receipt of an A Sample Atypical Finding, the Agency will conduct a review to determine whether the Atypical Finding was caused by a departure from the Testing and Investigations Standards, the Laboratory Standards, or any provision of the Protocol. If that review does not reveal any departure that caused the Atypical Finding, the Agency will conduct an investigation (including directing any Further Analysis) or take any other steps required to decide whether the Atypical Finding should be brought forward as an Adverse Analytical Finding, in accordance with the Atypical Findings Policy.

(b) The Agency may, but does not have to, provide notice of an Atypical Finding to anyone until it has made that decision unless one of the following circumstances exists:

(1) if the Agency determines that the B Sample should be analyzed prior to the conclusion of its investigation, the Agency may conduct the B Sample analysis after notifying the Responsible Person and the Owner, with such notice to include a description of the Atypical Finding and the information described in Rule 3245; or

(2) if the Atypical Finding is likely connected to a serious pathology that requires urgent veterinary attention.

(c) If the Agency ultimately decides not to pursue the Atypical Finding as an Adverse Analytical Finding, the Agency may, but does not have to, communicate that fact to the Responsible Person and Owner unless he or she has previously received notice of the Analytical Finding pursuant to Rule 3243(b).

(d) If the Agency decides to move forward with the matter as an Adverse Analytical Finding, the Agency shall promptly send an EAD Notice to the Responsible Person and each Interested Party.

Rule 3244. Review of Other Evidence of a Potential Anti-Doping Rule Violation

The Agency shall conduct any follow-up investigation required into any potential Anti-Doping Rule Violation not covered by Rules 3242 or 3243. At such time as the Agency is satisfied that it has sufficient evidence to establish that an Anti-Doping Rule Violation occurred, it shall promptly send an EAD Notice to the relevant Covered Person and each Interested Party.

Rule 3245. EAD Notice

(a) Where it is determined that a Covered Person may have committed one or more Anti-Doping Rule Violations, the Agency will promptly notify the Covered Person and each Interested Party in writing of the following (the EAD Notice):

(1) the alleged Anti-Doping Rule Violation and the Consequences if it is agreed or determined to have been committed;

(2) the Adverse Analytical Finding (with a copy of the Laboratory certificate of analysis in a form designated by the Agency) or a brief summary of the facts relied on by the Agency to assert the alleged violation (including, where applicable, the name of the Covered Horse implicated in the alleged violation, whether the alleged violation was in connection with a particular Covered Horserace, and the date of Sample collection or of the other relevant facts said to give rise to the violation);

(3) if applicable, the right of the Responsible Person and the Owner to receive copies of the A Sample Laboratory Documentation Package after the B Sample analysis has been completed or after such analysis is waived;

(4) if applicable, the following details regarding the B Sample analysis:

(i) that the B Sample has been (or will be) analyzed because the Agency has authorized immediate analysis to preserve the scientific integrity of the Sample;

(ii) if the B Sample has not been analyzed, the Responsible Person's and Owner's right to promptly request the analysis of the B Sample within no more than 5 days or (failing such request) that the B sample analysis shall be deemed to be waived;

(iii) an explanation that, where the Responsible Person or Owner requests the B Sample analysis within the applicable deadline, or where the Agency decides to proceed with the B Sample analysis, the Agency will notify

the Responsible Person and Owner of the date, time, and place where the B Sample will be analyzed and (where the analysis is requested by the Responsible Person or Owner) the amount that the Responsible Person or Owner must pay to have the B Sample tested and B Sample Laboratory Documentation Package prepared, and the date by which such payment must be received, failing which the B Sample analysis shall be deemed to have been waived; and

(5) the opportunity for the Covered Person to provide an explanation within a short deadline set by the Agency;

(6) the opportunity to provide Substantial Assistance, to admit the Anti-Doping Rule Violation, or to seek to resolve the matter without a hearing under Rule 3249;

(7) all relevant details relating to any Provisional Suspension (including, if applicable, the possibility to accept a voluntary Provisional Suspension) in accordance with Rule 3247; and

(8) if applicable, the ability for the automatic Disqualification of results to be applied immediately in accordance with Rule 3221(a)(2).

(b) Before sending an EAD Notice, for purposes of Rule 3228, the Agency shall seek to determine whether the Covered Person in question has committed any prior violations under the Protocol.

(c) Any defect in the EAD Notice (including a failure to identify the Covered Horseraces implicated in the alleged violation, if any) may be corrected by the Agency and shall not in any event invalidate the EAD Notice or affect the due application of the provisions of the Protocol (including the Disqualification provisions) in relation to that violation.

Rule 3246. B Sample Analysis

(a) Arrangements shall be made for analysis of the B Sample without undue delay, in accordance with the Protocol and the Laboratory Standards. Subject to Rule 3246(b), the Responsible Person or Owner must pay the costs of the B Sample analysis in advance, but, if the B Sample analysis does not confirm the A Sample analysis, they will be reimbursed that cost by the Agency. The Responsible Person and Owner or one representative each may attend the Laboratory to witness the opening and identification of the B Sample. They do not have any right to witness the analysis of the B Sample.

(b) The Responsible Person and Owner may (if they both agree) waive analysis of the B Sample (in which case they shall be deemed to accept the A Sample analytical results). If waived, the Agency may nonetheless elect to proceed with the B Sample analysis at its own expense.

(c) If the B Sample proves negative, the entire Test shall be considered negative, and the Responsible Person and Owner shall be so informed. In such circumstances, unless the Agency asserts an Anti-Doping Rule Violation under Rule 3213 (Use), the EAD Notice will be withdrawn, any Provisional Suspensions imposed shall be deemed automatically vacated with immediate effect (without the need for any order from the Arbitral Body), and no further disciplinary action will be taken against the Responsible Person, other Covered Person, or Covered Horse by the Agency in relation to the original Adverse Analytical Finding (provided, however, that the Agency may investigate why the B Sample did not match the A Sample). If the Agency asserts that a Rule 3213 (Use) violation has occurred, it shall send a Charge Letter to the Responsible Person and other Covered Person(s), with a copy to each Interested Party.

(d) If the presence of a Banned Substance or the Use of a Banned Method is confirmed by the B Sample analysis, or the B Sample analysis is waived, the Agency shall send a Charge Letter to the Responsible Person and any other relevant Covered Person(s), with a copy to each Interested Party, asserting that a Rule 3212 (presence) violation or a Rule 3213 (Use) violation (as applicable) has occurred.

Rule 3247. Provisional Suspensions

(a) Provisional Suspensions shall be imposed as follows:

(1) For each alleged violation of Rule 3212 (presence), 3213 (Use), or 3214(c) (Administration or Attempted Administration) that involves a Banned Substance that is not a Specified Substance, the Agency shall impose a Provisional Suspension, effective from the date specified by the Agency in the EAD Notice or in further correspondence up to and including the Charge Letter, on (i) the Covered Horse, (ii) the Responsible Person, and (iii) any other Covered Person charged with the violation.

(2) For each alleged violation of Rule 3215 (evading Sample collection; refusing or failing to submit to Sample collection; or refusing or failing to comply with all Sample collection procedure requirements), the Agency may impose a Provisional Suspension, effective from the date specified by the Agency in the EAD Notice or in further correspondence up to and including the Charge Letter, on (i) the Covered Horse, (ii) the Responsible Person, or (iii) any other Covered Person charged with the violation.

(3) For all other alleged Anti-Doping Rule Violations, the Agency may impose a Provisional Suspension, effective from the date specified by the Agency in the EAD Notice or in further correspondence up to and including the Charge Letter, on the Responsible Person, or any other Covered Person alleged to be implicated in the violation, but not on the Covered Horse.

(b) Where a Provisional Suspension is imposed pursuant to Rule 3247(a), the Responsible Person (on his or her own behalf and on behalf of the Covered Horse) and any other Covered Person made subject to the Provisional Suspension shall be given:

(1) an opportunity for a Provisional Hearing before imposition of the Provisional Suspension;

(2) an opportunity for a Provisional Hearing on a timely basis after imposition of the Provisional Suspension; or

(3) an opportunity for an expedited final adjudication in accordance with Rule 3262 on a timely basis after imposition of the Provisional Suspension.

(c) Provisional Hearings shall be conducted by the Arbitral Body and heard via telephone or video conference call within the time frame specified in accordance with the Arbitration Procedures. The sole issue to be determined by the Arbitral Body will be whether the Agency's decision to impose a Provisional Suspension shall be maintained. The Agency's decision to impose a Provisional Suspension shall be maintained unless the Responsible Person/Covered Person requesting the lifting of the Provisional Suspension establishes that:

(1) the allegation that an Anti-Doping Rule Violation has been committed has no reasonable prospect of being upheld, *e.g.,* because of a material defect in the evidence on which the allegation is based;

(2) the Responsible Person/Covered Person charged bears No Fault or Negligence for the Anti-Doping Rule Violation that is alleged to have been committed, so that any period of Ineligibility that might otherwise be imposed for such offense would be completely eliminated by application of Rule 3224. (This ground does not apply in respect of any Provisional Suspension imposed on a Covered Horse);

(3) Rule 3225 applies and the Responsible Person/Covered Person bears No Significant Fault or Negligence and he or she will likely be given a period of Ineligibility that is not longer than the period for which he or she has already been provisionally suspended

(this ground does not apply in respect of any Provisional Suspension imposed on a Covered Horse); or

(4) exceptional circumstances exist that make it clearly unfair, taking into account all of the circumstances of the case, to impose a Provisional Suspension prior to the final hearing on the merits. This ground is to be construed narrowly and applied only in truly exceptional circumstances. For example, the fact that the Provisional Suspension would prevent the Responsible Person, Covered Person, or Covered Horse from participating in a particular Timed and Reported Workout, Covered Horserace, or other activity shall not qualify as exceptional circumstances for these purposes.

(d) If the application is made before the Provisional Suspension comes into effect, the Provisional Suspension will not come into effect pending the decision on the application. If the application is made after the Provisional Suspension has come into effect, the Provisional Suspension will remain in place pending the decision on the application.

(e) If it considers it appropriate to do so on the specific facts of the case, the Agency may lift the Provisional Suspension.

(f) If the application to have a Provisional Suspension not imposed/lifted is not granted, a further application may not be made to lift the Provisional Suspension unless: (i) it is based on new and material evidence that the Responsible Person or other Covered Person was not aware of and could not reasonably have been aware of at the time he or she made the original application; or (ii) there has been some other significant and material change in circumstances since the original application was decided. If the Responsible Person or other Covered Person makes a further application that does not meet either of these requirements, costs may be awarded against him or her.

(g) Voluntary Provisional Suspension.

(1) In all cases where a Responsible Person/Covered Person has been notified of or charged with an Anti-Doping Rule Violation, but no Provisional Suspension has been imposed on him or her or on the Covered Horse, that person may (on his or her own behalf and, if the Responsible Person, on behalf of the Covered Horse) voluntarily accept a Provisional Suspension at any time by written notice to the Agency. A copy of the voluntary Provisional Suspension shall promptly be provided to each Interested Party.

(2) A Provisional Suspension that is voluntarily accepted will have effect (in the same manner as if the Provisional Suspension had been imposed under Rule 3247(a)) from the date that written notice of its acceptance is received by the Agency.

(h) No admission will be inferred, or other adverse inference drawn, from the decision of a Covered Person: (1) not to make an application to lift a Provisional Suspension; or (2) to accept a voluntary Provisional Suspension.

(i) If a Provisional Suspension is imposed or voluntarily accepted, and that Provisional Suspension is respected, then the Responsible Person/Covered Person and Covered Horse in question shall receive a credit for such period of Provisional Suspension against any period of Ineligibility that may ultimately be imposed. If the Responsible Person/Covered Person or Covered Horse does not respect a Provisional Suspension, the Responsible Person/Covered Person or Covered Horse shall receive no credit for any period of Provisional Suspension served. If a period of Ineligibility is served pursuant to a decision that is subsequently subject to review, the Responsible Person/Covered Person or Covered Horse shall receive a credit for such period of Ineligibility served against any period of Ineligibility that may ultimately be imposed on review.

(j) Notwithstanding any other provision in this Rule 3247 or elsewhere in the Protocol, any Provisional Suspension imposed on a Covered Horse will be automatically lifted (without the need for any hearing) if it has been in place for a period equal to the period of Ineligibility specified in the Protocol or Prohibited List.

Rule 3248. Charge Letter

If, after receipt of the Covered Person's explanation, or expiry of the deadline to provide such explanation, the Agency remains satisfied that the Covered Person has committed an Anti-Doping Rule Violation(s), the Agency shall promptly charge the Covered Person with the asserted Anti-Doping Rule Violation(s). In this letter of charge (Charge Letter), which will be copied to each Interested Party, the Agency shall:

(a) set out the Anti-Doping Rule Violation(s) that the Covered Person is charged with having committed;

(b) provide a summary of the relevant facts upon which the charge is based, enclosing a copy of the A Sample Laboratory Documentation Package and (if applicable and if requested) the B Sample Laboratory Documentation Package;

(c) specify the Consequences that will apply if the charge is upheld;

(d) grant a deadline of not more than 7 days from receipt of the Charge Letter (unless otherwise agreed by the Agency) for the Covered Person to either:

(1) admit the Anti-Doping Rule Violation(s) charged and:

(i) accept the Consequences proposed by the Agency, in which case the Agency will issue a decision under Rule 3249(b);

(ii) seek to agree to mitigated Consequences with the Agency pursuant to Rule 3249, failing which the Consequences may still be disputed at a hearing; or

(iii) dispute or seek to mitigate the proposed Consequences at a hearing in accordance with Rule 3261 and the Arbitration Procedures; or

(2) deny the Anti-Doping Rule Violation charged and dispute the proposed Consequences at a hearing in accordance with Rule 3261 and Arbitration Procedures;

(e) indicate that, if the Covered Person does not challenge the Agency's assertion of an Anti-Doping Rule Violation or the proposed Consequences within the prescribed deadline, the Covered Person shall be deemed to have waived his or her right to a hearing, admitted the Anti-Doping Rule Violation(s) charged, and accepted the Consequences specified by the Agency in the Charge Letter (without any mitigation of those Consequences);

(f) give the opportunity to provide Substantial Assistance in accordance with Rule 3226(a); and

(g) provide all relevant details relating to any Provisional Suspensions (including, if applicable, the possibility to accept a voluntary Provisional Suspension) in accordance with Rule 3247.

Rule 3249. Case Resolution Without a Hearing

(a) At any time prior to a final decision under the Arbitration Procedures: (1) the Agency may withdraw a Charge Letter for good cause, in which case any Provisional Suspension will be automatically lifted and (absent the emergence of new information) no further steps will be taken in relation to the violations alleged in the Charge Letter; or (2) the Covered Person may agree to admit the Anti-Doping Rule Violation(s) charged (or any other violation of the Protocol) and accede to specified Consequences consistent with the Protocol. In any such case, an adjudication under the Arbitration Procedures will not be required.

(b) In the event that the Covered Person admits the Anti-Doping Rule Violation(s) charged and accedes to Consequences specified by the Agency (or is deemed to have done so in accordance with Rule 3248(a)(5)), the Agency will (1) promptly issue a final decision confirming the commission of the Anti-Doping Rule Violation(s) and setting out the factual basis for the decision and all of the Consequences to be imposed (including a brief summary of the reasons for any period of Ineligibility imposed, unless doing so could compromise an ongoing investigation or proceeding), and (2) send notice of the decision to each Interested Party. The Agency will also Publicly Disclose the decision (or a summary thereof, at the discretion of the Agency) in accordance with Rule 3620.

(c) In the event that the Agency withdraws the Charge Letter, it will (1) promptly issue a summary decision confirming the withdrawal of the Charge Letter, (2) send notice of the decision to the Covered Person concerned, with a copy to each Interested Party, and (3) Publicly Disclose the decision (or a summary thereof, at the discretion of the Agency) in accordance with Rule 3620.

Rule 3250. Notification Requirements

(a) Notification of Anti-Doping Rule Violations will take place as set out in Rule 3245 and Rule 3248. If at any point after an EAD Notice has been provided the Agency decides not to move forward with the charge, it will notify the Covered Person(s) concerned and each Interested Party of that decision.

(b) Notification to a Covered Person by the Agency, for all purposes of the Protocol, may be accomplished either through actual or constructive notice. Actual notice may be accomplished by any means. Constructive notice shall be deemed to have been given when the information in question is delivered by third-party courier or U.S. postal mail to the Covered Person's most recent mailing address on file with the Authority or by email or text message to the Covered Person's most recent email address or mobile telephone number on file with the Authority.

*3260. Hearings and Review of Final Decisions*

Rule 3261. Hearing Before the Arbitral Body

Where a Covered Person is alleged to have committed an Anti-Doping Rule Violation or to have violated Rule 3229, the Covered Person shall be entitled to a hearing before the Arbitral Body in accordance with the Arbitration Procedures. A copy of the final decision of the Arbitral Body shall be sent to the Covered Person(s) concerned, with a copy to the Agency and each Interested Party. The decision (or a summary thereof, at the discretion of the Agency) shall be Publicly Disclosed as provided in Rule 3620. If an individual case involves allegations that both an Anti-Doping Rule Violation and a Controlled Medication Rule Violation have been committed, the matter shall be referred to and adjudicated by the Arbitral Body in accordance with the Arbitration Procedures.

The Arbitral Body may also adjudicate any other matter referred to it under the Protocol, and any other matter that might arise from time to time under the Protocol that the Agency considers should be determined by the Arbitral Body.

Rule 3262. Expedited Hearing

In Anti-Doping Rule Violation cases where the Covered Horse or Covered Person in question is not Provisionally Suspended and is likely to participate in a Covered Horserace within 45 days, the Agency may (if it sees fit) address the case on an expedited basis and shorten any deadlines in the Protocol or Arbitration Procedures proportionately to ensure resolution of the matter prior to the Covered Horserace.

Rule 3263. Finality

Subject to Rule 3264, decisions rendered by the Arbitral Body under the Protocol shall be final and binding.

Rule 3264. Review of Final Decisions

Any final decision by the Agency or the Arbitral Body is subject to review in accordance with section 3058 of the Act. Any final decision under review shall remain in effect pending resolution of the review unless ordered otherwise.

*3310. Controlled Medication Rule Violations*

Rule 3311. Definition of Controlled Medication Rule Violation and Responsibility for Violations

(a) Controlled medication cases will be initiated based on the assertion that one or more of Rules 3312 through 3315 has been violated (each, a Controlled Medication Rule Violation).

(b) The Controlled Medication Rule Violations described below may only be committed by Covered Persons, but the Consequences for Controlled Medication Rule Violations may apply to both the Covered Person(s) who commit(s) the violation and any Covered Horse(s) implicated by the violation.

(c) All Covered Persons are responsible for knowing what constitutes a Controlled Medication Rule Violation and what Controlled Medication Substances and what Controlled Medication Methods are included on the Prohibited List and Technical Document–Prohibited Substances.

Rule 3312. Presence of a Controlled Medication Substance

(a) It is the personal and non-delegable duty of the Responsible Person to ensure that no Controlled Medication Substance is present in the Post-Race Sample of his or her Covered Horse(s), and that no Controlled Medication Substance specifically identified on the Prohibited List as prohibited during Timed and Reported Workouts is present in the Post-Work Sample of his or her Covered Horse(s). The Responsible Person is therefore strictly liable for any Controlled Medication Substance or its Metabolites or Markers found to be present in a Post-Race Sample collected from his or her Covered Horse(s), and for any specifically prohibited Controlled Medication Substance or its Metabolites or Markers found to be present in a Post-Work Sample collected from his or her Covered Horse(s). Accordingly, it is not necessary to demonstrate intent, Fault, negligence, or knowing Use on the part of the Responsible Person in order to establish that the Responsible Person has committed a Rule 3312 Controlled Medication Rule Violation.

(b) Sufficient proof of a Rule 3312 Controlled Medication Rule Violation is established by any of the following:

(1) the presence of a Controlled Medication Substance or its Metabolites or Markers in the Covered Horse's A Sample where the Responsible Person waives analysis of the B Sample and the B Sample is not analyzed;

(2) the Covered Horse's B Sample is analyzed and the analysis of the B Sample confirms the presence of the Controlled Medication Substance or its Metabolites or Markers found in the A Sample; or

(3) where, in exceptional circumstances, the Laboratory (on instruction from the Agency) further splits the A or B Sample into two parts in accordance with the Laboratory Standards, the analysis of the second part of the resulting split Sample confirms the presence of the same Controlled Medication Substance or its Metabolites or Markers as were found in the first part of the split Sample, or the Responsible Person waives analysis of the second part of the split Sample.

(c) The general rule is that the presence of any amount of a Controlled Medication Substance or its Metabolites

or Markers in a Post-Race Sample or Post-Work Sample collected from a Covered Horse constitutes a Controlled Medication Rule Violation by the Responsible Person of that Covered Horse.

(d) As an exception to the general rule of Rule 3312(c), the Prohibited List, Standards, or Technical Documents may establish special criteria for the reporting or the evaluation of certain Controlled Medication Substances, including a Minimum Reporting Level, Screening Limit, Threshold, or Decision Limit.

(e) Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) and corticosteroids, which are Controlled Medication Substances prohibited during Timed and Reported Workouts and during the Race Period, are subject to Screening Limits.

(1) If one NSAID or one corticosteroid is detected in the Post-Race Sample or Post-Work Sample of a Covered Horse above the applicable Screening Limit, it constitutes a presence violation under Rule 3312.

(2) If more than one NSAID or more than one corticosteroid is detected in the Post-Race Sample or Post-Work Sample of a Covered Horse, each NSAID and each corticosteroid above the applicable Screening Limit constitutes a separate presence violation of Rule 3312.

(3) If more than one NSAID or more than one corticosteroid is detected in the Post-Race Sample or Post-Work Sample of a Covered Horse, but each are below the applicable Screening Limits (and so individually would not constitute a presence violation), they will together constitute a single presence violation under Rule 3312 (Stacking Violation).

Rule 3313. Use or Attempted Use of a Controlled Medication Substance or a Controlled Medication Method During the Race Period

(a) Subject to Rule 3313(c), the Use or Attempted Use of a Controlled Medication Substance or Controlled Medication Method in relation to a Covered Horse during the Race Period constitutes a Controlled Medication Rule Violation. The success or failure of that Use or Attempted Use is not material. For a Rule 3313 violation to be committed, it is sufficient that the Controlled Medication Substance or Controlled Medication Method was Used or Attempted to be Used on a Covered Horse during the Race Period.

(b) It is the personal and non-delegable duty of the Responsible Person to ensure that no Controlled Medication Substance or Controlled Medication Method is Used in relation to his or her Covered Horse during the Race Period. The Responsible Person is therefore strictly liable for any Use of a Controlled Medication Substance or Controlled Medication Method in relation to his or her Covered Horse(s). Accordingly, it is not necessary to demonstrate intent, Fault, negligence, or knowing Use on the part of the Responsible Person in order to establish that the Responsible Person has committed a Rule 3313 Controlled Medication Rule Violation of Use. However, in accordance with the definition of Attempt, it is necessary to show intent on the part of the Responsible Person in order to establish that the Responsible Person has committed a Rule 3313 Controlled Medication Rule Violation of Attempted Use.

(c) Use of a Controlled Medication Substance or a Controlled Medication Method outside the Race Period is not a Rule 3313 violation. However, if a Controlled Medication Substance or any of its Metabolites or Markers is still present in a Post-Race Sample or Post-Work Sample, that constitutes a Rule 3312 (presence) violation.

Rule 3314. Use of a Controlled Medication Substance or a Controlled Medication Method in a Manner Contrary to Horse Welfare

(a) Any Use of a Controlled Medication Substance or a Controlled Medication Method in relation to a Covered Horse must (1) be justified by the Covered Horse's health condition(s), (2) have been recommended by a Veterinarian in the context of a valid veterinarian-patient-client relationship or (if a prescription is not required) following sufficient due diligence regarding the substance or method, (3) go no further than the minimum necessary to address the health concerns, and (4) be in the best interests of the Covered Horse's health and welfare.

(b) It is the personal and non-delegable duty of the Responsible Person to ensure that no Controlled Medication Substance or Controlled Medication Method is Used on his or her Covered Horse in breach of the requirements set out in Rule 3314(a). The Responsible Person is therefore strictly liable for a violation of this Rule 3314. Accordingly, it is not necessary to demonstrate intent, Fault, negligence, or knowing Use on the part of the Responsible Person in order to establish that the Responsible Person has committed a Rule 3314 Controlled Medication Rule Violation.

Rule 3315. Other Controlled Medication Rule Violations Involving Controlled Medication Substances or Controlled Medication Methods

The following acts and omissions constitute Controlled Medication Rule Violations by the Covered Person(s) in question:

(a) The Administration or Attempted Administration of a Controlled Medication Substance or Controlled Medication Method by a Covered Person to a Covered Horse during the Race Period.

(b) The Possession of a Controlled Medication Substance or Controlled Medication Method by any Covered Person that is not in compliance with applicable State or Federal law.

(c) A Covered Person assisting, encouraging, aiding, abetting, conspiring, covering up, or engaging in any other type of intentional complicity or Attempted complicity involving (1) a Controlled Medication Rule Violation or Attempted Controlled Medication Rule Violation, or (2) a violation of Rule 3329 by another Covered Person.

Rule 3316. Tampering or Attempted Tampering With Medication Control

If the Agency establishes that a Covered Person committed a violation of Tampering or Attempted Tampering in connection with a Medication Control process, that will constitute an Anti-Doping Rule Violation under Rule 3216(a), and the matter will be dealt with in accordance with the procedures and Consequences applicable to Anti-Doping Rule Violations.

*3320. Sanctions*

Rule 3321. Disqualification of the Covered Horse's Results

(a) Automatic Disqualification of results.

(1) A Controlled Medication Rule Violation that arises from a Post-Race Sample, or that occurs during the Race Period, automatically leads to Disqualification of the results of the Covered Horse obtained on the Race Day(s) that fall(s) within the Race Period, even if any other sanction for the violation is eliminated or reduced under Rules 3324, 3325, or 3326.

(2) In circumstances where an ECM Notice has been sent as required under Rule 3345, and the B Sample analysis confirms the A Sample analysis, or the right to request the analysis of the B Sample is waived, the Agency, the Responsible Person, and the Owner of the Covered Horse in question may agree to apply Rule 3321 immediately, *i.e.,* prior to adjudication of any other issue, or (in the absence of such

agreement) any one of them may request that the Internal Adjudication Panel apply Rule 3321 immediately.

(b) No Disqualification of subsequent results.

Subsequent results obtained by the Covered Horse from the date a Controlled Medication Rule Violation first occurred through the commencement of any Provisional Suspension or Ineligibility period for the Covered Horse shall not be Disqualified.

(c) Consequence of Disqualification of results.

(1) If a Covered Horse has results Disqualified under the Protocol, all purses and other compensation, prizes, trophies, points, and rankings are forfeited and must be repaid or surrendered (as applicable) to the Race Organizer, and the results of the other Covered Horses in the race(s) in question must be adjusted accordingly and the purses, prizes, and trophies redistributed. Purses, prizes, trophies, and other compensation shall (where possible) be withheld for the Covered Horse in issue pending resolution of the relevant charge.

(2) The Covered Horses that participated in a Covered Horserace involving an alleged Controlled Medication Rule Violation are often entered in other Covered Horseraces prior to the final adjudication of the violation. The ultimate Disqualification of a Covered Horse in connection with final adjudication of a violation shall only impact that horse's conditions for eligibility. By way of example, a maiden that is Disqualified after finishing first in a maiden race shall remain a maiden until it has won another race, but the runner-up in the disputed Covered Horserace shall not be considered the winner for purposes of its future condition eligibility. The adjustment to the Disqualified horse's condition eligibility shall only occur once the violation has been finally adjudicated.

Rule 3322. Ineligibility for Covered Horses

(a) There shall be no period of Ineligibility for Covered Horses implicated in violations involving only Controlled Medication Substances.

(b) There may be a period of Ineligibility for Covered Horses implicated in violations involving Controlled Medication Methods. Where the Prohibited List specifies a period of Ineligibility, it shall be applied only prospectively (*i.e.,* going forward from the date that it is imposed), with no Disqualification of any results obtained by the Covered Horse before the date that the period of Ineligibility starts to run, other than as provided under Rule 3321(a)(1).

Rule 3323. Ineligibility and Financial Penalties for Covered Persons

(a) General.

(1) The periods of Ineligibility and financial penalties set out in this Rule 3323 apply to any Controlled Medication Rule Violation committed by a Covered Person. However:

(i) When determining if a Covered Person has committed multiple violations, the following prior Controlled Medication Rule Violations shall be disregarded: (A) violations that occurred more than 2 years prior to the violation now being sanctioned; and (B) violations for which the Covered Person was found to bear No Fault or Negligence.

(ii) A Controlled Medication Rule Violation will be considered a second or subsequent violation only if the Covered Person committed an offense in the same category/class in the previous 2 years. Violations in different categories will be taken into account when assigning penalty points under Rule 3328.

(iii) Unless specified otherwise, the periods of Ineligibility set out in this Rule 3323 are subject to potential elimination, reduction, or suspension pursuant to Rules 3324–3326, or increase pursuant to Rule 3327.

(2) In accordance with Rule 3347(j), any period of Provisional Suspension served by the Covered Person shall be credited against the period of Ineligibility ultimately imposed on that Covered Person for the violation in question.

(3) If a presence violation involves a Controlled Medication Substance that has not been assigned a Class A–C, the Agency shall determine the class of the substance. Any supplements or feed additives used in contravention of Rule 4211(a) of the Prohibited List that have not been assigned a class shall be designated as Class C substances, unless the Agency decides otherwise.

(4) If two or more Controlled Medication Rule Violations in the same category/class are adjudicated separately, the first violation adjudicated shall constitute the ''first violation'' for sanctioning purposes, the second violation adjudicated shall constitute the ''second violation,'' and so on, regardless of the chronological order in which those violations occurred.

(b) Consequences.

Subject to Rule 3323(a), and in addition to any other Consequences that apply under the Protocol, the periods of Ineligibility, fines, and Disqualification of results specified below shall apply to any Covered Person who commits multiple Controlled Medication Rule Violations. The Covered Person may also be required to pay some or all of the adjudication costs and the Agency's legal costs.

| Controlled medication rule violation | First violation (within 2-year period) | Second violation (within 2-year period) | Third or subsequent violation (within 2-year period) |
|---|---|---|---|
| Presence, Use or Attempted Use, or Administration or Attempted Administration of a Controlled Medication Substance (Rules 3312, 3313, and 3315(a)): | | | |
| Class A | 60 days | 90 days | 120 days. |
| | Fine of up to $5,000 or 5% of the total purse (whichever is greater). | Fine of up to $10,000 or 10% of the total purse (whichever is greater). | Fine of up to $25,000 or 25% of the total purse (whichever is greater). |
| | Automatic Disqualification of Race Day results (Rule 3321). | Automatic Disqualification of Race Day results (Rule 3321). | Automatic Disqualification of Race Day results (Rule 3321). |
| Class B | 15 days | 30 days | 60 days. |
| | Fine up to $1,000 | Fine up to $2,500 | Fine up to $5,000. |
| | Automatic Disqualification of Race Day results (Rule 3321). | Automatic Disqualification of Race Day results (Rule 3321). | Automatic Disqualification of Race Day results (Rule 3321). |

| Controlled medication rule violation | First violation (within 2-year period) | Second violation (within 2-year period) | Third or subsequent violation (within 2-year period) |
|---|---|---|---|
| Class C | .....<br>Fine up to $500<br>Automatic Disqualification of Race Day results (Rule 3321). | 15 days<br>Fine up to $1,000<br>Automatic Disqualification of Race Day results (Rule 3321). | 30 days.<br>Fine up to $2,500.<br>Automatic Disqualification of Race Day results (Rule 3321). |
| *Note: Sanctions apply for each Controlled Medication Substance detected in the Sample. A Stacking Violation shall be treated as a single violation for the purposes of sanctions.* | | | |
| Use or Attempted Use or Administration or Attempted Administration of a Controlled Medication Method (Rule 3313). | 60 days<br>Fine of up to $5,000 or 5% of the total purse (whichever is greater).<br>Automatic Disqualification of Race Day results (Rule 3321). | 90 days<br>Fine of up to $10,000 or 10% of the total purse (whichever is greater).<br>Automatic Disqualification of Race Day results (Rule 3321). | 120 days.<br>Fine of up to $25,000 or 25% of the total purse (whichever is greater).<br>Automatic Disqualification of Race Day results (Rule 3321). |
| Use of a Controlled Medication Substance or a Controlled Medication Method in a manner contrary to horse welfare (Rule 3314). | 60 days<br>Fine of up to $5,000 or 5% of the total purse (whichever is greater). | 90 days<br>Fine of up to $10,000 or 10% of the total purse (whichever is greater). | 120 days.<br>Fine of up to $25,000 or 25% of the total purse (whichever is greater). |
| Possession of a Controlled Medication Substance/Method that is not in compliance with applicable state or Federal law (Rule 3315(b)). | .....<br>Fine up to $500<br>Referral to the relevant State or Federal authority. | 15 days<br>Fine up to $1,000<br>Referral to the relevant State or Federal authority. | 30 days.<br>Fine up to $2,500.<br>Referral to the relevant State or Federal authority. |
| Complicity or Attempted complicity (Rule 3315(c)). | Same Consequences that apply to the principal actor, absent mitigating or aggravating circumstances. | Same Consequences that apply to the principal actor, absent mitigating or aggravating circumstances. | Same Consequences that apply to the principal actor, absent mitigating or aggravating circumstances. |

(c) Commencement of the period of Ineligibility for a Covered Person.

(1) Except as otherwise provided in this Rule 3323, the period of Ineligibility imposed on any Covered Person shall start on the date the period of Ineligibility is accepted or otherwise imposed in accordance with the Protocol.

(2) Where a Covered Person is already serving a period of Ineligibility for another violation of the Protocol, any new period of Ineligibility shall start to run the day after the original period of Ineligibility ends.

(3) Where there have been substantial delays in the adjudication process or other aspects of Medication Control that go well beyond the standard timeframes for Laboratory analyses and Results Management, and the Covered Person can establish that such delays are not attributable to him or her, the start date of the period of Ineligibility may be deemed back-dated to reflect such delays, but in no event may it be deemed back-dated to a date before the Controlled Medication Rule Violation last occurred.

(d) Additional rules for certain multiple violations.

(1) Multiple violations for the same Controlled Medication Substance/Method incurred by a Covered Person in relation to the same Covered Horse prior to delivery of an ECM Notice may (at the Agency's discretion) be treated together as a single Controlled Medication Rule Violation, unless the facts demonstrate that there was more than one administration. Multiple violations for the same Controlled Medication Substance/Method incurred by a Covered Person in relation to different Covered Horses prior to delivery of an ECM Notice may each be treated as a first Controlled Medication Rule Violation within the relevant category/class. Where multiple Controlled Medication Substances are detected in a single Post-Race Sample or Post-Work Sample, each Controlled Medication Substance may be treated as a separate violation and assigned separate penalty points.

(2) If the Agency establishes that prior to receiving an ECM Notice in respect of one Controlled Medication Rule Violation the Covered Person committed an additional Controlled Medication Rule Violation that occurred 12 months or more before or after the violation asserted in that ECM Notice, the period of Ineligibility for the additional violation shall be calculated as if the additional violation were a stand-alone first violation, and that period of Ineligibility will run consecutively to (rather than concurrently with) the period of Ineligibility imposed for the first-notified violation. Where this Rule applies, the violations taken together will constitute a single violation for purposes of Rule 3323(b).

(3) If the Agency establishes that the Covered Person has committed a further violation of the Protocol during a period of Ineligibility, any new period of Ineligibility shall start to run the day after the original period of Ineligibility ends.

(e) Violations involving both a Banned Substance or Method and a Controlled Medication Substance or Method.

Where a Covered Person is found, based on a common set of facts, to have committed a (1) violation involving one or more Banned Substance(s) or Banned Method(s), and (2) a violation involving one or more Controlled Medication Substance(s) or Controlled Medication Method(s), they shall be treated as separate violations, but shall be adjudicated together in consolidated proceedings pursuant to the procedure that applies to Anti-Doping Rule Violations under the Arbitration Procedures.

Rule 3324. Elimination of the Period of Ineligibility Where There Is No Fault or Negligence

(a) If a Covered Person establishes in an individual case that he or she bears No Fault or Negligence for the Controlled Medication Rule Violation(s) charged, the otherwise applicable period of Ineligibility and other Consequences for such Covered Person shall be eliminated (except for those set out in Rule 3321 and Rule 3620). When the violation is of Rule 3312 (presence of a Controlled Medication Substance), the Covered Person must also establish how the Controlled Medication Substance entered the Covered Horse's

system as a pre-condition to application of this Rule 3324. In the event the period of Ineligibility otherwise applicable is eliminated pursuant to this Rule 3324, the Controlled Medication Rule Violation shall not be considered a prior violation for the purpose of Rule 3323(b).

(b) Rule 3324 only applies in exceptional circumstances. In particular, it will not apply where the Controlled Medication Substance found to be present in a Sample: (1) came from a mislabeled or contaminated supplement; or (2) was administered to the Covered Horse by veterinary or other support personnel without the knowledge of the Responsible Person.

(c) A finding that the Covered Person bears No Fault or Negligence for a Controlled Medication Rule Violation shall not affect the Consequences of that violation that apply to the Covered Horse (*i.e.,* Ineligibility in accordance with Rule 3322(b) and Disqualification of results in accordance with Rule 3321).

Rule 3325. Reduction of the Period of Ineligibility Where There Is No Significant Fault or Negligence (Limited to Class A/B or Equivalent)

This Rule applies only to Controlled Medication Rule Violations involving Class A or Class B substances or a category of violation with sanctions equivalent to Class A or Class B substances. Reductions under this Rule 3325 are mutually exclusive and not cumulative, *i.e.,* no more than one of them may be applied in a particular case.

(a) General rule.

Where the Covered Person establishes that he or she bears No Significant Fault or Negligence for the Controlled Medication Rule Violation in question, then (unless Rule 3325(b) or 3325(c) applies) the period of Ineligibility may be reduced, depending on the Covered Person's degree of Fault, but the reduced period of Ineligibility may not be less than one-half of the otherwise applicable period of Ineligibility.

(b) Specified Substances.

Where the Covered Person establishes that he or she bears No Significant Fault or Negligence for the Controlled Medication Rule Violation in question, and the violation involves only a Specified Substance, the period of Ineligibility shall be, at a minimum, a reprimand and no period of Ineligibility, and, at a maximum, the otherwise applicable period of Ineligibility, depending on the Covered Person's degree of Fault.

(c) Contaminated Products or other contamination.

Where the Covered Person establishes that he or she bears No Significant Fault or Negligence for the Controlled Medication Rule Violation in question and that the Controlled Medication Substance in question came from a Contaminated Product or from another form of contamination, the period of Ineligibility shall be, at a minimum, a reprimand and no period of Ineligibility, and, at a maximum, the otherwise applicable period of Ineligibility, depending on the Covered Person's degree of Fault.

Rule 3326. Elimination, Reduction, or Suspension of Period of Ineligibility or Other Consequences for Reasons Unrelated to Degree of Fault

(a) Substantial Assistance. The Agency may suspend all or part of the Consequences imposed on a Covered Person in an individual Controlled Medication Rule Violation case—other than Disqualification of results pursuant to Rule 3321—based on the following:

(1) The Covered Person provides Substantial Assistance to the Agency, the Authority, or a State Racing Commission, a criminal authority, or a professional disciplinary body that results in:

(i) the Agency discovering or bringing forward an Anti-Doping Rule Violation or a Controlled Medication Rule Violation by another Covered Person; or

(ii) a criminal or disciplinary body discovering or bringing forward a sport-related criminal offense or the breach of professional or sports rules by another Person, including offenses arising out of a sport integrity violation or sport safety violation, or the violation of any rule or requirement in the Act, and the information provided by the Covered Person providing Substantial Assistance is also made available to the Agency.

(2) The extent to which the otherwise applicable period of Ineligibility may be suspended shall be based on the seriousness of the Controlled Medication Rule Violation committed by the Covered Person and the degree to which the Substantial Assistance provided by the Covered Person assists the effort to promote doping-free racing, compliance with the Protocol, or the integrity of racing. In any event, no more than three-quarters of the otherwise applicable period of Ineligibility may be suspended. For purposes of this Rule 3326, the otherwise applicable period of Ineligibility shall not include any period of Ineligibility that could be added under Rule 3323(d)(2).

(3) If so requested, the Agency shall allow the Covered Person who seeks to provide Substantial Assistance to provide the information to the Agency subject to a Without Prejudice Agreement.

(4) If the Covered Person fails to continue to cooperate or fails to provide the complete, accurate, and credible Substantial Assistance promised, the Agency shall reinstate the original Consequences. That decision is not subject to review.

(b) Voluntary Admission of a Controlled Medication Rule Violation in the absence of other evidence. If (1) the Covered Person voluntarily admits the commission of a Controlled Medication Rule Violation before receiving the ECM Notice or (in the case of a Rule 3312 violation) before having received notice of a Sample collection that could establish the Controlled Medication Rule Violation, and (2) that admission is the only reliable evidence of the violation at the time the admission is made, the otherwise applicable period of Ineligibility may be reduced by up to one-half.

(c) Application of multiple grounds for reduction of a sanction. If the Covered Person establishes entitlement to a reduction or suspension of the period of Ineligibility under 2 or more of Rules 3324, 3325, or 3326, the otherwise applicable period of Ineligibility shall be determined in accordance with Rules 3323, 3324, and 3325 before applying any reduction or suspension under Rule 3326. If the Covered Person establishes entitlement to a reduction or suspension of the period of Ineligibility under Rule 3326, up to three-quarters of the otherwise applicable period of Ineligibility may be reduced or suspended.

(d) Reductions for certain Controlled Medication Rule Violations based on early admission and acceptance of sanction. If the Covered Person admits the violation and accepts the asserted period of Ineligibility no more than 7 days after receiving the Charge Letter, the period of Ineligibility to be served will be automatically reduced by one-half (but no further reduction shall be allowed under any other Rule).

Rule 3327. Aggravating Circumstances

(a) If the Agency establishes in an individual Controlled Medication Rule Violation case that Aggravating Circumstances are present, the period of Ineligibility otherwise applicable shall be increased by up to 6 months depending on the seriousness of the Aggravating Circumstances, unless the Covered Person establishes that he or she did not knowingly commit the Controlled Medication Rule Violation. Where the period of Ineligibility is increased pursuant to this Rule, an

additional fine of up to $5,000 or an additional 5% of the total purse (whichever is greater) may also be imposed.

(b) Actions and circumstances constituting Aggravating Circumstances include:

(1) Administration of a Controlled Medication Substance or Use of a Controlled Medication Method that is detrimental to the health and welfare of the horse or is designed to deceive the betting public;

(2) prior violations under the Protocol; or

(3) the Covered Person engaged in deceptive or obstructive conduct to avoid the detection or adjudication of a Controlled Medication Rule Violation, for which the Covered Person has not been separately sanctioned for Tampering.

(c) For the avoidance of doubt, the examples set out in Rule 3327(b) are not exhaustive and other similar circumstances or conduct may also be deemed to amount to Aggravating Circumstances that justify the imposition of a longer period of Ineligibility.

Rule 3328. Penalty Points System for Multiple Controlled Medication Rule Violations

(a) The penalty points system established in this Rule 3328 does not replace or lessen in any way the Consequences that apply to the underlying Controlled Medication Rule Violation. Rather, the penalty points system is intended to apply additional uniform Consequences where the Covered Person is a repeat offender and exceeds the permissible number of points.

(b) Covered Persons shall be assigned penalty points as set out in the table below for each Controlled Medication Rule Violation that they commit. The imposition of the specified penalty points is automatic, without any consideration of mitigating or aggravating circumstances, except that:

(1) no points shall be assigned for any violations (i) where the Covered Person was found to bear No Fault or Negligence, or (ii) resulting from environmental contamination;

(2) fewer or no points may be assigned where the Covered Person provides Substantial Assistance in accordance with Rule 3326; and

(3) the penalty points for a complicity or Attempted complicity violation may be adjusted if there are mitigating or aggravating circumstances.

| Controlled medication rule violation | Penalty points |
|---|---|
| Presence, Use or Attempted Use, or Administration or Attempted Administration of a Controlled Medication Substance: | |
| Class A | 3. |
| Class B | 2. |
| Class C | 1½. |
| *Note: Points are assigned for each Controlled Medication Substance detected in the Sample. A Stacking Violation shall be treated as a single violation.* | |
| Use of a Controlled Medication Substance or a Controlled Medication Method in a manner contrary to horse welfare. | 3. |
| Use or Attempted Use or Administration or Attempted Administration of a Controlled Medication Method. | 3. |
| Possession of a Controlled Medication Substance or Controlled Medication Method that is not in compliance with applicable state or Federal law. | 1. |
| Complicity or Attempted complicity in a Controlled Medication Rule Violation committed by another Person. | Same number of points that apply to the Responsible Person, absent mitigating or aggravating circumstances. |
| Violation of Rule 3329 | Same number of points as were assigned for the underlying violation. |

(c) In addition to the Consequences applicable to the underlying Controlled Medication Rule Violation, the following Consequences shall be imposed based on the cumulative points contained in the Covered Person's official record:

| Cumulative penalty points | Additional period of ineligibility |
|---|---|
| 6–7 | 30 days. |
| 7.5–9 | 60 days. |
| 9.5–12 | 90 days. |
| 12.5 or more | 180 days. |

(d) Penalty points and the additional period of Ineligibility shall be applied automatically at the conclusion of the proceeding on the underlying violation, without any additional hearing or right of review. Penalty points shall be applied retroactively to start on the date on which the Controlled Medication Rule Violation occurred and shall expire after 2 years.

(e) The additional period of Ineligibility imposed based on penalty points shall run consecutive to any period of Ineligibility imposed for the underlying Controlled Medication Rule Violation.

(f) A Covered Person's official record of cumulative penalty points shall be maintained by the Agency.

Rule 3329. Status During Provisional Suspension or Ineligibility

(a) While serving a Provisional Suspension or period of Ineligibility for a Controlled Medication Rule Violation:

(1) a Covered Horse may not participate in any Timed and Reported Workout or Covered Horserace, but shall remain subject to Testing;

(2) a Covered Person may not participate in any capacity in any activity involving Covered Horses, or in any other activity (other than authorized anti-doping education or rehabilitation programs) taking place at a Racetrack or Training Facility, nor shall he or she permit anyone to participate in any capacity on his or her behalf in any such activities, except to the extent that the Covered Person is an Owner and the activity is necessary to ensure the safekeeping and wellbeing of the horse during the period of such Owner's Provisional Suspension or Ineligibility.

(b) The Covered Horse(s) of an Owner or Trainer who is subject to a Provisional Suspension or period of Ineligibility shall be subject to the following restrictions:

(1) The Covered Horse(s) of a Trainer who is subject to a Provisional Suspension or period of Ineligibility

may not participate in any Timed and Reported Workout or Covered Horserace unless and until they have been transferred to another Covered Person, except that such Covered Horses may participate in a Covered Horserace if they were entered in the race before the Trainer was notified of the Provisional Suspension or the period of Ineligibility was imposed or accepted (whichever is earlier). For the ''transfer'' to be valid, (i) the transfer must be registered with the Authority in accordance with its procedures, and (ii) if the Trainer is subject to a period of Ineligibility of more than 30 days, the Covered Horses must also be physically relocated to facilities under the care or control of a Covered Person who is not affiliated with the suspended Trainer (and failure to comply may constitute an Anti-Doping Rule Violation under Rule 3216(c), *i.e.,* Prohibited Association).

(2) The Covered Horse(s) of an Owner who is subject to a Provisional Suspension or period of Ineligibility may not participate in any Timed and Reported Workout or Covered Horserace unless and until they have been transferred in a bona fide transaction to a different Owner. If an Immediate Family Member has any ownership or property interest in the Covered Horse(s) following such transfer, the transfer shall not constitute a bona fide transaction to a different Owner.

Rule 3330. Consequences for Violation of the Prohibition on Participation During Ineligibility or Provisional Suspension Under Rule 3329

(a) Consequences for violation of the prohibition on participation during Ineligibility.

(1) If a Covered Person violates the prohibition against participation during Ineligibility described in Rule 3329, any results obtained from such participation shall be Disqualified and a new period of Ineligibility equal in length to the original period of Ineligibility shall be added to the end of the Covered Person's original period of Ineligibility.

(2) If a Covered Horse participates in any Timed and Reported Workout or Covered Horserace in violation of the prohibition against participation during Ineligibility described in Rule 3329, any results obtained from such participation shall be Disqualified, and the Responsible Person for that Covered Horse shall receive the following period of Ineligibility:

(i) if the Responsible Person was subject to an original period of Ineligibility, a new period of Ineligibility equal in length to the original period of Ineligibility shall be added to the end of the original period of Ineligibility. If the original period of Ineligibility has already expired, the new period of Ineligibility shall start on the date that it is accepted or imposed; or

(ii) if the Responsible Person was not subject to an original period of Ineligibility, the period of Ineligibility for violating Rule 3329 shall be from a reprimand to 1 year, depending on the Covered Person's degree of Fault.

(b) Consequences for violation of the prohibition on participation during Provisional Suspension.

(1) A Covered Person who violates the prohibition against participation during a Provisional Suspension shall receive no credit for any period of Provisional Suspension served and the results of such participation shall be Disqualified.

(2) If a Covered Horse participates in any Timed and Reported Workout or Covered Horserace in violation of the prohibition against participation during a Provisional Suspension described in Rule 3329, the Responsible Person for that Covered Horse and the Covered Horse shall receive no credit for any period of Provisional Suspension served and the results of such participation shall be Disqualified.

(c) The consequence of Disqualification under this Rule 3330 shall be the same as set out in Rule 3321(c).

(d) The Internal Adjudication Panel (or the Agency, if the Covered Person admits the violation and accepts the consequences) shall determine whether there has been a violation of the prohibition against participation during Provisional Suspension or Ineligibility and apply the appropriate consequences pursuant to Rule 3361.

Rule 3331. Automatic Public Disclosure

A mandatory part of each sanction shall include automatic Public Disclosure in accordance with Rule 3620.

Rule 3332. Conditions Precedent to Reinstatement for Covered Persons

(a) To be reinstated after commission of a Controlled Medication Rule Violation, the Covered Person must have respected his or her period of Ineligibility (Rule 3329); and repaid or surrendered any purses and other compensation, prizes, trophies, points, and rankings forfeited pursuant to Rule 3321, and paid any fines and reimbursed any costs imposed or accepted to the Agency, unless an installment plan was established pursuant to Rule 3332(b), in which case the Covered Person must have made all payments due under that plan. If any installment(s) subsequently become(s) overdue under that plan (*i.e.,* after reinstatement), the Covered Person and the Covered Horses under his or her ownership or training may not participate in any Timed and Reported Workout or Covered Horserace until such overdue installment(s) is/are paid in full.

(b) Where fairness requires, the Agency or the Internal Adjudication Panel may establish an installment plan for repayment of amounts due to be paid or reimbursed under the Protocol. The payment schedule may extend beyond any period of Ineligibility imposed upon the Covered Person.

Rule 3333. Conditions Precedent to Reinstatement for Covered Horses

(a) A Covered Horse shall be reinstated once its period of Ineligibility ends, provided that (1) the Ineligibility has been respected in full throughout that period in accordance with Rule 3329, (2) the Covered Horse has been made available for Testing during that period in accordance with Rule 3132(d), and (3) the Covered Horse has completed any Vets' List Workout(s) required by the Racetrack Safety Program or the Agency (for the avoidance of doubt, such workouts may be scheduled prior to the expiry of the period of Ineligibility and will not constitute a violation of Rule 3329).

(b) Any reinstatement pursuant to this Rule 3333 is without prejudice to any rest or stand down period that may be imposed on the Covered Horse (*e.g.,* due to injuries), and any requirements for release from the Veterinarians' List, pursuant to the Racetrack Safety Program.

*3340. Results Management*

Rule 3341. General

Where there is evidence of a potential Controlled Medication Rule Violation(s), the Agency will conduct Results Management in accordance with this section 3340 and the Testing and Investigations Standards.

Rule 3342. Review of Adverse Analytical Findings

(a) Upon receipt of an Adverse Analytical Finding in relation to an A Sample, the Agency will conduct a review of the Laboratory certificate of analysis supporting the Adverse Analytical Finding and the relevant Sample collection documentation and Testing documents to determine whether the Adverse Analytical Finding was caused by any apparent departure from the Testing and Investigations Standards, the Laboratory Standards, or any provision of the Protocol. Subject to

Rule 3342(b), the Agency may, but does not have to, communicate with the Responsible Person and Owner during such review.

(b) If the review under Rule 3342(a) reveals an apparent departure that caused the Adverse Analytical Finding, the entire test shall be considered negative, and the Agency shall promptly inform the Responsible Person and each Interested Party of that fact.

(c) If the initial review of an Adverse Analytical Finding under Rule 3342(a) does not reveal an apparent departure that caused the Adverse Analytical Finding, the Agency shall promptly send an ECM Notice to the Responsible Person and each Interested Party in accordance with Rule 3345.

Rule 3343. Review of Atypical Findings Relating to Controlled Medication Substances

(a) In certain circumstances, Laboratories may report the presence of certain Controlled Medication Substances as ''Atypical Findings'' in accordance with the Atypical Findings Policy set out at Appendix 1. Upon receipt of an A Sample Atypical Finding, the Agency will conduct a review to determine whether the Atypical Finding was caused by a departure from the Testing and Investigations Standards, the Laboratory Standards, or any provision of the Protocol. If that review does not reveal any departure that caused the Atypical Finding, the Agency will conduct an investigation (including directing any Further Analysis) or take any other steps required to decide whether the Atypical Finding should be brought forward as an Adverse Analytical Finding, in accordance with the Atypical Findings Policy.

(b) The Agency may, but does not have to, provide notice of an Atypical Finding to anyone until it has made that decision unless one of the following circumstances exists:

(1) if the Agency determines that the B Sample should be analyzed prior to the conclusion of its investigation, the Agency may conduct the B Sample analysis after notifying the Responsible Person and the Owner, with such notice to include a description of the Atypical Finding and the information described in Rule 3345; or

(2) if the Atypical Finding is likely connected to a serious pathology that requires urgent veterinary attention.

(c) If the Agency ultimately decides not to pursue the Atypical Finding as an Adverse Analytical Finding, the Agency may, but does not have to, communicate that fact to the Responsible Person and Owner unless he or she has previously received notice of the Analytical Finding pursuant to Rule 3343(b).

(d) If the Agency decides to move forward with the matter as an Adverse Analytical Finding, the Agency shall promptly send an ECM Notice to the Responsible Person and each Interested Party.

Rule 3344. Review of Other Evidence of a Potential Controlled Medication Rule Violation

The Agency shall conduct any follow-up investigation required into any potential Controlled Medication Rule Violation not covered by Rules 3342 or 3343. At such time as the Agency is satisfied that it has sufficient evidence to establish that a Controlled Medication Rule Violation occurred, it shall promptly send an ECM Notice to the relevant Covered Person and each Interested Party.

Rule 3345. ECM Notice

(a) Where it is determined that a Covered Person may have committed one or more Controlled Medication Rule Violations, the Agency will promptly notify the Covered Person and each Interested Party in writing of the following (the ECM Notice):

(1) the alleged Controlled Medication Rule Violation and the Consequences if it is agreed or determined to have been committed;

(2) the Adverse Analytical Finding (with a copy of the Laboratory certificate of analysis in a form designated by the Agency) or a brief summary of the facts relied on by the Agency to assert the alleged violation (including, where applicable, the name of the Covered Horse implicated in the alleged violation, whether the alleged violation was in connection with a particular Covered Horserace, and the date of Sample collection or of the other relevant facts said to give rise to the violation);

(3) if applicable, the right of the Responsible Person and the Owner to receive copies of the A Sample Laboratory Documentation Package after the B Sample analysis has been completed or after such analysis is waived;

(4) if applicable, the following details regarding the B Sample analysis:

(i) that the B Sample has been (or will be) analyzed because the Agency has authorized immediate analysis to preserve the scientific integrity of the Sample;

(ii) if the B Sample has not been analyzed, the Responsible Person's and Owner's right to promptly request the analysis of the B Sample within no more than 5 days or (failing such request) that the B sample analysis shall be deemed to be waived;

(iii) an explanation that where the Responsible Person or Owner requests the B Sample analysis within the applicable deadline, or where the Agency decides to proceed with the B Sample analysis, the Agency will notify the Responsible Person and Owner of the date, time, and place where the B Sample will be analyzed and (where the analysis is requested by the Responsible Person or Owner) the amount that the Responsible Person or Owner must pay to have the B Sample tested and B Sample Laboratory Documentation Package prepared, and the date by which such payment must be received, failing which the B Sample analysis shall be deemed to have been waived; and

(5) the opportunity for the Covered Person to provide an explanation within a short deadline set by the Agency;

(6) the opportunity to provide Substantial Assistance, to admit the Anti-Doping Rule Violation, or to seek to resolve the matter without a hearing under Rule 3349;

(7) all relevant details relating to any Provisional Suspension (including, if applicable, the possibility to accept a voluntary Provisional Suspension) in accordance with Rule 3347; and

(8) if applicable, the ability for the automatic Disqualification of results to be applied immediately in accordance with Rule 3321(a)(2).

(b) Before sending an ECM Notice, for purposes of Rule 3323, the Agency shall seek to determine whether the Covered Person in question has committed any prior violations under the Protocol.

(c) Any defect in the ECM Notice (including a failure to identify the Covered Horseraces implicated in the alleged violation, if any) may be corrected by the Agency and shall not in any event invalidate the ECM Notice or affect the due application of the provisions of the Protocol (including the Disqualification provisions) in relation to that violation.

Rule 3346. B Sample Analysis

(a) Arrangements shall be made for analysis of the B Sample without undue delay, in accordance with the Protocol and the Laboratory Standards. Subject to Rule 3346(b), the Responsible Person or Owner must pay the costs of the B Sample analysis in advance, but, if the B Sample analysis does not confirm the A Sample analysis, they will be reimbursed that cost by the Agency. The Responsible Person and Owner or one representative each may attend the Laboratory to witness the opening and identification of the B Sample. They do

not have any right to witness the analysis of the B Sample.

(b) The Responsible Person and Owner may (if they both agree) waive analysis of the B Sample (in which case they shall be deemed to accept the A Sample analytical results). If waived, the Agency may nonetheless elect to proceed with the B Sample analysis at its own expense.

(c) If the B Sample proves negative, the entire Test shall be considered negative, and the Responsible Person and Owner shall be so informed. In such circumstances, unless the Agency asserts a Controlled Medication Rule Violation under Rules 3313 or 3314 (Use), the ECM Notice will be withdrawn, any Provisional Suspensions imposed shall be deemed automatically vacated with immediate effect (without the need for any order from the Internal Adjudication Panel), and no further disciplinary action will be taken against the Responsible Person, other Covered Person, or Covered Horse by the Agency in relation to the original Adverse Analytical Finding (provided, however, that the Agency may investigate why the B Sample did not match the A Sample). If the Agency asserts that a Rule 3313 or 3314 (Use) violation has occurred, it shall send a Charge Letter to the Responsible Person and other Covered Person(s), with a copy to each Interested Party.

(d) If the presence of a Controlled Medication Substance or the Use of a Controlled Medication Method is confirmed by the B Sample analysis, or the B Sample analysis is waived, the Agency shall send a Charge Letter to the Responsible Person and any other relevant Covered Person(s), with a copy to each Interested Party, asserting that a Rule 3312 (presence) violation or a Rule 3313 (Use) violation (as applicable) has occurred.

Rule 3347. Provisional Suspensions

(a) The Agency shall not impose a Provisional Suspension on a Covered Horse for a Controlled Medication Rule Violation, unless the violation involves a Controlled Medication Method for which the Prohibited List specifies a period of Ineligibility.

(b) The Agency may impose a Provisional Suspension on a Covered Person for a Controlled Medication Rule Violation where it considers it appropriate to do so in the circumstances of the case, including where (1) the Covered Person admits the Controlled Medication Rule Violation and is likely to be subject to a period of Ineligibility, (2) there is an Adverse Analytical Finding for more than one Controlled Medication Substance and those substances are not Specified Substances, (3) the Covered Person has a pending Anti-Doping Rule Violation or Controlled Medication Rule Violation or prior violation that is likely to result in an increased period of Ineligibility, or (4) the individual represents a threat to the health, safety, or welfare of horses or the integrity of the sport of horseracing.

(c) Where a Provisional Suspension is imposed pursuant to Rule 3347(a) or (b), the Responsible Person (on his or her own behalf and on behalf of the Covered Horse) and any other Covered Person made subject to the Provisional Suspension shall be given:

(1) an opportunity for a Provisional Hearing before imposition of the Provisional Suspension;

(2) an opportunity for a Provisional Hearing on a timely basis after imposition of the Provisional Suspension; or

(3) an opportunity for an expedited final adjudication in accordance with Rule 3362 on a timely basis after imposition of the Provisional Suspension.

(d) Provisional Hearings shall be conducted by the Internal Adjudication Panel and heard via telephone or video conference call within the time frame specified in accordance with the Arbitration Procedures, except where the Internal Adjudication Panel decides to determine the matter based solely on the written submissions without a hearing. The sole issue to be determined by the Internal Adjudication Panel will be whether the Agency's decision to impose a Provisional Suspension shall be maintained. The Agency's decision to impose a Provisional Suspension shall be maintained unless the Responsible Person/Covered Person requesting the lifting of the Provisional Suspension establishes that:

(1) the allegation that a Controlled Medication Rule Violation has been committed has no reasonable prospect of being upheld, *e.g.,* because of a material defect in the evidence on which the allegation is based;

(2) the Responsible Person/Covered Person charged bears No Fault or Negligence for the Controlled Medication Rule Violation that is alleged to have been committed, so that any period of Ineligibility that might otherwise be imposed for such offense would be completely eliminated by application of Rule 3324. (This ground does not apply in respect of any Provisional Suspension imposed on a Covered Horse);

(3) Rule 3325 applies and the Responsible Person/Covered Person bears No Significant Fault or Negligence and he or she will likely be given a period of Ineligibility that is not longer than the period for which he or she has already been provisionally suspended. (This ground does not apply in respect of any Provisional Suspension imposed on a Covered Horse); or

(4) exceptional circumstances exist that make it clearly unfair, taking into account all of the circumstances of the case, to impose a Provisional Suspension prior to the final hearing on the merits. This ground is to be construed narrowly and applied only in truly exceptional circumstances. For example, the fact that the Provisional Suspension would prevent the Responsible Person, Covered Person, or Covered Horse from participating in a particular Timed and Reported Workout, Covered Horserace, or other activity shall not qualify as exceptional circumstances for these purposes.

(e) If the application is made before the Provisional Suspension comes into effect, the Provisional Suspension will not come into effect pending the decision on the application. If the application is made after the Provisional Suspension has come into effect, the Provisional Suspension will remain in place pending the decision on the application.

(f) If it considers it appropriate to do so on the specific facts of the case, the Agency may lift the Provisional Suspension.

(g) If the application to have a Provisional Suspension not imposed/lifted is not granted, a further application may not be made to lift the Provisional Suspension unless: (1) it is based on new and material evidence that the Responsible Person or other Covered Person was not aware of and could not reasonably have been aware of at the time he or she made the original application; or (2) there has been some other significant and material change in circumstances since the original application was decided. If the Responsible Person or other Covered Person makes a further application that does not meet either of these requirements, costs may be awarded against him or her.

(h) Voluntary Provisional Suspension.

(1) In all cases where a Responsible Person/Covered Person has been notified of or charged with a Controlled Medication Rule Violation, but no Provisional Suspension has been imposed on him or her or on the Covered Horse, that person may (on his or her own behalf and, if the Responsible Person, on behalf of the Covered Horse where it might be subject to a period of Ineligibility), voluntarily accept a Provisional Suspension at any

time by written notice to the Agency. A copy of the voluntary Provisional Suspension shall promptly be provided to each Interested Party.

(2) A Provisional Suspension that is voluntarily accepted will have effect (in the same manner as if the Provisional Suspension had been imposed under Rule 3347(a)) from the date that written notice of its acceptance is received by the Agency.

(i) No admission will be inferred, or other adverse inference drawn, from the decision of a Covered Person: (1) not to make an application to lift a Provisional Suspension; or (2) to accept a voluntary Provisional Suspension.

(j) If a Provisional Suspension is imposed or voluntarily accepted, and that Provisional Suspension is respected, then the Responsible Person/Covered Person and Covered Horse in question shall receive a credit for such period of Provisional Suspension against any period of Ineligibility that may ultimately be imposed. If the Responsible Person/Covered Person or Covered Horse does not respect a Provisional Suspension, the Responsible Person/Covered Person or Covered Horse shall receive no credit for any period of Provisional Suspension served. If a period of Ineligibility is served pursuant to a decision that is subsequently subject to review, the Responsible Person/Covered Person or Covered Horse shall receive a credit for such period of Ineligibility served against any period of Ineligibility that may ultimately be imposed on review.

(k) Notwithstanding any other provision in this Rule 3347 or elsewhere in the Protocol, any Provisional Suspension imposed on a Covered Horse will be automatically lifted (without the need for any hearing) if it has been in place for a period equal to the period of Ineligibility specified in the Protocol or Prohibited List.

Rule 3348. Charge Letter

If, after receipt of the Covered Person's explanation, or expiry of the deadline to provide such explanation, the Agency remains satisfied that the Covered Person has committed a Controlled Medication Rule Violation(s), the Agency shall promptly charge the Covered Person with the asserted Controlled Medication Rule Violation(s). In this letter of charge (Charge Letter), which will be copied to each Interested Party, the Agency shall:

(a) set out the Controlled Medication Rule Violation(s) that the Covered Person is charged with having committed;

(b) provide a summary of the relevant facts upon which the charge is based, enclosing a copy of the A Sample Laboratory Documentation Package and (if applicable and if requested) the B Sample Laboratory Documentation Package;

(c) specify the Consequences that will apply if the charge is upheld;

(d) grant a deadline of not more than 7 days from receipt of the Charge Letter (unless otherwise agreed by the Agency) for the Covered Person to either:

(1) admit the Controlled Medication Rule Violation(s) charged and:

(i) accept the Consequences proposed by the Agency, in which case the Agency will issue a decision under Rule 3349,

(ii) seek to agree mitigated Consequences with the Agency pursuant to Rule 3349 failing which the Consequences may still be disputed at a hearing; or

(iii) dispute or seek to mitigate the proposed Consequences at a hearing in accordance with Rule 3361 and the Arbitration Procedures; or

(2) deny the Controlled Medication Rule Violation charged and dispute the proposed Consequences at a hearing in accordance with Rule 3361 and Arbitration Procedures;

(e) indicate that if the Covered Person does not challenge the Agency's assertion of a Controlled Medication Rule Violation or the proposed Consequences within the prescribed deadline, the Covered Person shall be deemed to have waived his or her right to a hearing, admitted the Controlled Medication Rule Violation(s) charged, and accepted the Consequences specified by the Agency in the Charge Letter (without any mitigation of those Consequences);

(f) give the opportunity to provide Substantial Assistance in accordance with Rule 3326(a); and

(g) provide all relevant details relating to any Provisional Suspensions (including, if applicable, the possibility to accept a voluntary Provisional Suspension) in accordance with Rule 3347.

Rule 3349. Case Resolution Without a Hearing

(a) At any time prior to a final decision under the Arbitration Procedures: (1) the Agency may withdraw a Charge Letter for good cause, in which case any Provisional Suspension will be automatically lifted and (absent the emergence of new information) no further steps will be taken in relation to the violations alleged in the Charge Letter; or (2) the Covered Person may agree to admit the Controlled Medication Rule Violation(s) charged (or any other violation of the Protocol) and accede to specified Consequences consistent with the Protocol. In any such case, an adjudication under the Arbitration Procedures will not be required.

(b) In the event that the Covered Person admits the Controlled Medication Rule Violation(s) charged and accedes to Consequences specified by the Agency (or is deemed to have done so in accordance with Rule 3348(a)(5)), the Agency will (1) promptly issue a final decision confirming the commission of the Controlled Medication Rule Violation(s) and setting out the factual basis for the decision and all of the Consequences to be imposed (including a brief summary of the reasons for any period of Ineligibility imposed, unless doing so could compromise an ongoing investigation or proceeding), and (2) send notice of the decision to each Interested Party. The Agency will also Publicly Disclose the decision (or a summary thereof, at the discretion of the Agency) in accordance with Rule 3620.

(c) In the event that the Agency withdraws the Charge Letter, it will (1) promptly issue a summary decision confirming the withdrawal of the Charge Letter, (2) send notice of the decision to the Covered Person concerned, with a copy to each Interested Party, and (3) Publicly Disclose the decision (or a summary thereof, at the discretion of the Agency) in accordance with Rule 3620.

Rule 3350. Notification Requirements

(a) Notification of Controlled Medication Rule Violations will take place as set out in Rule 3345 and Rule 3348. If at any point after an ECM Notice has been provided the Agency decides not to move forward with the charge, it will notify the Covered Person(s) concerned and each Interested Party of that decision.

(b) Notification to a Covered Person by the Agency, for all purposes of the Protocol, may be accomplished either through actual or constructive notice. Actual notice may be accomplished by any means. Constructive notice shall be deemed to have been given when the information in question is delivered by third-party courier or U.S. postal mail to the Covered Person's most recent mailing address on file with the Authority or by email or text message to the Covered Person's most recent email address or mobile telephone number on file with the Authority.

*3360. Hearings and Review of Final Decisions*

Rule 3361. Procedure Before the Internal Adjudication Panel

Where a Covered Person is alleged to have committed a Controlled Medication Rule Violation, a violation of Rule 3329, or any violation of Rule 3510, the Covered Person shall be entitled to request a hearing before the Internal Adjudication Panel in accordance with the Arbitration Procedures. However, the Internal Adjudication Panel may decide, in its sole discretion, to determine the matter based solely on the written submissions without a hearing if the Internal Adjudication Panel considers itself sufficiently well-informed to render a decision on the written submissions alone. A copy of the final decision of the Internal Adjudication Panel shall be sent to the Agency and the Covered Person(s) concerned. Where the Agency considers it necessary or appropriate to do so, a copy of the decision may be sent to any Interested Party. The decision (or a summary thereof, at the discretion of the Agency) shall be Publicly Disclosed as provided in Rule 3620. The Internal Adjudication Panel may also adjudicate any other matter referred to it under the Protocol, and any other matter that might arise from time to time under the Protocol that the Agency considers should be determined by the Internal Adjudication Panel.

Rule 3362. Expedited Hearing

In Controlled Medication Rule Violation cases where the Covered Horse or Covered Person in question is not Provisionally Suspended and is likely to participate in a Covered Horserace within 45 days, the Agency may (if it sees fit) address the case on an expedited basis and shorten any deadlines in the Protocol or Arbitration Procedures proportionately to ensure resolution of the matter prior to the Covered Horserace.

Rule 3363. Finality

Subject to Rule 3364, decisions rendered by the Internal Adjudication Panel under the Protocol shall be final and binding.

Rule 3364. Review of Final Decisions

Any final decision by the Agency or the Internal Adjudication Panel is subject to review in accordance with section 3058 of the Act. Any final decision under review shall remain in effect pending resolution of the review unless ordered otherwise.

*3500. Other Violations*

Rule 3510. Other Violations Under the Protocol

Where a Covered Person:

(a) engages in disruptive or offensive conduct towards a Doping Control official or other Person involved in Doping Control that does not rise to the level of Tampering;

(b) refuses or fails to cooperate promptly and completely with the Authority or the Agency in the exercise of their respective powers under the Act and the Protocol and related rules, including any refusal or failure to comply with Rule 3040(a)(2);

(c) commits a Whereabouts Failure; or

(d) refuses or fails without compelling justification to comply with any other provision of the Protocol (where such refusal or failure does not constitute an Anti-Doping Rule Violation);

the Covered Person will not be deemed to have committed an Anti-Doping Rule Violation or Controlled Medication Rule Violation. However, disciplinary proceedings may be brought against him or her before the Internal Adjudication Panel in accordance with the Arbitration Procedures or resolved without a hearing applying the rules of proof set out in Rule 3120 and following the procedures set out in section 3360 (in each case, mutatis mutandis, *i.e.,* amended as required to reflect the different context). The Agency will send the Covered Person at issue a notice of the alleged violation, setting out a summary of the relevant facts upon which the charge is based, and giving the Covered Person the opportunity to provide an explanation within a short deadline. If the Internal Adjudication Panel finds the violation alleged to be proven, or if the Covered Person admits the violation alleged and does not request a hearing to determine the consequences, the Internal Adjudication Panel or the Agency (as applicable) may impose sanctions on Covered Persons as set out in Rule 3520.

Rule 3520. Sanctions for Other Violations Under the Protocol

(a) For a violation of Rule 3510(a) (disruptive or offensive conduct), the Covered Person shall be subject to, at a minimum, a reprimand and no period of Ineligibility, and, at a maximum, 30 days of Ineligibility, depending on the seriousness of the violation. A fine of up to $5,000 may also be imposed.

(b) For a violation of Rule 3510(b) (refusal or failure to cooperate), the Covered Person shall be subject to, at a minimum, a reprimand and no period of Ineligibility, and, at a maximum, a period of Ineligibility of up to 2 years, depending on the seriousness of the violation. A fine of up to $15,000 may also be imposed. A failure to comply with Rule 3040(b)(7) will be considered a particularly serious violation that will ordinarily warrant the imposition of the maximum sanction.

(c) For a violation of Rule 3510(c) (Whereabouts Failures), the Covered Person shall not be subject to any penalty for the first Whereabouts Failure, but shall be subject to a fine of $250 for the second Whereabouts Failure, and a fine of $500 for the third Whereabouts Failure. For any subsequent Whereabouts Failures, the fine will increase by $500 each time (*i.e.,* $1,000 for the fourth failure, $1,500 for the fifth failure, etc.).

(d) For a first violation of Rule 3510(d) (refusal or failure to comply with any other provision of the Protocol), the Covered Person shall be subject to, at a minimum, a reprimand and no period of Ineligibility, and, at a maximum, 30 days of Ineligibility, as well as a fine of up to $2,500, depending on the seriousness of the violation.

(e) For any second or subsequent Rule 3510 violation, the maximum potential Ineligibility and potential fine will be double what the maximum potential Ineligibility and potential fine was for the previous violation.

(f) Where a violation of Rule 3510 is alleged and the Covered Person represents a threat to the health, safety, or welfare of horses or the integrity of the sport of horseracing, the Agency may impose a Provisional Suspension on the Covered Person concerned pending resolution of the charge. The Covered Person may challenge the Provisional Suspension in accordance with Rule 3347 (which shall apply mutatis mutandis, *i.e.,* amended as required to reflect the different context).

*3600. Confidentiality and Reporting*

Rule 3610. Notice of Violations and Confidentiality

(a) Notice.

(1) Notice of Anti-Doping Rule Violation or Controlled Medication Rule Violations shall be sent to the Covered Persons concerned, with a copy to each Interested Party, as set out in Rules 3245/3248 and 3345/3348.

(2) Notice of other violations shall be sent to the Covered Persons concerned. The Agency may send a copy to any Interested Party where it considers it necessary or appropriate to do so in the circumstances.

(3) State Racing Commissions shall only be entitled to receive notice of violations of the Protocol as Interested

Parties if they first enter into an agreement with the Agency incorporating confidentiality provisions required by the Agency pursuant to the Act or the Protocol. The Agency may, in its sole discretion, delay notice to the State Racing Commission for case- or investigation-related reasons.

(b) Confidentiality and public reporting.

(1) Subject to the other provisions of this paragraph (b), the Agency will use its reasonable endeavors to ensure that Persons under its control do not publicly identify Covered Horses or Covered Persons who are alleged to have committed a violation under the Protocol, unless and until (i) in presence cases, the B Sample confirms the results of the A Sample analysis, or the B Sample analysis is waived, (ii) a Provisional Suspension has been imposed or voluntarily accepted, (iii) a charge has been brought, or (iv) a violation has been admitted, whichever is earlier.

(2) In such circumstances, subject to paragraph (3) below, the Agency shall publicly report:

(i) the identity of any Covered Person who is the subject of the alleged violation;

(ii) the identity of any relevant Covered Horse(s); and

(iii) the rule violated and, where appropriate, the basis of the asserted violation.

(3) The Agency shall not be required to publicly report a matter under this paragraph (b) if it would risk compromising an ongoing investigation or proceeding. When the Agency determines that an ongoing investigation or proceeding will no longer be compromised by public reporting, the Agency shall at such time make any public reporting required under this Rule.

(4) The mandatory public reporting under Rule 3610(b) shall not be required where the Covered Person who is alleged to have committed a violation is a Minor. Any optional public reporting in a case involving a Minor shall be proportionate to the facts and circumstances of the case.

(5) If at any time information pertaining to an alleged violation is publicly reported by a Person not affiliated with the Authority or the Agency, the Agency may respond to such public comment as it considers necessary.

(6) The Agency may publicly report any relevant information at any time, including prior to delivery of notice of a violation, if the Agency determines that such disclosure:

(i) concerns a violation or circumstance that poses a serious and imminent risk of harm to any Covered Person(s), Covered Horse(s), State Racing Commission(s), Racetrack(s), Race Organizer(s), Training Facilities, or the public; or

(ii) is otherwise in the best interest of horseracing conducted at Covered Horseraces.

(7) The Agency may at any time disclose to other Persons such information as the Agency considers necessary or appropriate to facilitate administration or enforcement of the Protocol (including Interested Parties and other Persons with a need to know), provided that each Person provides assurance satisfactory to the Agency that the organization will maintain all such information in confidence.

(8) Interested Parties and other Persons may not publicly report any information about an alleged violation unless the information has been publicly reported by the Agency or the Covered Person(s) concerned, or the Agency gives written authorization for him or her to publicly report the information.

Rule 3620. Public Disclosure

(a) The Agency shall Publicly Disclose the resolution of an alleged violation of the Protocol no later than 20 calendar days after:

(1) the final decision;

(2) a resolution between the Agency and the Covered Person; or

(3) the withdrawal of a charge or a final decision finding of no violation.

(b) Public Disclosure shall include:

(1) the name of the Covered Person who committed the violation(s) and any Covered Horse(s) implicated by the violation;

(2) the Rule(s) violated;

(3) the Prohibited Substance(s) or Prohibited Method(s) involved, if any;

(4) the Consequences imposed;

(5) any final decision or a summary thereof, unless publishing that decision could compromise an ongoing investigation or proceeding, and excluding decisions made by the Agency with respect to Atypical Findings pursuant to Appendix 1; and

(6) any review rights available in respect of the decision.

(c) The mandatory Public Disclosure required by this 3620 shall not be required where the Covered Person who has been found to have committed a violation is a Minor. Any optional Public Disclosure in a case involving a Minor shall be proportionate to the facts and circumstances of the case.

(d) Publication shall be accomplished by, at a minimum, placing the required information on the Agency's website.

Rule 3630. General Reporting

The Agency may publish general statistical reports of its Doping Control and Medication Control activities and may report as necessary on its activities to the U.S. Congress, the Commission, the Authority, the State Racing Commissions, and other Federal or State governmental bodies or agencies having jurisdiction over the sport of horseracing in the United States. The Agency may also publish reports showing the names of any Covered Horses Tested and the date of each Sample collection.

Rule 3640. Data Privacy

The Agency may collect, store, process, or disclose personal information relating to Covered Persons, Covered Horses, or other Persons and horses where necessary and appropriate to discharge its responsibilities under the Protocol, but shall take appropriate steps to maintain that information and its confidentiality in compliance with applicable law.

*3700. Implementation of Decisions*

Rule 3710. Application and Recognition of Decisions

(a) Any final decision issued pursuant to the Protocol that a violation of the Protocol has taken place and imposing Consequences or other sanctions for that violation shall be automatically and immediately recognized, respected, enforced and given full force and effect by the Authority, Racetracks, Race Organizers, Training Facilities, all Covered Persons, and all other relevant Persons within their respective spheres of authority.

(b) Where a third party with its own jurisdiction over Covered Persons or Covered Horses imposes consequences on them for violation of anti-doping or controlled medication rules that are consistent with the Protocol or the World Anti-Doping Code, that decision, upon review and acceptance by the Authority and the Agency, shall be immediately recognized, respected, enforced and given full force and effect by the Agency, the Authority, Racetracks, Race Organizers, all Covered Persons, and all other relevant Persons within their respective spheres of authority.

*3800. Education*

Rule 3810. Education Programs

The Agency shall plan, implement, evaluate, and monitor education programs for responsible medication use and doping-free horseracing.

*Rule Series 3000 Appendix 1: Atypical Findings Policy*

Overview

1. Atypical Findings occur when the Laboratory provides the results of its analysis of a Sample to the Agency and more investigation or review is needed to determine whether or not it should be treated as an Adverse Analytical Finding. This Atypical Findings Policy (Atypical Findings Policy) sets out the process by which the Agency will decide whether or not Atypical Findings will be pursued as Adverse Analytical Findings.

Prohibited Substances To Be Treated as Atypical Findings

2. If detected in the Sample of a Covered Horse, the following Prohibited Substances shall be investigated or reviewed as Atypical Findings:

(a) Specified Substances;

(b) endogenous substances;

(c) ractopamine; and

(d) zilpaterol.

3. The Laboratory may also report other Atypical Findings in relation to substances that are not specifically listed in the Prohibited List or Technical Document-Prohibited Substances.

Decisions Regarding Atypical Findings

4. The Agency is responsible for issuing a decision regarding whether or not an Atypical Finding will be pursued as an Adverse Analytical Finding.

5. Subject to the notification requirements set out below, the deliberations of the Agency shall be confidential.

Preliminary Steps

6. Initial review.

The Agency will first conduct a review to determine whether there is any apparent departure from any Standards or any provisions of the Protocol that caused the Atypical Finding. If that review does not reveal any departure that caused the Atypical Finding, the Agency will conduct the required investigation in accordance with this Atypical Findings Policy. The precise nature of the investigation will depend on basis for the Atypical Finding, including the Prohibited Substance(s) associated with the Atypical Finding (if applicable), and the level of cooperation of the Responsible Person.

7. Notification.

The Agency will promptly inform the Responsible Person and Interested Parties in writing of the Atypical Finding and any relevant information, such as the Covered Horserace to which the Atypical Finding relates, and the Responsible Person will have the opportunity to provide any information that he or she believes might assist the Agency in deciding whether or not to pursue the Atypical Finding as an Adverse Analytical Finding, as set forth in the criteria below. Such information must be provided to the Agency by the deadlines set by the Agency in order for it to be considered by the Agency.

8. Additional information.

The Agency may request such additional information or explanations from the Responsible Person as it considers necessary to evaluate the Atypical Finding, and the Responsible Person must comply fully and promptly with any such requests.

Criteria

*In deciding whether or not an Atypical Finding should be pursued as an Adverse Analytical Finding, the Agency will consider the following criteria:*

9. Proving source of the Prohibited Substance(s) as a precondition.

(a) The Responsible Person has the burden of proving how the Prohibited Substance(s) entered the body of the Covered Horse. If the Responsible Person is unable to discharge that burden, the Atypical Finding must be pursued as an Adverse Analytical Finding. If the Responsible Person proves the source, the Agency will determine whether or not the Analytical Finding should be pursued as an Adverse Analytical Finding.

(b) The Agency will take a number of factors into account when considering whether or not the source of the Atypical Finding has been established including, but not limited to:

(i) if there were Atypical Findings for the same Prohibited Substance(s) arising from other Samples collected at the relevant Covered Horserace;

(ii) if there were Atypical Findings for the same Prohibited Substance(s) arising from other Samples collected at previous Covered Horseraces held at the same Racetrack or in the same region;

(iii) if Samples taken from feed or bedding at the relevant Covered Horserace (if such samples are available) test positive for the Prohibited Substance(s) in question;

(iv) if there were other (non-Atypical Finding) Prohibited Substance(s) in the Sample; and

(v) the concentration level of the particular Prohibited Substance(s) in the Sample.

(c) In addition, the Agency may, in accordance with Rules 3246 and 3346 of the Protocol, request the B Sample analysis.

(d) If the Atypical Finding concerns a Prohibited Substance(s) that is an endogenous substance, the Agency will request that the Responsible Person provide any veterinary information that would assist in establishing if the result is due to a physiological or pathological condition, and such information shall be taken into account by the Agency.

(e) When trying to establish the source of the Prohibited Substance(s) in question, the Agency may consult, as necessary, with one or more experts to obtain further information on the Prohibited Substance(s) in order to assess whether or not: (i) the explanations provided by the Responsible Person (if any) are plausible; or (ii) the presence of the Prohibited Substance(s) in the Sample is likely to be due to contamination.

(f) The Agency will consider any measures the Responsible Person has in place to prevent Prohibited Substances entering the body of his or her Covered Horse(s), including:

(i) whether or not the Responsible Person keeps up-to-date treatment records;

(ii) whether or not the Responsible Person keeps a record of the feed or supplements given to his or her Covered Horses, and whether samples of such feed or supplements have been stored for potential analysis;

(iii) the security measures put in place by the Responsible Person at his or her stables and when travelling to or attending Covered Horseraces; and

(iv) other measures taken by the Responsible Person to prevent Prohibited Substances inadvertently entering the body of his or her Covered Horses.

10. Other factors.

The Agency may also have regard to other factors that it considers necessary or relevant, including, but not limited to:

(a) the security measures in place at the relevant Covered Horserace;

(b) the report(s) of the Veterinarians or stewards at the relevant Covered Horserace;

(c) the prevalence of the use of the Prohibited Substance(s); and

(d) whether or not the Responsible Person has any prior Anti-Doping Rule Violation(s) or Controlled Medication Rule Violation(s) (excluding any violations where the Responsible Person was found to bear No Fault or Negligence).

Conclusion of the Investigation and Notification

11. Following the Agency's investigation of the Atypical Finding in accordance with the criteria above, the

Agency shall decide whether or not the Atypical Finding should be pursued as an Adverse Analytical Finding. The Agency shall issue a written decision, with a short summary of the basis for that decision. The decision of the Agency is final and is not subject to review. The Agency will send a copy of its decision to the Responsible Person.

12. If the Agency determines that the Atypical Finding should not be pursued as an Adverse Analytical Finding, no further action will be taken, and no case will be opened against the Responsible Person.

13. If the Agency determines that the Atypical Finding should be pursued as an Adverse Analytical Finding, the Agency will follow the notification procedure set out in Rules 3250 and 3350 and will refer the matter for adjudication in accordance with the Arbitration Procedures (unless the matter is resolved by agreement without a hearing as permitted under the Protocol). The Agency may rely on any information submitted or obtained when investigating the Atypical Finding in the subsequent Adverse Analytical Finding case.

Publication of Atypical Findings

14. At the end of each year, the Agency may publish a report setting out the following information, on an anonymised basis:

(a) how many Atypical Findings were reported by Laboratories that year;

(b) how many Atypical Findings were pursued as Adverse Analytical Findings, and the Prohibited Substances in question;

(c) how many Atypical Findings were not pursued as Adverse Analytical Findings, and the Prohibited Substances in question; and

(d) how many Atypical Findings remain under investigation.

Public Comment

15. Unless there are compelling reasons (as determined by the Agency), no Person may make any public comment on the specific details of an Atypical Finding while the investigation is ongoing. If such a disclosure is made by a Person not affiliated with the Authority or the Agency, the Authority or the Agency may respond to such public comment as it considers necessary.

16. If an Atypical Finding is not pursued as an Adverse Analytical Finding, no Person may make any public comment on the details of that Atypical Finding without the prior consent of the Responsible Person. If such a disclosure is made by a Person not affiliated with the Authority or the Agency, the Authority or the Agency may respond to such public comment as it considers necessary.

*4000. Prohibited List*

4010. Purpose

In accordance with Rule 3111, the Prohibited List identifies substances and methods that are prohibited at all times (Banned Substances and Banned Methods) and those that are prohibited for Use or Administration in relation to a Covered Horse during the Race Period and prohibited to be present in a Post-Race Sample or Post-Work Sample, except as otherwise specified in the Prohibited List (Controlled Medication Substances and Controlled Medication Methods). In accordance with the definition of ''Race Period'' (see Rule 1020), the Prohibited List may specify that, for certain specified Controlled Medication Substances and Controlled Medication Methods, the Race Period shall be shorter or longer in duration. Prohibited Substances and Prohibited Methods may be included in the Prohibited List by general category (*e.g.,* anabolic steroids) or by specific reference to a particular substance or method. The Prohibited List is supplemented by the ''Technical Document—Prohibited Substances,'' which provides guidance on the Prohibited Substances that fall into the general categories listed in the Prohibited List and on the Screening Limits, Thresholds, or Detection Times for those Prohibited Substances (as applicable), and also designates certain Prohibited Substances as Specified Substances, which are those that pose a higher risk of being the result of contamination and, therefore, are subject to more flexible sanctions. Certain Prohibited Substances might also first be reported as Atypical Findings requiring further investigation before being declared as Adverse Analytical Findings, in accordance with the Atypical Findings Policy set out as Appendix 1 to the Protocol. The Prohibited List also sets out the periods of Ineligibility applicable to Covered Horses for Anti-Doping Rule Violations and Controlled Medication Rule Violations (see Rule 4300).

*4100. Banned Substances and Banned Methods*

4110. Banned Substances

Rule 4111. S0 Non-Approved Substances

Any pharmacological substance that (i) is not addressed by Rules 4112 through 4117, (ii) has no current approval by any governmental regulatory health authority for veterinary or human use, and (iii) is not universally recognized by veterinary regulatory authorities as a valid veterinary use, is prohibited at all times. For the avoidance of doubt, compounded products compliant with the Animal Medicinal Drug Use Clarification Act (AMDUCA) and the FDA Guidance for Industry (GFI) #256 (also known as Compounding Animal Drugs from Bulk Drug Substances) are not prohibited under this section S0.

Rule 4112. S1 Anabolic Agents

The following substances, and other substances with similar chemical structure or similar biological effect(s), are prohibited at all times:

(a) anabolic androgenic steroids when administered exogenously;

(b) other anabolic agents, including, but not limited to:

(1) Selective Androgen Receptor Modulators (SARMs);

(2) Zeranol;

(3) Zilpaterol; and

(4) Ractopamine.

Rule 4113. S2 Peptide Hormones, Growth Factors, Related Substances, and Mimetics

The following substances, and other substances with similar chemical structure or similar biological effect(s), are prohibited at all times:

(a) Erythropoietins (EPO) and agents affecting erythropoiesis, including, but not limited to:

(1) erythropoietin-receptor agonists;

(2) Hypoxia-Inducible Factor (HIF) activating agents;

(3) GATA (Erythroid Transcription Factor) inhibitors;

(4) Transforming Growth Factor-beta (TGF-β) signaling inhibitors; and

(5) innate repair receptor agonists.

(b) Peptide Hormones and their releasing factors, including, but not limited to:

(1) Chorionic Gonadotrophin (CG) and Luteinizing Hormone (LH) and their releasing factors in stallions, ridglings, and geldings;

(2) corticotrophins and their releasing factors (excluding ACTH if administered outside the Race Period);

(3) Growth Hormone (GH) and its analogues and fragments; and

(4) Growth Hormone (GH) releasing factors.

(c) Growth factors and growth factor modulators affecting muscle, tendon, or ligament protein synthesis/degradation, vascularization, energy utilization, regenerative capacity, or fiber type switching.

Rule 4114. S3 Beta-2 Agonists

The following substances, and other substances with similar chemical structure or similar biological effect(s), are prohibited at all times: all selective and non-selective beta-2 agonists, including all optical isomers. Notwithstanding the above, the following are not prohibited under this section S3:

(a) inhaled beta-2 agonists (*e.g.,* albuterol, salbutamol) when prescribed by a Veterinarian (in the context of a valid veterinarian-patient-client relationship) as a bronchodilator; and

(b) clenbuterol when prescribed by a Veterinarian (in the context of a valid veterinarian-patient-client relationship) for a duration not to exceed 30 days in a 6-month period and provided that, following administration of clenbuterol, the Covered Horse shall be placed on the Veterinarians' List and shall not be eligible to participate in any Timed and Reported Workout or Covered Horserace until a urine and a blood Sample have been collected from it by or on behalf of the Agency, and analysis by a Laboratory of those Samples does not detect the presence of clenbuterol or its Metabolites or Markers.

Rule 4115. S4 Hormone and Metabolic Modulators

The following substances, and other substances with similar chemical structure or similar biological effect(s), are prohibited at all times:

(a) aromatase inhibitors;

(b) anti-estrogenic substances, anti-estrogens, and selective estrogen receptor modulators (SERMS);

(c) agents preventing activin receptor IIB activation, including, but not limited to, myostatin inhibitors;

(d) metabolic modulators, including, but not limited to:

(1) insulins and insulin-mimetics;

(2) meldonium; and

(3) trimetazidine; and

(e) thyroid hormone and thyroid hormone modulators.

Rule 4116. S5 Diuretics and Masking Agents

(a) Diuretics and masking agents, and other substances with a similar chemical structure or similar biological effect(s), are prohibited at all times.

(b) Notwithstanding the above, the following are not prohibited under this section S5:

(1) drospirenone, pamabrom, and topical ophthalmic administration of carbonic anhydrase inhibitors (*e.g.,* dorzolamide, brinzolamide);

(2) trichlormethiazide for treatment of edema;

(3) plasma expanders for life-saving procedures; and

(4) furosemide (also known as Lasix/Salix), subject to the limitations set out in Rule 4212(d).

Rule 4117. S6 Miscellaneous Substances

The following substances, and other substances with similar chemical structure or similar biological effect(s), are prohibited at all times:

(a) bisphosphonates (except that bisphosphonates may be administered for the purpose of diagnostic imaging, *i.e.,* gamma scintigraphy);

(b) toxins (*e.g.,* botulinum toxin, botox);

(c) venoms of any species, their synthetic analogs, or derivatives thereof;

(d) altrenogest in stallions, ridglings, or geldings;

(e) pitcher plant extract (Sarapin); and

(f) perfluorocarbons.

4120. Banned Methods

Rule 4121. M1 Manipulation of Blood and Blood Components

The following are prohibited at all times:

(a) The Administration or reintroduction of any quantity of autologous, allogenic (homologous), or heterologous blood or red blood cell products of any origin into the circulatory system.

(b) Artificially enhancing the uptake, transport, or delivery of oxygen, including, but not limited to: perfluorochemicals; efaproxiral (RSR13); and modified haemoglobin products, *e.g.,* haemoglobin-based blood substitutes and microencapsulated haemoglobin products; excluding supplemental oxygen by inhalation.

(c) Any form of intravascular manipulation of the blood or blood components by physical or chemical means.

(d) Withdrawal of blood for any purpose other than for diagnostic/Laboratory Testing procedures.

(e) Notwithstanding the above, manipulation of blood or blood components is not prohibited under this section M1:

(1) procedures performed for life-saving purposes; and

(2) use of veterinary regenerative therapies (*i.e.,* autologous conditioned serum or platelet-rich plasma) for the treatment of musculoskeletal injury or disease.

Rule 4122. M2 Chemical Castration or Immunocastration

In case of chemical castration or immunocastration, the Covered Horse shall remain designated as an intact male. Designating a Covered Horse that has had chemical castration or immunocastration as a gelding constitutes Use of a Prohibited Method.

Rule 4123. M3 Gene and Cell Doping

The following, which have the potential to enhance performance or modify the heritable genome, are prohibited at all times:

(a) the use of nucleic acids or nucleic acid analogues that might alter genome sequences or alter gene expression by any mechanism. This includes, but is not limited to, gene editing, gene silencing, and gene transfer technologies;

(b) the use of normal or genetically modified cells; and

(c) modification of the heritable genome.

*4200. Controlled Medication Substances and Controlled Medication Methods*

4210. Controlled Medication Substances

Rule 4211. S7 Controlled Medication Substances

(a) Subject to Rule 4212, only feed, hay, and water are permitted during the Race Period. Accordingly, subject to Rule 4212, any substance administered during the Race Period or present in a Post-Race Sample (including any metabolite(s), artifact(s), and isomer(s) of such substance(s)) that does not otherwise qualify as a Banned Substance shall constitute a prohibited Controlled Medication Substance.

(b) The following Controlled Medication Substances are prohibited from presence in a Post-Work Sample:

(1) analgesics;

(2) Nonsteroidal Anti-Inflammatory Drugs (NSAIDs);

(3) local anesthetics; and

(4) corticosteroids.

(c) S7 Controlled Medication Substances exclude those substances that fall under section S0, which are Banned Substances.

Rule 4212. Exceptions to Rule 4211

(a) Medications administered or authorized by a Regulatory Veterinarian or Test Barn Veterinarian to provide medical care to a Covered Horse as a result of an injury sustained, or other adverse health event, during the Race Period are not prohibited.

(b) The following may be administered up to 24 hours prior to Post-Time:

(1) orally administered vitamins;

(2) licensed vaccines against infectious agents;

(3) anti-ulcer medications (*e.g.,* Cimetidine, Omeprazole, and Ranitidine);

(4) unsupplemented isotonic electrolyte solutions by oral or intravenous administration;

(5) altrenogest in female horses;

(6) antimicrobials (antibiotics) and other anti-infective agents, excluding procaine penicillin or other antimicrobial/anti-infective agents containing or metabolizing to Prohibited Substances; and

(7) antiparasitic/anthelmintics approved and registered for use in horses, excluding levamisole or other antiparasitic/anthelmintics metabolizing to or containing other Prohibited Substances.

(c) Unsupplemented isotonic electrolyte solutions may be consumed by the horse's free choice at any time (but may not be administered except as provided in paragraph (b) above).

(d) Furosemide (also known as Lasix or Salix):

(1) is permitted during Timed and Reported Workouts and Vets' List Workouts; and

(2) may be administered during the Race Period in accordance with specific provisions of the Act and any guidance or exceptions approved by the Authority, but shall not be administered within the 4 hours prior to Post-Time.

(e) The Use or Administration of supplements or feed additives during the Race Period shall not be prohibited if the Responsible Person or Covered Person establishes, or the Agency expressly accepts, that such substances are not capable at any time of causing an action or effect, or both an action and effect, within one or more of the following mammalian body systems:

(1) the blood system;
(2) the urinary system;
(3) the cardiovascular system;
(4) the digestive system;
(5) the endocrine system;
(6) the immune system;
(7) the musculoskeletal system;
(8) the nervous system;
(9) the reproductive system; or
(10) the respiratory system.

4220. Controlled Medication Method(s)

In addition to any prohibited practices set forth in the Rule 2000 Series (Racetrack Safety Program):

Rule 4221. M4 Alkalinization or Use/Administration of an Alkalinizing Agent

Alkalinization or Use/Administration of an alkalinizing agent is prohibited on Race Day. A threshold concentration of total carbon dioxide (TCO2) in the blood in excess of 37 mmol constitutes prima facie evidence of alkalinization or Use/Administration of an alkalinizing agent.

Rule 4222. M5 Intra-Articular Injections

Intra-articular injections are prohibited on Race Day; within 14 days prior to Post-Time; and within 7 days prior to any Timed and Reported Workout.

Rule 4223. M6 Nasogastric Tube

The use of a nasogastric tube for any purpose is prohibited within 24 hours prior to Post-Time.

Rule 4224. M7 Intra-Articular Injections of Polyacrylamide Hydrogels

Intra-articular injections of polyacrylamide hydrogels are prohibited within 180 days prior to Post-Time.

Rule 4225. Modification of Race Period

The start of the ''Race Period'' shall be modified for each of the Controlled Medication Methods above (*i.e.,* each of M4–M7) based on the restricted administration time period specified for such method (*e.g.,* the Race Period for M7 shall start 180 days prior to Post-Time).

*4300. Ineligibility Periods for Covered Horse*

4310. Violations Involving Prohibited Substances

The period of Ineligibility of a Covered Horse resulting from a violation involving a Prohibited Substance shall be as set forth in Table 1 below:

TABLE 1

| Violation | Ineligibility period |
|---|---|
| S0 BANNED Substances-non-approved substances | Up to 14 months. |
| S1 BANNED Substances-anabolic agents | 14 months. |
| S2 BANNED Substances-peptide hormones | 6 months |
| S3 BANNED Substances-beta-2 agonists | 14 months. |
| S4 BANNED Substances-hormone and metabolic modulators | 3 months. |
| S5 BANNED Substances-diuretics and masking agents | 0 months. |
| S6 BANNED Substances-miscellaneous substances: | |
| (1) Bisphosphonates | Life. |
| (2) All other S6 miscellaneous substances | 0 months. |
| S7 CONTROLLED Medication Substances | 0 months.<br>The Covered Horse may be placed on the Veterinarians' List, and if so, a subsequent Vets' List Workout must be scheduled. A post-Vets' List Workout Sample may be required. |

4320. Violations Involving Prohibited Methods

The period of Ineligibility of a Covered Horse resulting from a violation involving a Prohibited Method shall be as set forth in Table 2 below:

TABLE 2

| Violation | Ineligibility period |
|---|---|
| M1 Manipulation of blood and blood components | 6 months. |
| M2 Chemical castration or immunocastration | 0 months. |
| M3 Gene and cell doping | Life. |
| M4 Alkalinization | 0 months. |
| M5 Intra-articular injection | 1 month. |
| M6 Nasogastric tube | 0 months. |

TABLE 2—Continued

| Violation | Ineligibility period |
|---|---|
| M7 Intra-articular injection of polyacrylamide hydrogel ..... | 12 months. |

4330. Other Violations Leading to a Period of Ineligibility for the Covered Horse

The period of Ineligibility of a Covered Horse resulting from a violation of Rule 3215 shall be as set forth in Table 3 below:

TABLE 3

| Violation | Ineligibility Period |
|---|---|
| Evading collection of a Sample from a Covered Horse; refusing or failing without compelling justification to submit a Covered Horse to Sample collection; or refusing or failing to comply with all Sample collection procedure requirements (Rule 3215). | *Evasion:* 18 months.<br>*Refusal or failure:* 18 months, unless it is established by the Responsible Person that fairness requires otherwise, in which case the period of Ineligibility may be reduced, depending on the specific circumstances of the case and considerations of horse welfare. |

**Appendix 1 to Rule Series 4000: Technical Document—Prohibited Substances**

| HISA listed as | HISA status | Penalty subclassification (specified substances are designated with 'x') | Substance | Action | Commercial name(s) (developmental names) | Detection time | Screening limit* |
|---|---|---|---|---|---|---|---|
| BANNED | S1 | | Δ-1-androstene-3, 17diol | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S1 | | Δ-1-androstene-3, 17dione | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S1 | | Δ-1-dihydrotestosterone | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S1 | | 19-Norandrostenediol | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S1 | | 19-Norandrostenedione | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S1 | | 19-Noretiocholanolone | Anabolic | Lacks FDA approval. | | |
| BANNED | S1 | | 1-androstenediol (5α androst-1-ene-3β, 17βdiol). | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S1 | | 1-androstenedione (5αandrost-1-ene-3, 17dione). | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S1 | | 1-testosterone (17βhydroxy-5α-androst-1en-3-one). | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S0 | | 2-Aminoheptane (Tuaminoheptane). | Sympathomimetic/Vasoconstrictor. | Lacks FDA approval. | | |
| BANNED | S4 | | 2-androstenol(5α-androstane-2-en-17-ol). | Pheromone/Reproductive Hormone. | Lacks FDA approval. | | |
| BANNED | S4 | | 2-androstenone (5α-androst-2-en-17-one). | Pheromone/Reproductive Hormone. | Lacks FDA approval. | | |
| BANNED | S0 | | 3,4-methylenedioxypyrovalerone (MDVP). | Stimulant | Lacks FDA approval. | | |
| BANNED | S4 | | 3-androstenol (5α-androst-3-en-17-ol). | Pheromone/Reproductive Hormone. | Lacks FDA approval. | | |
| BANNED | S4 | | 3-androstenone (5α-androst-3-en-17-one). | Pheromone/Reproductive Hormone. | Lacks FDA approval. | | |
| CONTROLLED | S7 | A | 3-Methoxytyramine | Neurotransmitter | Endogenous substance | | Threshold: 4 mcg/mL total (free and conjugated) 3-methoxytyramine in urine. |
| BANNED | S4 | | 4-androstenediol (androst-4-ene- 3β,17βdiol). | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S4 | | 4-chlorometatandienone | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S1 | | 4-Hydroxytestosterone | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S4 | | 5-androstenedione (androst-5-ene- 3,17dione). | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S1 | | 5α-Andros-2-ene-17one | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S1 | | 5α-Androstane-3α, 17 α-diol | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S1 | | 5α-Androstane-3α, 17 β-diol | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S1 | | 5α-Androstane-3β, 17α-diol | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S1 | | 5α-Androstane-3β, 17β -diol | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S1 | | 5β-androstane-3 α, 17βdiol, androst-4- ene3α,17α-diol. | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S1 | | 7-keto-dhea | Anabolic. | | | |
| BANNED | S1 | | 7α-hydroxy-dhea | Anabolic. | | | |
| BANNED | S1 | | 7β-hydroxy-dhea | Anabolic. | | | |
| BANNED | S5 | | Acebutolol | Antihypertensive | Generic. | | |
| BANNED | S0 | | Acecarbromal | Sedative hypnotic | Lacks FDA approval. | | |
| BANNED | S0 | | Acefylline | Bronchodilator | Lacks FDA approval. | | |

| HISA listed as | HISA status | Penalty subclassification (specified substances are designated with 'x') | Substance | Action | Commercial name(s) (developmental names) | Detection time | Screening limit* |
|---|---|---|---|---|---|---|---|
| BANNED | S0 | | Acemetacin | NSAID | Lacks FDA approval. | | |
| BANNED | S0 | | Acenocoumarol | Anticoagulant | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Acepromazine | Sedative | PromAce, Aceproject | Detection Time: 72 hrs 0.15 mg/kg single oral dose (6 horses). Detection Time: 48 hrs 0.05 mg/kg single IV dose (20 horses). | 10 ng/mL as 2-(1-hydroxyethyl) promazine sulfoxide (HEPS) in urine; 0.02 ng/mL in serum or plasma. |
| CONTROLLED | S7 | C | Acetaminophen (Paracetamol) | NSAID | Tylenol. | | |
| BANNED | S0 | | Acetanilide | NSAID | Lacks FDA approval. | | |
| BANNED | S5 | | Acetazolamide | Carbonic Anhydrase Inhibitor | Generic. | | |
| BANNED | S0 | | Acetohexamide | Insulin secretion | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Acetophenazine | Antipsychotic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Acetophenetidin (Phenacetin) | NSAID | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Acetylcysteine | Mucolytic | Mucomyst, Parvolex. | | |
| BANNED | S0 | | Acetylmorphine | Opioid Analgesic | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Acetylsalicylic acid (Aspirin) | NSAID | Generic. | | |
| BANNED | S0 | | Aclidinium bromide | Bronchodilator | Tudorza Pressair; Dualkir Pressair (with formoterol). | | |
| BANNED | S0 | | Adinazolam | Sedative/Anxiolytic | Lacks FDA approval. | | |
| BANNED | S0 | | Adiphenine | Antispasmodic | Lacks FDA approval. | | |
| BANNED | S0 | | Adrafinil | Stimulant | Lacks FDA approval. | | |
| BANNED | S4 | | AICAR (5-Aminoimidazole-4-carboxamide ribonucleotide). | Metabolic modulator | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Albuterol (Salbutamol) | Bronchodilator | FDA-approved equine product Torpex no longer commercially available. Available as FDA-approved for human use via inhalation as Proair HFA, Ventolin HFA, and generic formulations. | Detection Time: 72 hours at 5 × 100 µg actuations per dose for 2 days dosed every 4 hours. *Note:* Albuterol administered by any route other than inhalation is a Banned Substance. Evidence that albuterol was administered by a route other than inhalation, regardless of the albuterol concentration in a urine sample, constitutes a Doping Violation. | SL: 0.5 ng/mL in urine. |
| BANNED | S0 | | Alclofenac | NSAID | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Alclometasone | Corticosteroid | Generic. | | |
| BANNED | S0 | | Alcuronium | Muscle relaxant | Lacks FDA approval. | | |
| BANNED | S5 | | Aldosterone | Diuretic | Lacks FDA approval. | | |
| BANNED | S6 | | Alendronate | Bisphosphonate | Fosamax, Binosto. | | |
| BANNED | S2 | | Alexamorelin | Growth Hormone | Lacks FDA approval. | | |
| CONTROLLED | S7 | A | Alfentanil | Opioid Analgesic | Alfenta. DEA Schedule II. | | |
| CONTROLLED | S7 | B | Allopurinol | Xanthine oxidase inhibitor | Lopurin, Zyloprim, Aloprim. | | |
| BANNED | S0 | | Almotriptan | Selective Serotonin Receptor Agonist. | Generic. | | |
| BANNED | S0 | | Alpha- pyrrolidinovalerophenone (Alpha PVP and "Bath Salts"). | Stimulant/Hallucinogen | Lacks FDA approval. DEA Schedule I. | | |
| BANNED | S2 | | Alpha-casozepine | Sedative | Lacks FDA approval. | | |
| BANNED | S0 | | Alphadolone (Alfadolone) acetate. | Anesthetic | Lacks FDA approval. | | |
| BANNED | S0 | | Alphaprodine | Opioid Analgesic | Lacks FDA approval. DEA Schedule II. | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| BANNED | S0 | | Alphenal | Barbiturate/Anticonvulsant | Lacks FDA approval. | | |
| BANNED | S0 | | Alpidem | Anxiolytic | Lacks FDA approval. | | |
| CONTROLLED | S7 | A | Alprazolam | Sedative/Anxiolytic | Xanax. DEA Schedule IV. | | |
| BANNED | S0 | | Alprenolol | Antihypertensive | Generic. | | |
| BANNED | S0 | | Althesin | Anesthetic | Lacks FDA approval. | | |
| BANNED | S5 | | Althiazide | Diuretic | Lacks FDA approval. | | |
| CONTROLLED—fillies and mares. | S7 | C | Altrenogest | Progestogen/Estrus Suppression. | Regumate. | | |
| BANNED-Intact males, geldings, spayed females. | S6 | | Altrenogest | Progestogen/Estrus Suppression. | Regumate. | | |
| BANNED | S0 | | Alverine | Antispasmodic | Lacks FDA approval. | | |
| BANNED | S0 | | Amantadine | Dopamine agonist | Gocovri, Osmolex ER. | | |
| BANNED | S0 | | Ambenonium | Cholinesterase Inhibitor | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Ambroxol | Mucolytic | Lacks FDA approval. | | |
| BANNED | S0 | | Ambucetamide | Antispasmodic | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Amcinonide | Corticosteroid | Generic. | | |
| BANNED | S0 | | Amfepramone | Antidepressant | Lacks FDA approval. | | |
| BANNED | S0 | | Amfetaminil | Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Amidephrine | Stimulant | Lacks FDA approval. | | |
| BANNED | S5 | | Amiloride | Diuretic | Midamor. | | |
| BANNED | S0 | | Amineptine | Antidepressant | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Aminocaproic acid | Anti-fibrinolytic | Amicar. | | |
| BANNED | S4 | | Aminoglutethimide | Aromatase inhibitor | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Aminomethylbenzoic acid | Anti-fibrinolytic | Lacks FDA approval. | | |
| BANNED | S0 | | Aminometradine | Diuretic | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Aminophylline | Bronchodilator | Generic. | | |
| BANNED | S0 | | Aminopterin | Anti-neoplastic/Immunosuppressive. | Lacks FDA approval. | | |
| BANNED | S0 | | Aminopyrine (Pyramidon) | Analgesic | Lacks FDA approval. | | |
| BANNED | S0 | (x) | Aminorex | Stimulant | Lacks FDA approval. DEA Schedule I. | | |
| CONTROLLED | S7 | C | Aminosalicylic acid (Salicylic acid/Salicylate). | NSAID | Paser | | 750 mcg/mL in urine or 6.5 mcg/mL in serum or plasma. |
| CONTROLLED | S7 | B | Amiodarone | Antiarrhythmic | Nexterone, Pacerone. | | |
| BANNED | S0 | | Amiphenazole | Respiratory Stimulant | Lacks FDA approval. | | |
| BANNED | S5 | | Amisometradine | Diuretic | Lacks FDA approval. | | |
| BANNED | S0 | | Amisulpride | Antipsychotic | Barhemsys. | | |
| CONTROLLED | S7 | A | Amitraz | Stimulant | Mitaban. | | |
| CONTROLLED | S7 | A | Amitriptyline | Antidepressant | Elavil. | | |
| BANNED | S5 | | Amlodipine | Antihypertensive | Norvasc. | | |
| BANNED | S0 | | Ammonium Chloride | Chemical neurectomy | Generic. | | |
| BANNED | S0 | | Ammonium Sulphate | Chemical neurectomy | Lacks FDA approval. | | |
| BANNED | S0 | | Ammonium Sulphide | Chemical neurectomy | Lacks FDA approval. | | |
| BANNED | S0 | | Amobarbital | Bartiburate/Anticonvulsant | Lacks FDA approval. DEA Schedule II. | | |
| BANNED | S0 | | Amoxapine | Antidepressant | Generic. | | |
| BANNED | S0 | | Amperozide | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S0 | | Amphetamine | Stimulant | Adzenys XR-ODT, Dyanavel XR, Evekeo. DEA Schedule II. | | |
| BANNED | S0 | | Amphetaminil | Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Ampyrone | NSAID | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Amrinone (inamrinone) | Vasodilator | Amicor, Cardiotone. | | |
| BANNED | S0 | | Amyl nitrite | Antihypertensive/CNS Depressant. | Lacks FDA approval. | | |
| BANNED | S0 | | Amylocaine | Local anesthetic | Lacks FDA approval. | | |
| BANNED | S2 | | Anamorelin | Growth Hormone | New Drug Application submitted; currently lacks FDA approval. | | |
| BANNED | S4 | | Anastrozole | Anti-estrogen | Arimidex. | | |
| BANNED | S1 | | Andarine | Selective Androgen Receptor Modulator (SARM). | Lacks FDA approval. | | |
| BANNED | S1 | | Androst-4-ene-3$\alpha$,17$\beta$ diol | Anabolic | DEA Schedule III. | | |
| BANNED | S1 | | Androst-4-ene-3$\beta$,17$\alpha$ diol | Anabolic | DEA Schedule III. | | |

| HISA listed as | HISA status | Penalty subclassification (specified substances are designated with 'x') | Substance | Action | Commercial name(s) (developmental names) | Detection time | Screening limit* |
|---|---|---|---|---|---|---|---|
| BANNED | S1 | | Androst-5-ene-3α,17α diol | Anabolic | DEA Schedule III. | | |
| BANNED | S1 | | Androst-5-ene-3α,17β diol | Anabolic | DEA Schedule III. | | |
| BANNED | S1 | | Androst-5-ene-3β,17α diol | Anabolic | DEA Schedule III. | | |
| BANNED | S4 | | Androstatrienedione (Androsta-1,4,6-triene-3,17-ddione). | Anabolic | DEA Schedule III. | | |
| BANNED | S4 | | Androstenediol (androst-5-ene-3β, 17βdiol). | Anabolic | DEA Schedule III. | | |
| BANNED | S4 | | Androstenedione (androst-4-ene-3, 17dione). | Anabolic | DEA Schedule III. | | |
| BANNED | S4 | | Androsterone (3 βhydroxy-5 α—androstan-17-one). | Anabolic | DEA Schedule III. | | |
| BANNED | S0 | | Anileridine | Opioid Analgesic | Discontinued, no FDA-approved product commercially available. DEA Schedule II. | | |
| BANNED | S0 | | Anilopam | Opioid Analgesic | Lacks FDA approval. | | |
| BANNED | S0 | | Anisindione | Anticoagulant | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Anisotropine (Octatropine methylbromide). | Anticholinergic | Discontinued, no FDA-approved product commercially available. | | |
| CONTROLLED | S7 | B | Antazoline | Antihistamine (ophthalmic) | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Antipyrine | NSAID | Lacks FDA approval. | | |
| BANNED | S0 | | Apazone (Azapropazone) | NSAID | Lacks FDA approval. | | |
| BANNED | S0 | | Apocodeine | Dopamine agonist | Lacks FDA approval. | | |
| BANNED | S0 | | Apomorphine | Opioid Analgesic | Kynmobi, Apokyn. | | |
| BANNED | S0 | | Aprindine | Antiarrhythmic | Lacks FDA approval. | | |
| BANNED | S0 | | Aprobarbital | Barbiturate | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S0 | | Apronalide | Sedative hypnotic | Lacks FDA approval. | | |
| BANNED | S2 | | ARA-290 | Erythropoiesis | FDA Orphan Drug status. | | |
| BANNED | S0 | | Arecoline | Stimulant | Lacks FDA approval. | | |
| BANNED | S3 | | Arformoterol | Beta-2 agonist-bronchodilator | Brovana. | | |
| BANNED | S2 | | Argon | Hypoxia Inducible Factor activating. | | | |
| BANNED | S4 | | Arimistane (Anrosta-3,5-diene-7,17-dione). | Anabolic | Lacks FDA approval. | | |
| CONTROLLED | S7 | A | Aripiprazole | Antipsychotic | Abilify. | | |
| CONTROLLED | S7 | B (x) | Arsenic | Stimulant | Environmental substance | | 0.3 mcg.mL total (free and conjugated) in urine. |
| CONTROLLED | S7 | B | Articaine | Local anesthetic | Orabloc, Septocaine. | | |
| BANNED | S2 | | Asialo EPO | Erythropoiesis. | | | |
| BANNED | S0 | | Atenolol | Antihypertensive | Tenormin. | | |
| CONTROLLED | S7 | A | Atipamezole | Alpha adrenergic antagonist | Antisedan, Revertidine. | | |
| BANNED | S0 | | Atomoxetine | Stimulant | Strattera. | | |
| CONTROLLED | S7 | A | Atracurium | Muscle relaxant | Generic. | | |
| CONTROLLED | S7 | B (x) | Atropine | Anticholinergic | Atropen | | 60 ng/mL total (free and conjugated) in urine. |
| BANNED | S0 | | Azacylonol (γ-pipradrol) | CNS depressant | Lacks FDA approval. | | |
| BANNED | S0 | | Azaperone | Sedative | Stresnil. | | |
| BANNED | S0 | | Azapetine | Vasodilator | Lacks FDA approval. | | |
| BANNED | S0 | | Azapropazone | NSAID | Lacks FDA approval. | | |
| BANNED | S0 | | Azathioprine | Immunosuppressor | Imuran. | | |
| BANNED | S0 | | Azatidine (Azatadine) | Antihistamine | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S5 | | Azosemide | Diuretic | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Baclofen | Muscle relaxant | Lyvispah, Gablofen, Lioresal, Ozobax, Fleqsuvy. | | |
| BANNED | S0 | | Bambuterol | Beta-2 agonist-bronchodilator | Lacks FDA approval. | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| BANNED | S0 | | Bamifylline | Bronchodilator | Lacks FDA approval. | | |
| BANNED | S0 | | Barbital (barbitone) | Sedative hypnotic | Lacks FDA approval. DEA Schedule IV. | | |
| BANNED | S4 | | Bazedoxifene | Selective Estrogen Receptor Modulator (SERM). | FDA-approved in combination with Premarin as Duavee. | | |
| BANNED | S0 | | Beclamide | Anticonvulsant | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Beclomethasone | Corticosteroid | Qvar, Qnasl, Beclovent. | | |
| BANNED | S0 | | Bemegride | Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Benactyzine | Anticholinergic | Lacks FDA approval. | | |
| BANNED | S0 | | Benapryzine | Anticholinergic | Lacks FDA approval. | | |
| BANNED | S0 | | Benazepril | Antihypertensive | Lotensin, Lotrel (with amlodipine). | | |
| BANNED | S5 | | Bendroflumethiazide | Diuretic | Naturetin, Corzide. | | |
| BANNED | S0 | | Benorilate | NSAID | Lacks FDA approval. | | |
| BANNED | S0 | | Benoxaprofen | NSAID | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Benoxinate(Oxybucaine, Oxybuprocaine). | Local anesthetic | Altafluor Benox [with fluorescein stain]. | | |
| BANNED | S0 | | Benperidol | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S0 | | Bentazepam | Anxioytic | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Benzocaine | Local anesthetic | Orajel, Anbesol, Lanacane. | | |
| BANNED | S0 | | Benzoctamine | Sedative/Anxiolytic | Lacks FDA approval. | | |
| BANNED | S0 | | Benzonatate | Antitussive (cough suppressant) | Tessalon. | | |
| BANNED | S0 | | Benzphetamine | Stimulant | Generic. DEA Schedule III. | | |
| BANNED | S0 | | Benzquinamide | Antipsychotic/Antiemetic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Benzthiazide | Diuretic | Discontinued, no FDA-approved product commercially available. | | |
| CONTROLLED | S7 | A | Benztropine | Anticholinergic | Generic. | | |
| BANNED | S0 | | Benzydamine | NSAID | Lacks FDA approval. | | |
| BANNED | S0 | | Benzylpiperazine (BZP) | Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Bepridil | Antihypertensive | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Betamethasone | Corticosteroid | Betavet, Celestone | | 0.2 ng/mL in urine. |
| BANNED | S0 | | Betaprodine | Opioid Analgesic | Lacks FDA approval. DEA Schedule I. | | |
| BANNED | S0 | | Betaxolol | Antihypertensive | Betoptic. | | |
| CONTROLLED | S7 | C | Bethanechol | Cholinergic | Duovoid. | | |
| BANNED | S0 | | Bethanidine (Betanidine) | Antihypertensive | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S4 | | Bimagrumab | Anabolic | Lacks FDA approval (Orphan drug designation withdrawn). | | |
| BANNED | S0 | | Biperiden | Anticholinergic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Biphenamine | Local anesthetic | Lacks FDA approval. | | |
| BANNED | S0 | | Biprsoprolol | Antihypertensive | Ziac [with hydrochlorothiazide]. | | |
| BANNED | S0 | | Biriperone (Centbutindole) | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S0 | | Bitolterol | Beta-2 agonist-bronchodilator | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S1 | | Bolandiol (estr-4-ene3β, 17β-diol). | Anabolic | Lacks FDA approval. | | |
| BANNED | S1 | | Bolasterone (7α, 17α-dimethyltestosterone). | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S1 | | Boldenone | Anabolic | Equipoise. DEA Schedule III | | Threshold: 0.015 mcg free and conjugated boldenone per mL in urine in male horses (other than geldings). |
| BANNED | S1 | | Boldione | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S6 | | Botulinum toxin | Neurotoxin | Botox, Dysport, Jeuveau. | | |
| BANNED | S0 | | Brallobarbital | Barbiturate | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Bretylium | Antiarrhythmic | Generic. | | |
| BANNED | S0 | | Brimonidine | Antihypertensive | Alphagan P, Qoliana, Lumify. | | |
| CONTROLLED | S7 | B | Brinzolamide | Carbonic Anhydrase Inhibitor | Simbrinza, Azopt. | | |
| BANNED | S0 | | Bromantan | Psychostimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Bromazepam | Anxiolytic | Lacks FDA approval. DEA Schedule IV. | | |
| CONTROLLED | S7 | A | Bromfenac | NSAID | Prolensa, Bromsite. | | |

| HISA listed as | HISA status | Penalty subclassification (specified substances are designated with 'x') | Substance | Action | Commercial name(s) (developmental names) | Detection time | Screening limit* |
|---|---|---|---|---|---|---|---|
| BANNED | S0 | | Bromhexine | Mucolytic | Lacks FDA approval. | | |
| BANNED | S0 | | Bromisovalum | Sedative/Hypnotic | Lacks FDA approval. | | |
| BANNED | S0 | | Bromocriptine | Anticholinergic | Parlodel, Cycloset. | | |
| CONTROLLED | S7 | B | Bromodiphenhydramine | Antihistamine | Ambodryl, Ambrodil. | | |
| BANNED | S0 | | Bromophenethylamine | Psychedelic | Lacks FDA approval. | | |
| BANNED | S0 | | Bromperidol | Antipsychotic | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Brompheniramine | Antihistamine | Dimetapp. | | |
| BANNED | S0 | | Brotizolam | Sedative/Hypnotic | Lacks FDA approval. | | |
| BANNED | S0 | | Bucetin | NSAID | Lacks FDA approval. | | |
| BANNED | S0 | | Buclizine | Antihistamine/Anti-emetic | Discontinued, no FDA-approved product commercially available. | | |
| CONTROLLED | S7 | C | Budesonide | Corticosteroid | Uceris, Entocort, Tarpeyo, Ortikos, Pulmicor Flexhaler, Symbicort (with formoterol), Rhinocort Allergy. | | |
| BANNED | S0 | | Bufexamac | NSAID | Lacks FDA approval. | | |
| BANNED | S0 | | Buflomedil | Vasodilator | Lacks FDA approval. | | |
| BANNED | S0 | (x) | Bufotenine | Hallucinogen | Lacks FDA approval. DEA Schedule I. | | 10 mcg/mL Total (free and conjugated) in urine. |
| BANNED | S5 | | Bumetanide | Diuretic | Bumex. | | |
| BANNED | S0 | | Bunitrolol | Vasodilator | Lacks FDA approval. | | |
| BANNED | S0 | | Bunolol | Anti-hypertensive | Betagan. | | |
| BANNED | S0 | | Buphenine (nylidrin) | Vasodilator | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Bupivacaine | Local anesthetic | Marcaine, Sensorcaine, Exparel. | | |
| BANNED | S0 | | Bupranolol | Antihypertensive | Lacks FDA approval. | | |
| CONTROLLED | S7 | A | Buprenorphine | Analgesic | Simbadol, Zorbium,Butrans, Sublocade, Belbuca, Buprenex, Zubsolv. DEA Schedule III. | | |
| BANNED | S0 | | Bupropion | Antidepressant | Wellbutrin, Zyban. | | |
| BANNED | S4 | | Buserelin | Gonadotropin Releasing Hormone. | Lacks FDA approval. | | |
| CONTROLLED | S7 | A | Buspirone | Anxiolytic | Generic. | | |
| BANNED | S0 | | Butabarbital (Secbutobarbitone) | Barbiturate | Discontinued, no FDA-approved product commercially available. DEA Schedule III. | | |
| BANNED | S0 | | Butacaine | Local anesthetic | Lacks FDA approval. | | |
| BANNED | S0 | | Butalbital (Talbutal) | Barbiturate | Esgic, Fioricet. DEA Schedule III. | | |
| CONTROLLED | S7 | C | Butamben (butyl aminobenzoate). | Local anesthetic | Cetacaine. | | |
| BANNED | S0 | | Butanilicaine | Local anesthetic | Lacks FDA approval. | | |
| BANNED | S0 | | Butaperazine | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S0 | | Butoctamide | Serotonin release | Lacks FDA approval. | | |
| BANNED | S0 | | Butofilolol | Antihypertensive | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Butorphanol | Sedative | Torbugesic, Tobutrol, Stadol, Dolorex. DEA Schedule IV. | Detection Time: 72 hrs. 0.1 mg/kg single IV dose (6 horses). | 1 ng/mL in hydrolyzed urine or 0.01 ng/mL plasma or serum. |
| BANNED | S0 | | Butoxycaine | Local anesthetic | Lacks FDA approval. | | |
| BANNED | S0 | | Cafedrine | Cardiac Stimulant | Lacks FDA approval. | | |
| CONTROLLED | S7 | B (x) | Caffeine | Stimulant | Cafcit, Migergot (with ergotamine), combined with NSAIDs in OTC formulations. Recognized by IFHA as Feed Contaminant. | | 50 ng/mL (free and conjugated) in urine. |
| BANNED | S0 | | Calcium dobesilate | Vasoprotective | Lacks FDA approval. | | |
| BANNED | S1 | | Calusterone (*Methosarb, Riedemil, NSC–88536, U–22550*). | Anabolic | Lacks FDA approval. (*NSC–88536, U–22550*) DEA Schedule III. | | |
| BANNED | S0 | | Camazepam | Anxiolytic | Lacks FDA approval. DEA Schedule IV. | | |

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|---|---|---|---|---|---|---|---|
| CONTROLLED | S7 | C | Camphor | Local anesthetic | Vicks VapoRub. | | |
| BANNED | S0 | | Candesartan | Antihypertensive | Atacand. | | |
| CONTROLLED | S7 | B | Cannabidiol (CBD) | Analgesic/anti-inflammatory. | | | |
| BANNED | S0 | (x) | Cannabinoids (natural, synthetic and other cannabimimetics). | Psychotropic | Lack FDA approval. | | |
| BANNED | S5 | | Canrenone | Diuretic | Lacks FDA approval. | | |
| BANNED | S1 | | Capromorelin | Anabolic | Entyce, Elura. | | |
| CONTROLLED | S7 | B | Capsaicin | Topical analgesic/irritant | Zostrix, Salonpas Hot. | | |
| BANNED | S0 | | Captodiame (captodiamine) | Antihistamine | Lacks FDA approval. | | |
| BANNED | S0 | | Captopril | Antihypertensive | Generic. | | |
| BANNED | S0 | | Caramiphen | Anticholinergic | Lacks FDA approval. | | |
| BANNED | S0 | | Carazolol | Antihypertensive | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Carbachol | Cholinergic | Miostat. | | |
| CONTROLLED | S7 | B | Carbamazepine | Anticonvulsant | Tegretol, Carbatrol, Equetro, Teril. | | |
| BANNED | S2 | | Carbamylated EPO (CEPO) | Erythropoiesis. | | | |
| BANNED | S0 | | Carbazochrome (Adrenochrome monosemicarbazone). | Hemostatic | Lacks FDA approval. | | |
| BANNED | S0 | | Carbetapentane (pentoxyverine) | Antitussive | Lacks FDA approval. | | |
| BANNED | S0 | | Carbidopa | Decarboxylase Inhibitor | Lodosyn; Stalevo, Rytary, Duopa, Dhivy, Sinemet (all with levodopa). | | |
| BANNED | S0 | | Carbimazole | Anti-hyperthyroidism | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Carbinoxamine | Antihistamine | Karbinal ER. | | |
| BANNED | S0 | | Carbocysteine | Mucolytic | Lacks FDA approval. | | |
| BANNED | S0 | | Carbomral | Sedative hypnotic | Lacks FDA approval. | | |
| BANNED | S0 | | Carbuterol | Beta-2 agonist-bronchodilator | Lacks FDA approval. | | |
| BANNED | S1 | | Cardarine (GW–501, GW516, GSK–516). | Selective Androgen Receptor Modulator (SARM). | Lacks FDA approval. | | |
| BANNED | S0 | | Carfentanil | Opioid Analgesic | Lacks FDA approval. DEA Schedule II. | | |
| CONTROLLED | S7 | B | Carisoprodol | Muscle relaxant | Soma. DEA Schedule IV. | | |
| BANNED | S0 | | Carphedon | Psychostimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Carphenazine | Antipsychotic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Carpipramine | Antipsychotic | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Carprofen | NSAID | Rimadyl. | | |
| BANNED | S3 | | Carteolol | Antihypertensive | Generic. | | |
| CONTROLLED | S7 | B | Carticaine (see Articaine) | Local anesthetic | Septocaine, Orbloc. | | |
| BANNED | S0 | | Carvedilol | Antihypertensive | Coreg. | | |
| BANNED | S0 | | Cathinone | Stimulant | Lacks FDA approval. DEA Schedule I. | | |
| CONTROLLED | S7 | B | Celecoxib | NSAID | Celebrex. | | |
| BANNED | S0 | | Celiprolol | Anti-hypertensive | Lacks FDA approval. | | |
| BANNED | S0 | | Cephaeline | Emetic, plant alkaloid | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Cetirizine | Antihistamine | Quzyttir, Zerviate, Zyrtec | Detection Time: 48 hours. 0.4 mg/kg twice daily for 5 doses. (9 horses). | 3 ng/mL in serum or plasma. |
| BANNED | S0 | | Chlomethiazole | Anticonvulsant | Lacks FDA approval. | | |
| BANNED | S0 | | Chloral (cloral) betaine | Sedative/Hypnotic | Lacks FDA approval. DEA Schedule IV. | | |
| BANNED | S0 | | Chloral hydrate | Sedative | Lacks FDA approval. DEA Schedule IV. | | |
| BANNED | S0 | | Chloralose (AlphaChloralose) | Anxiolytic | Lacks FDA approval. | | |
| BANNED | S0 | | Chlorcyclizine | Antihistamine | Lacks FDA approval. | | |
| BANNED | S0 | | Chlordiazepoxide | Anxiolytic | Librium; Librax (with chlordiazepoxide hydrochloride). DEA Schedule IV. | | |
| BANNED | S0 | | Chlormadinone acetate | Reproductive hormone | Lacks FDA approval. | | |
| BANNED | S0 | | Chlormerodrin | Diuretic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Chlormezanone | Muscle relaxant | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Chloroform | Anesthetic | Lacks FDA approval. | | |
| BANNED | S0 | | Chlorophenylpiperazine | Psychoactive | Lacks FDA approval. | | |
| CONTROLLED | S7 | A | Chloroprocaine | Local anesthetic | Nesacaine. | | |
| BANNED | S0 | | Chloropyramine | Antihistamine | Lacks FDA approval. | | |

| HISA listed as | HISA status | Penalty subclassification (specified substances are designated with 'x') | Substance | Action | Commercial name(s) (developmental names) | Detection time | Screening limit* |
|---|---|---|---|---|---|---|---|
| BANNED | S5 | | Chlorothiazide | Diuretic | Diuril. | | |
| BANNED | S0 | | Chlorphenesin | Muscle relaxant | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Chlorphenesin | Muscle relaxant | Discontinued, no FDA-approved product commercially available. | | |
| CONTROLLED | S7 | B | Chlorpheniramine | Antihistamine | ChlorTrimeton. | | |
| BANNED | S0 | | Chlorphenoxamine | Antihistamine | Lacks FDA approval. | | |
| BANNED | S0 | | Chlorphentermine | Stimulant | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Chlorproethazine | Muscle relaxant | Lacks FDA approval. | | |
| BANNED | S0 | | Chlorpromazine | Sedative | Generic. | | |
| BANNED | S0 | | Chlorpropamide | Hypoglycemic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Chlorprothixene | Antipsychotic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S5 | | Chlorthalidone | Diuretic | Thalitone. | | |
| BANNED | S0 | | Chlorthenoxazine | NSAID | Lacks FDA approval. | | |
| BANNED | S5 | | Chlorthiazide (Chlorothiazide) | Diuretic | Diuril. | | |
| CONTROLLED | S7 | B | Chlorzoxazone | Muscle relaxant | Generic. | | |
| CONTROLLED—fillies and mares. | S7 | B | Chorionic Gonadotropin (CG) | Reproductive hormone | Pregnyl—biologic, does not require FDA approval. | | |
| BANNED—intact males and geldings. | S2 | | Chorionic Gonadotropin (CG) | Reproductive hormone | Pregnyl. | | |
| CONTROLLED | S7 | C | Ciclesonide | Corticosteroid | Aservo EquiHaler, Alvesco | Detection Time: 48 hours. 5.5 mg/day × 5 days, then 4.1 mg/day × 5 days via inhalation (Aservo Equihaler). (6 horses). | |
| BANNED | S0 | | Cicloprofen | NSAID | Lacks FDA approval. | | |
| BANNED | S0 | | Cilazapril | Anti-hypertensive | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Cilostazol | Vasodilator | Pletal. | | |
| BANNED | S0 | | Cimaterol | Beta-2 agonist-bronchodilator | Lacks FDA approval. | | |
| BANNED | S3 | | Cimbuterol | Beta-2 agonist-bronchodilator | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Cimetidine | Anti-ulcer | Tagamet | Restricted administration time: 24 hours. 20 mg/kg orally twice daily for a total of 7 doses (9 horses). | 400 ng/mL in serum or plasma. |
| BANNED | S0 | | Cinchocaine | Local anesthetic | Lacks FDA approval. | | |
| BANNED | S0 | | Cinchophen | NSAID | Lacks FDA approval. | | |
| BANNED | S0 | | Cinnarizine | Antihistamine | Lacks FDA approval. | | |
| BANNED | S0 | | Citalopram | Antidepressant | Celexa. | | |
| BANNED | S0 | | Clanobutin | Cholerectic | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Clemastine | Antihistamine | Tavist, Dayhist. | | |
| BANNED | S0 | | Clemizole | Antihistamine | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Clenbuterol | Beta-2 agonist-bronchodilator | Ventipulmin | Treated horse Vet Listed for minimum 21 days after last treatment. Official Workout and Clearance Testing (blood and urine) required to re-establish eligibility to race. Dosing specification: 0.8 mcg/kg orally twice daily for up to 30 days total in a 6 month period. | |

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| BANNED | S3 | | Clenpenterol | Beta-2 agonist-bronchodilator | Lacks FDA approval. | | |
| BANNED | S0 | | Clibucaine | Local anesthetic | Lacks FDA approval. | | |
| BANNED | S0 | | Clidinium | Anticholinergic | No FDA-approved product. | | |
| BANNED | S0 | | Clobazam | Anxiolytic | Sympazan, Onfi. DEA Schedule IV. | | |
| BANNED | S0 | | Clobenzorex | Stimulant | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Clobetaso | Corticosteroid | Olux, Cormax, Embeline, Impoyz, Clobex, Impeklo. | | |
| CONTROLLED | S7 | C | Clocortolone | Corticosteroid | Cloderm. | | |
| BANNED | S6 | | Clodronate (Clodronic acid) | Bisphosphonate | OsPhos. | | |
| BANNED | S5 | | Clofenamid | Carbonic Anhydrase Inhibitor | Lacks FDA approval. | | |
| BANNED | S0 | | Clomethiazole (Chlormethiazole) | Sedative/Hypnotic | Lacks FDA approval. | | |
| BANNED | S4 | | Clomifene | Induce ovulation | Generic. | | |
| BANNED | S0 | | Clomipramine | Antidepressant | Clomicalm. | | |
| BANNED | S0 | | Clonazepam | Anxiolytic | Klonopin. DEA Schedule IV. | | |
| CONTROLLED | S7 | A | Clonidine | Antihypertensive/Analgesic | Catapres-TTS. | | |
| BANNED | S0 | | Clonixin | NSAID | Lacks FDA approval. | | |
| BANNED | S5 | | Clopamide | Diuretic | Lacks FDA approval. | | |
| BANNED | S0 | | Cloranolol | Antihypertensive | Lacks FDA approval. | | |
| BANNED | S0 | | Clorazepate | Anxiolytic | Lacks FDA approval. DEA Schedule IV. | | |
| BANNED | S0 | | Clormecaine | Local anesthetic | Lacks FDA approval. | | |
| BANNED | S0 | | Clorprenaline | Bronchodilator | Lacks FDA approval. | | |
| BANNED | S1 | | Clostebol | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S0 | | Clotiapine | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S0 | | Clotiazepam | Anxiolytic | Lacks FDA approval. | | |
| BANNED | S0 | | Cloxazolam | Anxiolytic | Lacks FDA approval. DEA Schedule IV. | | |
| BANNED | S0 | | Clozapine | Antipsychotic | Clozaril, Versacloz. | | |
| BANNED | S2 | | CNTO 530 | Erythropoiesis | Lacks FDA approval. | | |
| BANNED | S2 | | Cobalt Salts (*e.g.*, $CoCl_2$) | Erythropoiesis | | | Threshold: 0.1 mcg/mL total Cobalt in urine OR 0.025 mcg/mL total (free and protein bound)/mL in serum or plasma. |
| BANNED | S6 | | Cobratoxin, alpha | Neurotoxin | Lacks FDA approval. | | |
| BANNED | S0 | | Cocaine (metabolite: benzoylecgonine). | Stimulant | Goprelto, Numbrino. DEA Schedule II. | | |
| BANNED | S0 | | Codeine | Opioid Analgesic | Generic (DEA Schedule II or in combination with NSAIDs, caffeine and other drugs (DEA Schedule III). | | |
| CONTROLLED | S7 | B (x) | Colchicine | Anti-gout | Colcrys, Mitigare. | | |
| BANNED | S0 | | Conorphone | Opioid Analgesic | Lacks FDA approval. | | |
| BANNED | S2 | | Corticorelin | Corticosteroid stimulation | Approved Oprhan Drug. | | |
| CONTROLLED | S7 | B | Corticotrophin | Corticosteroid stimulation | ACTH–80, Acthar Gel. | | |
| BANNED | S0 | | Cortivazol | Glucocorticoid | Lacks FDA approval. | | |
| BANNED | S0 | | Cotinine (Cotinine is a metabolite of nicotine. If there is credible evidence that the presence of cotinine in a horse's sample is a consequence of nicotine exposure, the classification of cotinine may be revised to S7(A).). | Psychoactive/Anxiolytic | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Cromolyn (Cromoglycate) | Mast Cell Stabilizer | Gastrocrom. | | |
| BANNED | S0 | | Cropropamide | Respiratory Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Crotethamide | Respiratory Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Cyamemazine | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S0 | | Cyclandelate | Vasodilator | Lacks FDA approval. | | |
| BANNED | S0 | | Cyclizine | Antihistamine | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Cyclobarbital | Barbiturate | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Cyclobenzaprine | Muscle relaxant | Flexeril, Amrix. | | |

| HISA listed as | HISA status | Penalty subclassification (specified substances are designated with 'x') | Substance | Action | Commercial name(s) (developmental names) | Detection time | Screening limit* |
|---|---|---|---|---|---|---|---|
| BANNED | S4 | | Cyclofenil | Selective Estrogen Receptor Modulator (SERM). | Lacks FDA approval. | | |
| BANNED | S0 | | Cycloguanil | Antimalarial | Lacks FDA approval. | | |
| BANNED | S0 | | Cyclomethycaine | Local anesthetic | Lacks FDA approval. | | |
| BANNED | S0 | | Cyclopentamine | Vasoconstrictor | Lacks FDA approval. | | |
| CONTROLLED | S7 | | Cyclopentolate | Mydriatic | Akpentolate, Cyclogyl, Pentolair, Cyclomydril. | | |
| BANNED | S0 | | Cyclophenil | Selective Estrogen Receptor Modulator (SERM). | Lacks FDA approval. | | |
| BANNED | S0 | | Cyclothiazide | Diuretic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Cycrimine | Anticholinergic | Discontinued, no FDA-approved product commercially available. | | |
| CONTROLLED | S7 | B | Cyproheptadine | Antihistamine | Periactin. | | |
| BANNED | S4 | | Dalantercept (ACE–041) | Anti-neoplastic | Lacks FDA approval. | | |
| BANNED | S1 | | Danazol | Anabolic | Generic. | | |
| CONTROLLED | S7 | C | Dantrolene | Muscle relaxant | Dantrium | Detection Time: 48 hrs. 500 mg orally once daily for 3 days. (12 horses). | 3 ng/mL of 5-hydroxydantrolene in urine; 0.1 ng/mL in serum or plasma as 3′-hydroxydantrolene. |
| BANNED | S2 | | Darbepoetin (dEPO) | Erythropoiesis | Aranesp. | | |
| BANNED | S0 | | Decamethonium | Muscle relaxant | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S1 | | Dehydrochloromethylte stosterone. | Anabolic | Turinabol. DEA Schedule III. | | |
| BANNED | S0 | | Delmadinone acetate | Reproductive hormone | Lacks FDA approval. | | |
| BANNED | S0 | | Delorazepam | Anxiolytic | Lacks FDA approval. DEA Schedule IV. | | |
| BANNED | S0 | | Dembroxol (Dembrexine) | Mucolytic | Lacks FDA approval. | | |
| BANNED | S0 | (x) | Demecolcine | Anti-neoplastic/ Immunomodulator. | Lacks FDA approval. | | |
| BANNED | S0 | | Demoxepam | Anxiolytic | Lacks FDA approval. | | |
| BANNED | S0 | | Deoxycorticosterone | Minerlocorticoid | Lacks FDA approval. | | |
| BANNED | S0 | | Deptropine | Antihistamine | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Deracoxib | NSAID | Deramaxx. | | |
| BANNED | S6 | | Dermorphin | Opioid Receptor Agonist | Lacks FDA approval. | | |
| BANNED | S0 | | Deserpidine | Antihypertensive | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Desipramine | Antidepressant | Norpramin. | | |
| CONTROLLED—Fillies and Mares. | S7 | B | Deslorelin | Induce ovulation | Ovuplant, SucroMate, Suprelorin. | | |
| BANNED—intact males and geldings. | S4 | | Deslorelin | Reproductive hormone | Ovuplant, SucroMate, Suprelorin. | | |
| BANNED | S5 | | Desmopressin | Anti-diuretic | DDAVP, Nocdurna. | | |
| CONTROLLED | S7 | C | Desonide | Corticosteroid | Verdeso, Desowen. | | |
| CONTROLLED | S7 | C | Desoximethasone (desoxymethasone, desoximetasone). | Corticosteroid | Topicort. | | |
| BANNED | S1 | | Desoxymethyltestosterone | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S1 | | Desoxyvinyl-testosterone | Anabolic | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Detomidine | Sedative/Analgesic | Dormosedan | Detection Time: 48 hrs. 0.02 mg/kg single IV dose (10 horses). | 2 ng/mL 3-carboxydetomidine in urine; 0.02 ng/mL in serum or plasma. |
| CONTROLLED | S7 | C | Dexamethasone | Corticosteroid | Azium, Dexasone | Detection Time: 72 hours. Single 20 mg IV, IM, or oral dose (20 horses). | 0.2 ng/mL in urine. |

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|---|---|---|---|---|---|---|---|
| CONTROLLED | S7 | C | Dexamethasone Sodium phosphate. | Corticosteroid | Generic | Detection Time: 72 hours. 0.06 mg/kg single IV dose (6 horses). | |
| CONTROLLED | S7 | B | Dextromethorphan | Antitussive | Delsym, Robitussin. | | |
| BANNED | S0 | | Dextromoramide | Opioid Analgesic | Lacks FDA approval. DEA Schedule I. | | |
| BANNED | S0 | | Dextropropoxyphene | Opioid Analgesic | Discontinued, no FDA-approved product commercially available. DEA Schedule IV. | | |
| BANNED | S0 | | Dextrorphan (Dextrorphan may be present as a metabolite of dextromethorphan. If there is credible evidence that the presence of dextrorphan in the horse's sample is the consequence of dextromethorphan administration, the classification of dextrorphan may be revised to S7(A).). | Psychoactive/Antitussive | Lacks FDA approval. | | |
| BANNED | S0 | | Dezocine | Opioid Analgesic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Diacerein | Anti-osteoarthritic | Lacks FDA approval. | | |
| BANNED | S0 | | Diamorphine (diacetylmorphine) | Opioid Analgesic | Lacks FDA approval. DEA Schedule I. | | |
| CONTROLLED | S7 | B | Diazepam | Anxiolytic | Valium. DEA Schedule IV. | | |
| BANNED | S0 | | Diazoxide | Antihypertensive/Hyperglycemic | Proglycem. | | |
| BANNED | S0 | | Dibenzepin | Antidepressant | Lacks FDA approval. | | |
| BANNED | S0 | | Dibucaine | Local anesthetic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Dichlorisone | Corticosteroid | Lacks FDA approval. | | |
| BANNED | S0 | | Dichloroacetate | Anti-neoplastic | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Dichlorphenamide | Carbonic Anhydrase Inhibitor | Keveyis. | | |
| CONTROLLED | S7 | C | Diclofenac | NSAID | Surpass, Voltaren | | 50 ng/mL in urine. |
| BANNED | S0 | | Dicumarol | Anticoagulant | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Diethylpropion | Stimulant | Lacks FDA approval. DEA Schedule IV. | | |
| BANNED | S0 | | Diethylthiambutene | Opioid Analgesic | Lacks FDA approval. DEA Schedule I. | | |
| BANNED | S0 | | Diethyltryptamine (DET) | Hallucinogen | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Diflorasone | Corticosteroid | Florone. | | |
| BANNED | S0 | | Diflucortolone | Corticosteroid | Lacks FDA approval. | | |
| BANNED | S0 | | Diflunisal | NSAID | Generic. | | |
| BANNED | S0 | | Digitoxin | Antiarrhythmic | Discontinued, no FDA-approved product commercially available. | | |
| CONTROLLED | S7 | B | Digoxin | Antiarrhythmic | Lanoxin. | | |
| BANNED | S0 | | Dihydrocodeine | Opioid Analgesic | Trezix (with acetaminophen and caffeine) DEA Schedule III. | | |
| BANNED | S0 | | Dihydrocodeinone | Opioid Analgesic | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Dihydroergotamine mesylate | Ergot alkaloid | Migranal, Trudhesa. | | |
| BANNED | S0 | | Dihydromorphine | Opioid Analgesic | Lacks FDA approval. DEA Schedule I. | | |
| BANNED | S1 | | Dihydrotestosterone (17β-hydroxy- 5a androstan-3-one, Androstanolone). | Anabolic | Anabolex, Andractimm, Pesomax, Stanolone. DEA Schedule III. | | |
| BANNED | S0 | | Diisopropylamine | Vasodilator | Lacks FDA approval. | | |
| BANNED | S0 | | Diltiazem | Antihypertensive | Cardizem CD, Taztia XT, Tiazac. | | |
| BANNED | S0 | | Dimefline | Respiratory Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Dimethindene | Antihistamine | Lacks FDA approval. | | |
| BANNED | S0 | | Dimethisoquin (quinocaine) | Local anesthetic | Lacks FDA approval. | | |
| BANNED | S0 | | Dimethylamphetamine | Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Dimethylphenidate | Stimulant | Lacks FDA approval. | | |

| HISA listed as | HISA status | Penalty subclassification (specified substances are designated with 'x') | Substance | Action | Commercial name(s) (developmental names) | Detection time | Screening limit* |
|---|---|---|---|---|---|---|---|
| CONTROLLED | S7 | C | Dimethylsulfoxide (DMSO) | NSAID | Domoso | Detection Time: 48 hrs. 70 mL 90% DMSO in 500 mL LRS IV single administration (30 horses). | 15 mcg/mL in urine or 1,000 ng/mL in serum or plasma. *Note:* The detection of more than one NSAID in a horse's post-Race or Post-Official Workout blood sample constitutes a Stacking Violation. |
| BANNED | S0 | (x) | Dimethyltryptamine (DMT) | Hallucinogen | Lacks FDA approval. DEA Schedule I. | | Threshold: 10 mcg/mL total (free and conjugated) in urine. |
| BANNED | S0 | | Diphenadione | Anticoagulant | No FDA-approved product. Rodenticide. | | |
| CONTROLLED | S7 | B | Diphenhydramine | Antihistamine | Benadryl. | | |
| CONTROLLED | S7 | B | Diphenoxylate | Anti-diarrheal | DEA Schedule II. Lomotil (with atropine), DEA Schedule II. | | |
| BANNED | S0 | | Diphenylpyraline | Antihistamine | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Dipipanone | Opioid Analgesic | Lacks FDA approval. DEA Schedule I. | | |
| BANNED | S0 | | Diprenorphine | Narcotic antagonist | M50–50. | | |
| BANNED | S0 | | Diprophylline | Bronchodilator | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Dipyridamole | Platelet inhibitor | Persantine. | | |
| CONTROLLED | S7 | C | Dipyrone | NSAID/Anti-pyretic | Zimeta | Detection Time: 72 hrs. 30 mg/kg single IV dose (10 horses). | 1,000 ng/mL of 4-methylaminoantipyrine in urine. *Note:* The detection of more than one NSAID in a horse's post-Race or Post-Official Workout blood sample constitutes a Stacking Violation. |
| CONTROLLED | S7 | B | Disopyramide | Antiarrhythmic | Norpace, Rythmodan. | | |
| BANNED | S0 | | Disulfiram | Alcohol antagonist | Generic. | | |
| BANNED | S0 | | Divalproex | Anticonvulsant | Depakote. | | |
| BANNED | S0 | | Dixyrazine | Antipsychotic | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Dobutamine | Beta-1 agonist | Generic. | | |
| BANNED | S4 | | Domagrozumab | Anabolic | Lacks FDA approval. | | |
| BANNED | S0 | | Donepezil | Behavior and Cognitive Modifier | Adilarity, Aricept. | | |
| CONTROLLED | S7 | A | Dopamine | Neurotransmitter | Generic. | | |
| BANNED | S0 | | Dopexamine | Vasodilator | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Dorzolamide | Carbonic Anhydrase Inhibitor | Cosopt. | | |
| BANNED | S0 | | Dothiepin | Antidepressant | Lacks FDA approval. | | |
| BANNED | S0 | | Doxacurium | Muscle relaxant | Discontinued, no FDA-approved product commercially available. | | |
| CONTROLLED | S7 | A | Doxapram | Respiratory Stimulant | Dopram, Respiram. | | |
| BANNED | S0 | | Doxazosin | Antihypertensive | Cardura. | | |
| BANNED | S0 | | Doxefazepam | Anxiolytic | Lacks FDA approval. | | |
| CONTROLLED | S7 | A | Doxepin | Antidepressant | Generic. | | |
| CONTROLLED | S7 | B | Doxylamine | Antihistamine | Unisom. | | |
| BANNED | S1 | | Dromostanolone (drostanolone) | Anabolic | Lacks FDA approval. | | |
| BANNED | S0 | | Droperidol | Antipsychotic | Inapsine. | | |
| BANNED | S0 | | Drospirenone | Reproductive hormone | Slynd, Nextstellis, Angeliq, Lo-Zumandimine, Loryna, elamisa, Nikki, Yaz. | | |
| BANNED | S0 | | Duloxetine | Antidepressant | Cymbalta, Drizalma. | | |
| CONTROLLED | S7 | C | Dyclonine | Topical anesthetic | Dyclopro. | | |

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|---|---|---|---|---|---|---|---|
| BANNED | S0 | | Dyphylline (Diphylline) | Antipsychotic/Antiemetic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Edrophonium | Muscle strengthener | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S2 | | Efaproxiral (RSR13) | Hemoglobin modifier | FDA orphan drug. | | |
| BANNED | S0 | | Eletripan | Selective Serotonin Receptor Agonist. | Relpax. | | |
| BANNED | S0 | | Eltenac | NSAID | Lacks FDA approval. | | |
| BANNED | S0 | | Embramine | Antihistamine | Lacks FDA approval. | | |
| BANNED | S0 | | Embutramide | Opioid Analgesic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S0 | | Emepronium | Antispasmodic | Lacks FDA approval. | | |
| BANNED | S0 | | Emidonol | Anti-inflammatory | Lacks FDA approval. | | |
| BANNED | S0 | | Enalapril (metabolite enaloprilat) | Angiotensin-converting enzyme inhibitor. | Vasotec. | | |
| BANNED | S0 | | Enciprazine | Anxiolytic/Antipsychotic | Lacks FDA approval. | | |
| CONTROLLED | S7 | A | Ephedrine | Stimulant | Akovaz, Corphedra, Emerphed. | | |
| BANNED | S6 | | Epibatidine | Analgesic | Lacks FDA approval. | | |
| BANNED | S1 | | Epi-dihydrotestosterone | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| CONTROLLED | S7 | A | Epinephrine | Stimulant | Adrenalin, Epipen, Adrenaclick, Auvi-Q, Symjepi, Primatene Mist. | | |
| BANNED | S1 | | Epitestosterone | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S0 | | Eplerenone | Antihypertensive | Inspra. | | |
| BANNED | S2 | | EPO-based constructs (*e.g.,* EPO-Fc). | Erythropoiesis | Lacks FDA approval. | | |
| BANNED | S2 | | EPO-mimetic agents (*e.g.,* CNTO–530, peginesatide). | Erythropoiesis. | | | |
| BANNED | S0 | | Ergonovine | Ergot alkaloid | Lacks FDA approval. | | |
| BANNED | S0 | (x) | Ergotamine | Ergot alkaloid | Ergomar, Migergot (with caffeine). | | |
| BANNED | S0 | | Erythritol tetranitrate | Vasodilator | Lacks FDA approval. | | |
| BANNED | S2 | | Erythropoietin (EPO) | Erythropoiesis. | | | |
| BANNED | S0 | | Esmolol | Antihypertensive | Brevibloc. | | |
| CONTROLLED | S7 | C | Esomeprazole | Anti-ulcer | Nexium. | | |
| BANNED | S0 | | Estazolam | Sedative/Anti-convulsant | Prosom. DE Schedule IV. | | |
| CONTROLLED—in male horses (other than geldings). | S7 | B | Estranediol | Estrogen | | | Threshold: 0.045 mcg/mL total (free and conjugated) 5α-estrane-3β, 17α-diol per millilitre in urine when, at screening, the total 5α-estrane-3β, 17α-diol exceeds the total 5,10 estrene-3β,17α-diol in urine. |
| BANNED | S0 | | Eszopiclone | Hypnotic | Lunesta. | | |
| BANNED | S0 | | Etafedrine | Bronchodilator | Lacks FDA approval. | | |
| BANNED | S0 | | Etamiphylline | Respiratory Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Etamivan (Ethamivan) | Respiratory Stimulant | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Etanercept | NSAID | Enbrel. | | |
| BANNED | S5 | | Ethacrynic acid (Etacrynic acid) | Diuretic | Edecrin. | | |
| BANNED | S0 | | Ethamivan | Respiratory Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Ethamsylate | Antihemorrhagic | Lacks FDA approval. | | |
| BANNED | S0 | | Ethanol | Depressant | Grain alcohol, Everclear. | | |
| BANNED | S0 | | Ethaverine | Vasodilator | Lacks FDA approval. | | |
| BANNED | S0 | | Ethchlorvynol | Sedative/Hypnotic | Discontinued, no FDA-approved product commercially available. DEA Schedule IV. | | |
| BANNED | S0 | | Ethiazide | Diuretic | Lacks FDA approval. | | |
| BANNED | S0 | | Ethinamate | Sedative/Hypnotic | Discontinued, no FDA-approved product commercially available. DEA Schedule IV. | | |
| BANNED | S0 | | Ethinylestradiol | Reproductive hormone | Lacks FDA approval. | | |
| BANNED | S0 | | Ethoheptazine | Analgesic | Lacks FDA approval. | | |

| HISA listed as | HISA status | Penalty subclassification (specified substances are designated with 'x') | Substance | Action | Commercial name(s) (developmental names) | Detection time | Screening limit * |
|---|---|---|---|---|---|---|---|
| BANNED | S0 | | Ethopropazine | Anticholinergic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Ethopropazine | Anticholinergic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Ethosuximide | Anticonvulsant | Zarontin. | | |
| BANNED | S0 | | Ethotoin | Anticonvulsant | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Ethoxzolamide | Carbonic Anhydrase Inhibitor | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Ethyl isobutrazine | Sedative | Lacks FDA approval. | | |
| BANNED | S0 | | Ethyl Loflazepate | Sedative Anxiolytic | Discontinued, no FDA-approved product commercially available. DEA Schedule IV. | | |
| CONTROLLED | S7 | C | Ethylaminobenzoate (Benzocaine). | Local anesthetic | Orajel. | | |
| BANNED | S0 | | Ethylamphetamine | Stimulant | Lacks FDA approval. | | |
| BANNED | S1 | | Ethylestrenol | Anabolic | Discontinued, no FDA-approved product commercially available. DEA Schedule III. | | |
| BANNED | S0 | | Ethylmorphine | Opioid Analgesic | Lacks FDA approval. DEA Schedule II. | | |
| BANNED | S0 | | Ethylnorepinephrine | Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Ethylphenidate | Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Etidocaine | Local anesthetic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Etifoxine | Anticonvulsant | Lacks FDA approval. | | |
| BANNED | S0 | | Etifoxine (etafenoxine) | Anticonvulsant | Lacks FDA approval. | | |
| BANNED | S0 | | Etilefrine | Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Etiocholanolone | Anabolic | Lacks FDA approval. | | |
| BANNED | S0 | | Etizolam | Anxiolytic | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Etodolac | NSAID | Generic. | | |
| BANNED | S0 | | Etodroxizine | Antihistamine | Lacks FDA approval. | | |
| BANNED | S0 | | Etofenamate | NSAID | Lacks FDA approval. | | |
| BANNED | S0 | | Etomidate | Anesthetic | Amidate. | | |
| BANNED | S0 | | Etoricoxib | NSAID | Lacks FDA approval. | | |
| BANNED | S0 | | Etorphine HCl | Opioid analgesic | M99. DEA Schedule II. | | |
| BANNED | S2 | | Examorelin (hexarelin) | Growth Hormone | Lacks FDA approval. | | |
| BANNED | S4 | | Exemestane | Aromatase inhibitor | Aromasin. | | |
| CONTROLLED | S7 | C | Famotidine | Anti-ulcer | Duexis, Pepcid. | | |
| BANNED | S0 | | Famprofazone | NSAID | Lacks FDA approval. | | |
| BANNED | S0 | | Febarbamate | Anxiolytic | Lacks FDA approval. | | |
| BANNED | S0 | | Felbamate | Anticonvulsant | Trezix, Tuxari, Triacin-C. | | |
| BANNED | S0 | | Felbinac | NSAID | Lacks FDA approval. | | |
| BANNED | S0 | | Felodipine | Antihypertensive | Generic. | | |
| BANNED | S0 | | Fenbufen | NSAID | Felbatol. | | |
| BANNED | S0 | | Fenbutrazate | Psychostimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Fencamfamine | Stimulant | Lacks FDA approval. DEA Schedule IV. | | |
| BANNED | S0 | | Fencamine | Psychostimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Fenclofenac | NSAID | Lacks FDA approval. | | |
| BANNED | S0 | | Fenclozic acid | NSAID | Lacks FDA approval. | | |
| BANNED | S0 | | Fenetylline (fenetylline, phenethylline, phenetylline). | Psychostimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Fenfluramine | Stimulant | Fintepla. DEA Schedule IV. | | |
| CONTROLLED | S7 | B | Fenoldopam | Vasodilator | Corlopam. | | |
| CONTROLLED | S7 | B | Fenoprofen | NSAID | Nalfon. | | |
| BANNED | S3 | | Fenoterol | Beta-2 agonist-bronchodilator | Lacks FDA approval. | | |
| BANNED | S0 | | Fenozolone | Psychostimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Fenpiprane | Antispasmodic | Lacks FDA approval. | | |

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|---|---|---|---|---|---|---|---|
| BANNED | S0 | | Fenproporex | Stimulant | Lacks FDA approval. DEA Schedule IV. | | |
| BANNED | S0 | | Fenspiride | Bronchodilator | Lacks FDA approval. | | |
| CONTROLLED | S7 | A | Fentanyl (fentanil) | Opioid Analgesic | Actiq, Fentora, Lazanda, Sublimaze, Subsys. DEA Schedule II. | | |
| BANNED | S0 | | Fentiazac | NSAID | Lacks FDA approval. | | |
| BANNED | S0 | | Feprazone | NSAID | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Fexofenadine | Antihistamine | Allegra. | | |
| BANNED | S2 | | Fibroblast Growth Factors (FGFs). | Growth Hormone. | | | |
| CONTROLLED | S7 | C | Firocoxib | NSAID | Equioxx, Previcox | Detection Time: 360 hrs. 100 mcg/kg orally once daily for total of 7 doses. (20 horses). | 2 ng/mL in serum or plasma. |
| BANNED | S0 | | Flavoxate | Anticholinergic | Generic. | | |
| CONTROLLED | S7 | B | Flecainide | Antiarrhythmic | Generic. | | |
| BANNED | S0 | | Floctafenine | NSAID | Lacks FDA approval. | | |
| BANNED | S0 | | Fluanisone | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S0 | | Fludiazepam | Anxiolytic | Lacks FDA approval. DEA Schedule IV. | | |
| BANNED | S0 | | Fludrocortisone | Corticosteroid | Generic. | | |
| BANNED | S0 | | Flufenamic acid | NSAID | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Flumethasone (flumetasone) | Corticosteroid | Flucort, Anaprime. | | |
| BANNED | S5 | | Flumethiazide | Diuretic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Flunarizine | Calcium channel blocker | Lacks FDA approval. | | |
| BANNED | S0 | | Flunisolide | Corticosteroid | Generic. | | |
| BANNED | S0 | | Flunitrazepam | Sedative/Anxiolytic | Lacks FDA approval. DEA Schedule IV. | | |
| CONTROLLED | S7 | C | Flunixin | NSAID (3 NSAIDs (Flunixin, Ketoprofen, Phenylbutazone) are associated with a Detection Time of 48 hours. Only one of the three may be administered using a Withdrawal Interval based on the 48 hour Detection Time. To avoid a stacking violation (detection of more than 1 NSAID in a blood sample) the following secondary Detection Times should be applied for the following 3 NSAIDs: Flunixin: 144 hours; Ketoprofen 96 hours; Phenylbutazone: 168 hours.). | Banamine, Flunixamine, Equileve, Meflosyl. | Detection Time: 48 hrs. 1.1 mg/kg single IV dose (16 horses); 500 mg single IV dose (12 horses). | 4 ng/mL in serum or plasma. *Note:* The detection of more than one NSAID in a horse's post-Race or Post-Official Workout blood sample constitutes a Stacking Violation. |
| CONTROLLED | S7 | C | Fluocinolone acetonide | Corticosteroid | Flucort-N. | | |
| CONTROLLED | S7 | C | Fluocinonide | Corticosteroid | Fluonex, Lidex, Lonide, Lyderm. | | |
| BANNED | S0 | | Fluocortolone | Corticosteroid | Lacks FDA approval. | | |
| BANNED | S0 | | Fluopromazine (Triflupromazine) | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S0 | | Fluoresone | Anticonvulsant | Lacks FDA approval. | | |
| BANNED | S0 | | Fluorocortisone | Corticosteroid | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Fluorometholone | Corticosteroid | FML Forte. | | |
| BANNED | S0 | | Fluorophenethylamine | Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Fluoroprednisolone | Corticosteroid | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Fluoxetine | Antidepressant | Prozac. | | |
| BANNED | S1 | | Fluoxymesterone | Anabolic | Discontinued, no FDA-approved product commercially available. DEA Schedule III. | | |
| BANNED | S0 | | Flupenthixol (flupentixol) | Antipsychotic | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Fluphenazine | Antipsychotic | Generic. | | |
| BANNED | S0 | | Flupirtine | Analgesic | Lacks FDA approval. | | |
| BANNED | S0 | | Fluprednisolone | Corticosteroid | Discontinued, no FDA-approved product commercially available. | | |

| HISA listed as | HISA status | Penalty subclassification (specified substances are designated with 'x') | Substance | Action | Commercial name(s) (developmental names) | Detection time | Screening limit* |
|---|---|---|---|---|---|---|---|
| CONTROLLED | S7 | C | Flurandrenolide (Flurandrenolone, Fludroxycortide). | Corticosteroid | Cordran. | | |
| BANNED | S0 | | Flurazepam | Sedative/Anxiolytic | Generic. DEA Schedule IV. | | |
| CONTROLLED | S7 | B | Flurbiprofen | NSAID | Ansaid, Ocufen, Strepfen. | | |
| BANNED | S0 | | Fluspirilene | Antipsychotic | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Fluticasone | Corticosteroid | Flovent, Flonase. | | |
| BANNED | S0 | | Flutoprazepam | Sedative/Anxiolytic | Lacks FDA approval. | | |
| BANNED | S0 | | Fluvoxamine | Antidepressant | Luvox. | | |
| BANNED | S4 | | Follistatin | Myostatin inhibitor. | | | |
| BANNED | S1 | | Formebolone | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S4 | | Formestane | Aromatase inhibitor | Lacks FDA approval. | | |
| BANNED | S3 | | Formoterol (Aformoterol) | Beta-2 agonist-bronchodilator | Brovana; Breyna (with budesonide); Duaklir Pressair (with aclidinium). | | |
| BANNED | S0 | | Fosinopril | Antihypertensive | Generic. | | |
| BANNED | S0 | | Fosphenytoin | Anticonvulsant | Cerebyx. | | |
| BANNED | S4 | | Fulvestrant | Estrogen antagonist | Falsodex. | | |
| BANNED | S1 | | Furazabol | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S0 | | Furazadrol | Anabolic | Lacks FDA approval. | | |
| BANNED | S0 | | Furfenorex | Stimulant | Lacks FDA approval. | | |
| CONTROLLED-(Permitted at all times during Workouts, Official Workouts, and other training exercise). | S7 | C | Furosemide | Diuretic | Lasix, Salix | Restricted Administration: 48 hrs. 1 mg/kg single IV dose (6 horses). | 50 ng/mL in urine or 0.1 ng/mL in serum or plasma. |
| CONTROLLED-where permitted on race day. | S7 | C | Furosemide (where permitted by exemption). | Diuretic | Lasix, Salix | Shall not be administered within 4 hours prior to Post-Time. | 100 ng/mL in serum or plasma AND urine S.G. >1.010. |
| CONTROLLED | S7 | B | Gabapentin | Anticonvulsant | Horizant, Gralise, Neurontin. | | |
| BANNED | S0 | | Galantamine | Acetylcholinesterase inhibitor | Razadyne. | | |
| BANNED | S0 | | Gallamine | Muscle relaxant | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Gamma Aminobutyric Acid (GABA). | Neurotransmitter | Endogenous substance. | | |
| BANNED | S0 | | Gamma-butyrolactone (GBL) | Neurohormone | Lacks FDA approval. | | |
| BANNED | S0 | | Gamma-hydroxybutyrate (GHB) | CNS depressant | Lacks FDA approval. | | |
| BANNED | S0 | | Gepirone | Antidepressant | Lacks FDA approval. | | |
| BANNED | S1 | | Gestrinone | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S1 | | GH-Releasing Peptides (ghrps), *e.g.,* alexamorelin, GHRP–6, hexarelin and pralmorelin (GHRP–2). | Growth Hormone. | | | |
| BANNED | S0 | (x) | Glaucine | Antitussive (cough suppressant) | Lacks FDA approval | | 0.5 ng/mL in serum or plasma. |
| BANNED | S0 | | Glutethimide (chlorhexidol) | Sedative | Discontinued, no FDA-approved product commercially available. DEA Schedule II. | | |
| CONTROLLED | S7 | C | Glycopyrrolate | Anticholinergic | Robinul | Detection Time: 48 hours. 1 mg single dose IV. (20 horses). | 0.003 ng/mL in serum or plasma. |
| CONTROLLED—fillies and mares. | S7 | B | Gonadorelin | Induce ovulation | Cystorelin, Factrel, Fertelin, OvaCyst, Fertagyl, Gonabreed. | | |
| BANNED—intact males and geldings. | S4 | | Gonadorelin | Reproductive hormone modulator. | Cystorelin, Factrel, Fertelin, OvaCyst, Fertagyl, Gonabreed. | | |

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|---|---|---|---|---|---|---|---|
| BANNED | S2 | | Goserelin | Reproductive hormone modulator. | Zoladex. | | |
| BANNED | S1 | | Growth Hormone Releasing Hormone (GHRH). | Anabolic. | | | |
| CONTROLLED | S7 | C | Guaifenesin (glycerol guiacolate). | Expectorant | Mucinex | Detection Time: 48 hrs. 2 grams total body dose, orally twice daily for 5 doses. (9 horses). | 1 ng/mL in serum or plasma. |
| BANNED | S0 | | | Antihypertensive | Generic. | | |
| BANNED | S0 | | Guanadrel | Antihypertensive | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Guanethidine | Antihypertensive | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Guanoclor | Antihypertensive | Lacks FDA approval. | | |
| BANNED | S0 | | Halazepam | Sedative/Anxiolytic | Discontinued, no FDA-approved product commercially available. DEA Schedule IV. | | |
| CONTROLLED | S7 | C | Halcinonide | Corticosteroid | Halog. | | |
| BANNED | S0 | | Haldrol | Anabolic | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Halobetasol | Corticosteroid | Lexette, Bryhali, Ultravate. | | |
| BANNED | S0 | | Haloperidol | Antipsychotic | Haldol. | | |
| BANNED | S0 | | Haloxazolam | Sedative/Anxiolytic | Lacks FDA approval. | | |
| BANNED | S0 | | Harmaline | Psychoactive | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Harpagoside (Devil's Claw) | Anti-inflammatory | Glycoside of plangt origin. No FDA-approved products commercially available. Constituent of multiple, unregulated OTC herbal remedies. | | |
| BANNED | S2 | | Hepatocyte Growth Factor (HGF). | Growth Hormone. | | | |
| BANNED | S0 | | Heptaminol | Cardiac stimulant. | | | |
| BANNED | S0 | | Hexafluorenium | Muscle relaxant | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Hexobarbital | Sedative | Lacks FDA approval. | | |
| BANNED | S0 | | Hexocyclium | Anticholinergic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Hexylcaine | Local anesthetic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S3 | | Higenamine (norclaurine, demethylcoclaurine). | Bronchodilator | Constituent of numerous OTC dietary supplements marketed for weight loss or as sports/energy supplements. Lacks FDA approval. | | |
| BANNED | S0 | | Histapyrrodine | Antihistamine | Lacks FDA approval. | | |
| BANNED | S4 | | Histrelin | GnRH agonist | Supprelin LA, Vantas. | | |
| CONTROLLED | S7 | B | Homatropine | Anticholinergic | Hycodan [with hydrocodone]. | | |
| BANNED | S0 | | Homophenazine | Antipsychotic | Lacks FDA approval. | | |
| CONTROLLED | S7 | A (x) | Hordenine | Stimulant | Plant alkaloid (*e.g.,* barley). Constituent of numerous OTC dietary supplements marketed for weight loss. Lacks FDA approval. | | 80 mcg/mL total (free and conjugated) in urine. |
| CONTROLLED | S7 | B | Hydralazine | Vasodilator | Hydra-Zide, Bidil. | | |
| BANNED | S5 | | Hydrochlorthiazide | Diuretic | Lotensin (with bisoprolol); Vaseretic (with enalapril); Avilide (with irbesartan); Zestoretic (with lisinopril); Lopressor (with metoprolol); Micardis (with telmisartan); and others. | | |
| BANNED | S0 | | Hydrocodone (dihydrocodienone). | Opioid Analgesic | Hysingla; Apadaz, Anexsia (with acetaminophen); Hycodan (with homatropine) DEA Schedule II. | | |

| HISA listed as | HISA status | Penalty subclassification (specified substances are designated with 'x') | Substance | Action | Commercial name(s) (developmental names) | Detection time | Screening limit* |
|---|---|---|---|---|---|---|---|
| CONTROLLED | S7 | C | Hydrocortisone | Corticosteroid | Cortef. *Note:* hydrocortisone is a component of numerous products, particularly those for topical, ophthalmic, and otic applications. The Responsible Person is advised to read all medication labels prior to authorizing administration.. | | Threshold: 1 mcg/mL in urine. |
| BANNED | S5 | | Hydroflumethiazide | Diuretic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Hydromorphinol | Opioid Analgesic | Lacks FDA approval. | | |
| BANNED | S0 | | Hydromorphone | Opioid Analgesic | Dilaudid. DEA Schedule II. | | |
| BANNED | S0 | | Hydroxyamphetamine | Stimulant | Paremyd (with tropicamide). | | |
| BANNED | S0 | | Hydroxy-gamma amino butyric acid. | Neurohormone | Lacks FDA approval. | | |
| BANNED | S0 | | Hydroxytestosterone | Anabolic | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Hydroxyzine | Antihistamine | Atarax | Detection time: 96 hours. Hydroxyzine: 190 mg twice daily for a total of 9 doses (2 horses). | |
| BANNED | S6 | | Ibandronate | Bisphosphonate | Generic. | | |
| BANNED | S0 | | Ibogaine | Psychoactive | Lacks FDA approval. DEA Schedule I. | | |
| CONTROLLED | S7 | C | Ibuprofen | NSAID | Advil, Motrin. | | |
| BANNED | S2 | | Ibutamoren | Growth Hormone | Investigational New Drug (in clinical trials). | | |
| CONTROLLED | S7 | B | Ibutilide | Antiarrhythmic | Corvert. | | |
| BANNED | S0 | | Iloprost | Vasodilator | Ventavis. | | |
| CONTROLLED | S7 | A | Imipramine | Antidepressant | Tofranil. | | |
| BANNED | S3 | | Indacaterol | Beta-2 agonist-bronchodilator | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S5 | | Indapamide | Diuretic | Generic. | | |
| CONTROLLED | S7 | B | Indomethacin | NSAID | Indocin. | | |
| BANNED | S0 | | Indoprofen | NSAID | Lacks FDA approval. | | |
| BANNED | S0 | | Indoramin | Antihypertensive | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Infliximab | Immunosuppressor | Remicade. | | |
| BANNED | S2 | | Insulin- like Growth Factor-1 (IGF–1) and its analogues. | Peptide hormone. | | | |
| BANNED | S2 | | Insulins | Anti-hyperglycemics. | | | |
| BANNED | S2 | | IOX–2 | Erythropoiesis | Lacks FDA approval. | | |
| BANNED | S2 | | Ipamorelin | Growth Hormone | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Ipratropium | Bronchodilator | Atrovent | Detection Time: 120 hrs. 5.5 mcg/kg once daily via nebulization for 3 total doses (6 horses). | 0.25 ng/mL in urine. |
| CONTROLLED | S7 | B | Ipratropium bromide | Bronchodilator | Atrovent; Combivent (with albuterol). | | |
| BANNED | S0 | | Iprindole | Antidepressant | Lacks FDA approval. | | |
| BANNED | S0 | | Iproniazid | Antidepressant | Lacks FDA approval. | | |
| BANNED | S0 | | Ipsapirone | Antidepressant | Lacks FDA approval. | | |
| BANNED | S0 | | Irbesartan | Antihypertensive | Avalide, Avapro. | | |
| BANNED | S5 | | Irbesartan | Antihypertensive | Avalide, Avapro. | | |
| BANNED | S0 | | Isoaminile | Antitussive | Lacks FDA approval. | | |
| BANNED | S0 | | Isocarboxazid | Antidepressant | Marplan. | | |
| BANNED | S0 | | Isoetharine | Bronchodilator | Discontinued, no FDA-approved product commercially available. | | |

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|---|---|---|---|---|---|---|---|
| CONTROLLED | S7 | C | Isoflupredone | Corticosteroid | Predef 2x | 14 day stand down for all intra-articular injections. Serum concentrations associated with an experimental dose of 8 mg IA single joint (6 horses) were all below Limit of Detection by 14 days. | |
| BANNED | S0 | | Isomethadone (isoamidone) | Synthetic opioid analgesic | Lacks FDA approval. DEA Schedule II. | | |
| BANNED | S0 | | Isometheptene | Sympathomimetic | Lacks FDA approval. | | |
| BANNED | S0 | | Isopropamide | Anticholinergic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S3 | | Isoproterenol | Beta-2 agonist | Generic. | | |
| BANNED | S0 | | Isopyrin (Raminfenazone) | NSAID | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Isosorbide dinitrate | Vasodilator | Isordil. | | |
| BANNED | S0 | | Isothipendyl | Antihistamine | Lacks FDA approval. | | |
| BANNED | S0 | | Isoxicam | NSAID | Lacks FDA approval. | | |
| BANNED | S0 | | Isradipine | Antihypertensive | Generic. | | |
| BANNED | S0 | | Isoxsuprine | Vasodilator | Lacks FDA approval. | | |
| BANNED | S0 | | Kebuzone | NSAID | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Ketamine/norketamine | Anesthetic | Ketaset, Vetalar. DEA Schedule III. | | |
| BANNED | S0 | | Ketazolam | Sedative/Anxiolytic | Lacks FDA approval. DEA Schedule IV.F722. | | |
| CONTROLLED | S7 | C | Ketoprofen | NSAID | Ketofen | Detection Time: 48 hrs. 2.2 mg/kg single IV dose. (24 horses). | 4 ng/mL in serum or plasma. *Note:* The detection of more than one NSAID in a horse's post-Race or Post-Official Workout blood sample constitutes a Stacking Violation. 3 NSAIDs (Flunixin, Ketoprofen, Phenylbutazone) are associated with a Detection Time of 48 hours. Only one of the three may be administered using a Withdrawal Interval based on the 48 hour Detection Time. To avoid a stacking violation (detection of more than 1 NSAID in a blood sample) the following secondary Detection Times should be applied for the following NSAIDs: Flunixin: 144 hours; Ketoprofen 96 hours; Phenylbutazone: 168 hours. |
| CONTROLLED | S7 | A | Ketorolac | NSAID | Acular, Acuvail, Sprix, Omidria. | | |
| CONTROLLED | S7 | B | Ketotifen | Antihistamine | Alaway, Zaditor. | | |
| BANNED | S2 | | Krypton | Hypoxia Inducible Factor activating. | | | |
| BANNED | S0 | | Labetalol | Antihypertensive | Trandate. | | |
| CONTROLLED | S7 | A | Lamotrigine | Anticonvulsant | Lamictal. | | |
| BANNED | S4 | | Landogrozumab | Myostatin inhibitor | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Lansoprazole | Anti-ulcer | Prevacid. | | |
| BANNED | S2 | | Lenomorelin (ghrelin) | Growth Hormone | Lacks FDA approval. | | |
| BANNED | S0 | | Lenperone | Antipsychotic | Lacks FDA approval. | | |

| HISA listed as | HISA status | Penalty subclassification (specified substances are designated with 'x') | Substance | Action | Commercial name(s) (developmental names) | Detection time | Screening limit* |
|---|---|---|---|---|---|---|---|
| BANNED | S0 | | Leptazole (Pentylenetetrazole) | Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Letosteine | Mucolytic | Lacks FDA approval. | | |
| BANNED | S2 | | Letrozole | Aromatase inhibitor | Femara. | | |
| BANNED | S2 | | Leuprorelin (leuprolide) | Reproductive hormone modulator. | Eligard Kit, Fensolvi Kit, Camcevi Kit. | | |
| BANNED | S0 | | Levallorphan | Opioid Antagonist | Discontinued, no FDA-approved product commercially available. | | |
| CONTROLLED | S7 | B | Levamisole | Anthelmintic/Immunostimulant | Ripercol, Tramisol, Levasole, Prohibit, LevaMed. | | |
| BANNED | S0 | | Levobunolol | Antihypertensive | Betagan. | | |
| BANNED | S0 | | Levocabastine | Antihistamine | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Levodopa | Decarboxylase Inhibitor | Inbrija; Stalevo, Rytary, Duopa, Dhivy, Sinemet (all with carbidopa). | | |
| BANNED | S0 | | Levomethadone | Opioid Analgesic | Lacks FDA approval. | | |
| BANNED | S0 | | Levomethorphan | Opioid Analgesic | Lacks FDA approval. DEA Schedule II. | | |
| BANNED | S0 | | Levophacetoperane | Psychostimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Levorphanol | Opioid Analgesic | Generic. DEA Schedule II+F755. | | |
| BANNED | S3 | | Levosalbutamol (levalbuterol) | Beta-2 agonist-bronchodilator | Xopenex. | | |
| BANNED | S4 | | Levothyroxine | Metabolic hormone | Thyro-Tabs, ThyroKare, Tirosint, Ermeza,Euthyrox, Levolet, Synthroid, Levoxyl, Unithroid. | | |
| CONTROLLED | S7 | B | Lidocaine | Local anesthetic | Xylocaine [with epinephrine], Lignospan, Ztlido, Akten. | Detection Time: 48 hours. 200 mg of lidocaine as its hydrochloride salt administered subcutaneously (6 horses). | 10 ng/mL as 3-hydroxylidocaine in urine; 0.02 ng/mL as 3-hydroxylidocaine in serum or plasma. |
| BANNED | S0 | | Lidoflazine | Vasodilator | Lacks FDA approval. | | |
| BANNED | S4 | | Ligandrol (LGD–4033) | Selective Androgen Receptor Modulator (SARM). | Lacks FDA approval. | | |
| BANNED | S0 | | Lisinopril | Antihypertensive | Zestoretic, Qbrelis. | | |
| BANNED | S0 | | Lithium | Mood Stabilizer | Lithobid. | | |
| BANNED | S0 | (x) | Lobeline | Respiratory Stimulant | Plant alkaloid (Lobelia, Indian Tobacco) Environmental substance. Lacks FDA approval. | | 2 ng/mL in serum or plasma. |
| BANNED | S0 | | Lofentanil | Opioid Analgesic | Lacks FDA approval. | | |
| BANNED | S0 | | Lofepramine | Antidepressant | Lacks FDA approval. | | |
| BANNED | S0 | | Loflazepate, Ethyl | Anxiolytic | Lacks FDA approval. | | |
| BANNED | S2 | | Lonapegsomatropin | Growth Hormone | FDA Orphan Drug. | | |
| CONTROLLED | S7 | B | Loperamide | Anti-diarrheal | Imodium. | | |
| BANNED | S0 | | Loprazolam | Anxiolytic | Lacks FDA approval. DEA Schedule IV. | | |
| CONTROLLED | S7 | C | Loratidine | Antihistamine | Claritin. | | |
| BANNED | S0 | | Lorazepam | Anxiolytic | Ativan. DEA Schedule IV. | | |
| BANNED | S0 | | Lormetazepam | Sedative/Anxiolytic | Lacks FDA approval. | | |
| BANNED | S0 | | Lornoxicam | NSAID | Lacks FDA approval. DEA Schedule IV. | | |
| BANNED | S0 | | Losartan | Antihypertensive | Cozaar, Hyzaar [with hydrochlorothiazide]. | | |
| BANNED | S0 | | Loxapine | Antipsychotic | Adasuve. | | |
| BANNED | S3 | | Lubabegron | Beta adrenergic modulator | Experior. | | |
| BANNED | S0 | | Lumiracoxib | NSAID | Lacks FDA approval. | | |
| BANNED | S2 | | Luspatercept | Erythropoiesis | FDA Orphan Drug. | | |
| CONTROLLED—fillies and mares. | S7 | B | Luteinizing Hormone (LH) | Reproductive hormone modulator. | | | |

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|---|---|---|---|---|---|---|---|
| BANNED—intact males and geldings. | S2 | | Luteinizing Hormone (LH) | Reproductive hormone modulator. | | | |
| BANNED | S3 | | Mabuterol | Beta-2 agonist-bronchodilator | Lacks FDA approval. | | |
| BANNED | S2 | | Macimorelin | Growth Hormone | Macrilen. | | |
| CONTROLLED | S7 | B | Magnesium sulfate | Sedative/Laxative | Generic. | | |
| BANNED | S0 | | Maprotiline | Antidepressant | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Maprotiline | Antidepressant | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Mazindol | Stimulant | Discontinued, no FDA-approved product commercially available. DEA Schedule IV. | | |
| BANNED | S0 | | Mebanazine | Antidepressant | Lacks FDA approval. | | |
| BANNED | S0 | | Mebeverine | Antispasmodic | Lacks FDA approval. | | |
| BANNED | S0 | | Mebhyroline (Mebhydrolin) | Antihistamine | Lacks FDA approval. | | |
| BANNED | S0 | | Mebutamate | Sedative/Anxiolytic | Discontinued, no FDA-approved product commercially available. DEA Schedule IV. | | |
| BANNED | S0 | | Mecamylamine | Vasodilator | Generic. | | |
| BANNED | S2 | | Mechano Growth Factors (MGFs). | Growth Hormone. | | | |
| BANNED | S0 | | Meclizine | Antihistamine | Antivert. | | |
| CONTROLLED | S7 | B | Meclofenamic acid | NSAID | Discontinued, no FDA-approved product commercially available. Routinely compounded. | | |
| BANNED | S1 | | Meclofenoxate | Cholinergic nootropic | Lacks FDA approval. | | |
| BANNED | S0 | (x) | Meconine | Opioid | Lacks FDA approval. | | |
| BANNED | S0 | | Medazepam | Sedative/Anxiolytic | Lacks FDA approval. DEA Schedule IV. | | |
| CONTROLLED | S7 | B | Medetomidine | Sedative/Analgesic | Domitor, Placadine | | 5 ng/mL as 3-hydroxydetomidine in urine. |
| CONTROLLED | S7 | B | Medroxyprogesterone | Reproductive hormone | Depo-Provera. | | |
| BANNED | S0 | | Medrylamine | Antihistamine | Lacks FDA approval. | | |
| BANNED | S0 | | Medrysone | Corticosteroid | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Mefenamic acid | NSAID | Ponstel. | | |
| BANNED | S0 | | Mefenorex | Stimulant | Lacks FDA approval. DEA Schedule IV. | | |
| BANNED | S0 | | Mefexamide | Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Mefruside | Diuretic | Lacks FDA approval. | | |
| BANNED | S2 | | Meldonium | Anti-ischemic | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Meloxicam | NSAID | Metacam. | | |
| BANNED | S0 | | Melperone | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S0 | | Memantine | Alzheimer's treatment | Namenda; Namzaric (with donepezil). | | |
| BANNED | S0 | | Meparfynol (methylpentynol) | Sedative | Lacks FDA approval. | | |
| BANNED | S0 | | Mepazine | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S0 | | Mepednisone | Corticosteroid | Lacks FDA approval. | | |
| BANNED | S0 | | Mepenzolate | Anti-ulcer | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Meperidine | Opioid analgesic | Demerol. DEA Schedule II. | | |
| BANNED | S0 | | Mephenesin | Muscle relaxant | Lacks FDA approval. | | |
| BANNED | S0 | | Mephenoxalone | Muscle relaxant | Lacks FDA approval. | | |
| BANNED | S0 | | Mephentermine | Cardiac stimulant | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Mephenytoin | Anticonvulsant | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Mephobarbital (Methylphenobarbital). | Sedative/Anxiolytic | Lacks FDA approval. | | |
| BANNED | S0 | | Mepindolol | Beta blocker | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Mepivacaine | Local anesthetic | Carbocaine, Polocaine, Scandonest. | Detection Time: 72 hrs. 40 mg (2 ml) single dose SQ distal limb (6 horses). | 10 ng/mL as 3-hydroxymepivacaine in urine; 0.05 ng/mL in serum or plasma. |

| HISA listed as | HISA status | Penalty subclassification (specified substances are designated with 'x') | Substance | Action | Commercial name(s) (developmental names) | Detection time | Screening limit* |
|---|---|---|---|---|---|---|---|
| BANNED | S0 | | Meprobamate (Meprobamate is a metabolite of carisoprodol. If there is credible evidence that the presence of meprobamate in a horse's sample is the consequence of carisoprodol administration, the classification of meprobamate may be revised to S7(A).). | Anxiolytic | Generic. DEA Schedule IV. | | |
| BANNED | S0 | | Meprylcaine | Local anesthetic | Lacks FDA approval. | | |
| BANNED | S0 | | Meptazinol | Narcotic | Lacks FDA approval. | | |
| BANNED | S5 | | Meralluride | Diuretic | Lacks FDA approval. | | |
| BANNED | S5 | | Merbaphen | Diuretic | Lacks FDA approval. | | |
| BANNED | S5 | | Mercaptomerin | Diuretic | Lacks FDA approval. | | |
| BANNED | S0 | | Mersalyl | Diuretic | Discontinued, no FDA-approved product commercially available. | | |
| CONTROLLED | S7 | C | Mesalamine (mesalazine) | Anti-inflammatory | Delzicol, Pentasa,Sfrowasa, Canasa, Lialda. | | |
| BANNED | S0 | | Mesocarb | Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Mesoridazine | Antipsychotic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S1 | | Mestanolone | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S1 | | Mesterolone | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S0 | | Metaclazepam | Anxiolytic | Lacks FDA approval. | | |
| BANNED | S1 | | Metandienone | Anabolic | Lacks FDA approval. | | |
| BANNED | S3 | | Metaproterenol (Orciprenaline) | Beta-2 agonist-bronchodilator | Generic. | | |
| BANNED | S0 | | Metaraminol | Anti-hypotensive | Generic. | | |
| BANNED | S0 | | Metaxalone | Muscle relaxant | Skelaxin. | | |
| BANNED | S0 | | Metazocine | Opioid analgesic | Lacks FDA approval. DEA Schedule II. | | |
| BANNED | S1 | | Metenolone | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S0 | | Metformin | Anti-hyperglycemic | Fortamet, Glumetza, Glucophage. | | |
| BANNED | S0 | | Methacholine | Bronchoconstrictor | Provocholine. | | |
| BANNED | S0 | | Methadone | Synthetic opioid agonist | Methadose. DEA Schedule II. | | |
| BANNED | S0 | | Methallenestril | Synthetic estrogen | Lacks FDA approval. | | |
| BANNED | S0 | | Methamphetamine | Stimulant | Desoxyn. DEA Schedule II. | | |
| BANNED | S1 | | Methandienone | Anabolic steroid | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S1 | | Methandriol (Methylandrostenediol). | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S1 | | Methandrostenolone | Anabolic | Lacks FDA approval. | | |
| BANNED | S0 | | Methantheline | Anticholinergic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Methapyrilene | Antihistamine | Lacks FDA approval. | | |
| BANNED | S0 | | Methaqualone | Sedative | Lacks FDA approval. DEA Schedule I. | | |
| BANNED | S0 | | Metharbital | Sedative | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S1 | | Methasterone | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S0 | | Methazolamide | Carbonic Anhydrase Inhibitor | Generic. | | |
| BANNED | S0 | | Methcathinone | Stimulant | Lacks FDA approval. DEA Schedule I. | | |
| BANNED | S0 | | Methdilazine | Antihistamine | Discontinued, no FDA-approved product commercially available. | | |

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| BANNED | S1 | | Methenolone | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S0 | | Methimazole | Anti-thyroid | Generic. | | |
| BANNED | S0 | | Methixene | Anticholinergic | Discontinued, no FDA-approved product commercially available. | | |
| CONTROLLED | S7 | C | Methocarbamol | Muscle relaxant | Robaxin | Detection Time: 48 hours. 15 mg/kg single IV dose. (20 horses). | 1 ng/mL in serum or plasma. |
| BANNED | S0 | | Methohexital | Sedative | Brevital. | | |
| CONTROLLED | S7 | B | Methotrexate | Immunomodulator | Otrexup, Rasuvo, Reditrex, Trexall. | | |
| BANNED | S0 | | Methotrimeprazine | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S0 | | Methoxamine | Stimulant | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S3 | | Methoxyphenamine | Bronchodilator | Lacks FDA approval. | | |
| BANNED | S2 | | Methoxypolyethylene glycol-epoetin beta (CERA). | Erythropoiesis | Micera. | | |
| BANNED | S0 | | Methoxytyramine (3-) | Neuromodulator | Endogenous substance | | Threshold: 4 mcg/mL total (free and conjugated) 3-methoxytyra-mine per mL in urine. |
| BANNED | S0 | | Methscopolamine (Methyl scopolamine). | Anticholinergic | Generic. | | |
| BANNED | S0 | | Methsuximide | Anticonvulsant | Celontin. | | |
| BANNED | S1 | | Methyl-1-testosterone | Anabolic | Android 25. DEA Schedule III. | | |
| BANNED | S0 | | Methylaminorex | Stimulant | Lacks FDA approval. DEA schedule I. | | |
| BANNED | S0 | | Methylatropine | Anticholinergic | Lacks FDA approval. | | |
| BANNED | S0 | | Methylchlorthiazide (Methylclothiazide). | Diuretic | Lacks FDA approval. | | |
| BANNED | S1 | | Methylclostebol | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S5 | | Methylclothiazide | Diuretic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S1 | | Methyldienolone | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S0 | | Methyldopa | Antihypertensive | Generic. | | |
| BANNED | S0 | | Methylenedioxyamphetamine (MDA). | Stimulant | Lacks FDA approval. DEA Schedule I. | | |
| BANNED | S0 | | Methylenedioxyethylamphetamine (MDEA). | Stimulant | Lacks FDA approval. DEA Schedule I. | | |
| BANNED | S0 | | Methylenedioxymethamphetamine (MDMA). | Stimulant | Lacks FDA approval. DEA Schedule I. | | |
| BANNED | S0 | | Methylephedrine | Stimulant | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Methylergonovine | Ergot alkaloid | Methergine. | | |
| BANNED | S0 | | Methylhexanamine (Methylhexaneamine). | Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Methylmethcathinone | Stimulant | Lacks FDA approval. | | |
| BANNED | S1 | | Methylnortestosterone (Trestolone). | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S0 | | Methylphenidate | Stimulant | Ritalin. DEA Schedule II. | | |
| CONTROLLED | S7 | C | Methylprednisolone | Corticosteroid | Depo-Medrol. | | |
| BANNED | S0 | | Methylprylone (methprylon) | Sedative | Lacks FDA approval. | | |
| BANNED | S0 | | Methylpseudoephedrine | Stimulant | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Methylsalicylate | NSAID | Salonpas (with menthol). | | |
| CONTROLLED | S7 | C | Methylsulfonylmethane (MSM) | Anti-inflammatory | Feed contaminant per IFHA | | 1200 mcg/mL in urine. |
| BANNED | S1 | | Methyltestosterone | Anabolic | Android 25. DEA Schedule III. | | |
| BANNED | S1 | | Methyltrienolone (metribolone) | Anabolic | Lacks FDA approval. DEA Schedule III.F896. | | |
| BANNED | S0 | | Methyprylon | Sedative | Discontinued, no FDA-approved product commercially available. DEA Schedule III. | | |
| BANNED | S0 | | Methysergide | Ergot alkaloid | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Metiamide | Antihistamine | Lacks FDA approval. | | |
| BANNED | S5 | | Meticrane | Diuretic | Lacks FDA approval. | | |
| BANNED | S0 | | Metipranolol | Antihypertensive | Lacks FDA approval. | | |

| HISA listed as | HISA status | Penalty subclassification (specified substances are designated with 'x') | Substance | Action | Commercial name(s) (developmental names) | Detection time | Screening limit* |
|---|---|---|---|---|---|---|---|
| CONTROLLED | S7 | C | Metoclopramide | Anti-emetic/Prokinetic | Gimoti, Reglan. | | |
| BANNED | S0 | | Metocurine | Muscle relaxant | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S5 | | Metolazone | Diuretic | Generic. | | |
| BANNED | S0 | | Metomidate | Sedative/Hypnotic | Lacks FDA approval. | | |
| BANNED | S0 | | Metopon (methydihydromorphinone). | Opioid analgesic | Lacks FDA approval. DEA Schedule II. | | |
| BANNED | S0 | | Metoprolol | Antihypertensive | Lopressor. | | |
| BANNED | S0 | | Metrenperone | Myositis preventative | Lacks FDA approval. | | |
| BANNED | S1 | | Metribolone | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S0 | | Metyrapone | Hydrocortisone synthesis inhibitor. | Metopirone. | | |
| BANNED | S0 | | Mexazolam | Anxiolytic | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Mexiletine | Antiarrhythmic | Generic. | | |
| BANNED | S0 | | Mianserin | Antidepressant | Lacks FDA approval. | | |
| BANNED | S0 | | Mibefradil | Antihypertensive | Lacks FDA approval. | | |
| BANNED | S1 | | Mibolerone | Anabolic | Cheque Drops. DEA Schedule III. | | |
| CONTROLLED | S7 | B | Midazolam | Anticonvulsant | Seizalam. DEA Schedule IV. | | |
| BANNED | S0 | | Midodrine | Antiphyptensive | Orvaten. | | |
| CONTROLLED | S7 | B | Milrinone | Vasodilator | Generic. | | |
| BANNED | S0 | | Minoxidil | Antihypertensive | Rogaine. | | |
| BANNED | S0 | | Mirtazapine | Antidepressant | Remeron. | | |
| CONTROLLED | S7 | C | Misoprostol | Prostaglandin analog | Cytotec | Detection Time: 48 hrs. 5 mcg/kg orally twice daily for 14 days. (6 horses). | |
| BANNED | S0 | | Mitragynine | Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Mivacurium | Muscle relaxant | Generic. | | |
| BANNED | S0 | | Modafinil | Stimulant | Provigil. DEA Schedule IV. | | |
| BANNED | S0 | | Moexipril (metabolite, moexiprilat). | Antihypertensive | Generic. | | |
| BANNED | S0 | | Mofebutazone | NSAID | Lacks FDA approval. | | |
| BANNED | S2 | | Molidustat (BAY 85–3934) | Erythropoiesis | Lacks FDA approval. | | |
| BANNED | S0 | | Molindone | Antipsychotic | Generic. | | |
| CONTROLLED | S7 | C | Mometasone | Corticosteroid | Asmanex, Sinuva, Elocon, Ryaltris, Nasonex. | | |
| CONTROLLED | S7 | C | Montelukast | Leukotriene receptor antagonist | Singulair. | | |
| BANNED | S0 | | Moperone | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S0 | | Moprolol | Antihypertensive | Lacks FDA approval. | | |
| BANNED | S0 | | Morpheridine | Analgesic | Lacks FDA approval. | | |
| CONTROLLED | S7 | A (x) | Morphine | Opioid Analgesic | Duramorph, Infumorph, Mitigo, MS Contin. DEA Schedule II; Dietary substance per IFHA. | | 30 ng/mL total (free and conjugated) in urine. |
| BANNED | S0 | | Mosapramine | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S0 | | Moxaverine | Vasodilator | Lacks FDA approval. | | |
| BANNED | S0 | (x) | Muscarine | Cholinergic | Plant alkaloid. | | |
| BANNED | S0 | | Myo-inositol trispyrophosphate (ITPP, OXY111A). | Oxygen transfer | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Nabumetone | NSAID | Generic. | | |
| BANNED | S0 | | Nadolol | Antihypertensive | Corgard. | | |
| BANNED | S0 | | Nadoxolol | Antihypertensive | Lacks FDA approval. | | |
| BANNED | S0 | | Naepaine | Local anesthetic | Lacks FDA approval. | | |
| BANNED | S2 | | Nafarelin | Reproductive hormone modulator. | Synarel. | | |
| BANNED | S0 | | Naftidrofuryl | Vasodilator | Lacks FDA approval. | | |
| BANNED | S0 | | Nalbuphine | Opioid receptor agonist and antagonist. | Generic. | | |
| CONTROLLED | S7 | A | Nalmefene | Opioid antagonist | Revex. | | |

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|---|---|---|---|---|---|---|---|
| BANNED | S0 | | Nalorphine | Opioid receptor agonist and antagonist. | Nalline. DEA Schedule III.F943. | | |
| CONTROLLED | S7 | B | Naloxone | Opioid antagonist | Narcan, Zimhi, Suboxone (with buprenorphine hydrochloride), Zubsolv (with buprenorphine hydrochloride). | | |
| CONTROLLED | S7 | A | Naltrexone | Opioid antagonist | Trexonil. | | |
| BANNED-fillies, mares and geldings. | S1 | | Nandrolone (19-nortestosterone) | Anabolic | Discontinued, no FDA-approved product commercially available. DEA schedule III. | | |
| CONTROLLED | S7 | B | Naphazoline | Sympathomimetic | Naphcon-A (with pheniramine maleate), Opcon-A (with pheniramine maleate), Visine (with pheniramine maleate). | | |
| CONTROLLED | S7 | C | Naproxen | NSAID | Aleve, Naprosyn, Anaprox. | | |
| BANNED | S0 | | Naratriptan | Selective Serotonin Receptor Agonist. | Amerge. | | |
| CONTROLLED | S7 | C | N-Butylscopolammonium | Anti-cholinergic | Buscopan | Detection Time: 48 hrs. 0.3 mg/kg single IV dose (6 horses). | 25 ng/mL in urine. |
| BANNED | S0 | | Nebivolol | Antihypertensive | Bystolic. | | |
| CONTROLLED | S7 | C | Nedocromil | Mast Cell Stabilizer | Alocril. | | |
| BANNED | S0 | | Nefazodone | Antidepressant | Generic. | | |
| BANNED | S0 | | Nefopam | Analgesic | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Neostigmine | Anticholinesterase | Bloxiverz. | | |
| BANNED | S6 | | Neridronate | Bisphosphonate | Lacks FDA approval. | | |
| BANNED | S0 | | Nialamide | Antidepressant | Lacks FDA approval. | | |
| BANNED | S0 | | Nicardipine | Antihypertensive | Generic. | | |
| BANNED | S0 | | Nicoumalone | Anticoagulant | Lacks FDA approval. | | |
| BANNED | S0 | | Nifedipine | Antihypertensive | Procardia. | | |
| BANNED | S0 | | Nifenalol | Antihypertensive/Antiarrhythmic | Lacks FDA approval. | | |
| BANNED | S0 | | Niflumic acid | NSAID | Lacks FDA approval. | | |
| BANNED | S0 | | Nikethamide | Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Nimesulide | NSAID | Lacks FDA approval. | | |
| BANNED | S0 | | Nimetazepam | Hypnotic | Lacks FDA approval. DEA Schedule IV. | | |
| BANNED | S0 | | Nimodipine | Calcium channel blocker | Generic. | | |
| BANNED | S0 | | Nitrazepam | Sedative/Anxiolytic | Lacks FDA approval. DEA Schedule IV. | | |
| BANNED | S0 | | Nitroglycerin | Vasodilator | Nitromist, Nitro-Dur, Nitrostat. | | |
| CONTROLLED | S7 | C | Nizatidine | Anti-ulcer | Axid. | | |
| BANNED | S0 | | Nomifensine | Antidepressant | Lacks FDA approval. | | |
| BANNED | S1 | | Norandrostenediol | Anabolic | Lacks FDA approval. | | |
| BANNED | S1 | | Norandrostenedione | Anabolic | Lacks FDA approval. | | |
| BANNED | S1 | | Norandrosterone | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S1 | | Norbolethone/Norboletone | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S1 | | Norclostebol | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S0 | | Nordiazepam/Nordazepam (Nordiazepam is a metabolite of diazepam. If there is credible evidence that the presence of nordiazepam in a horse's sample is the consequence of exposure to diazepam, the classification of nordiazepam may be revised to S7(A).). | Sedative/Anxiolytic | Lacks FDA approval. DEA Schedule IV. | | |
| CONTROLLED | S7 | A | Norepinephrine | Stimulant | Levophed. | | |
| BANNED | S1 | | Norethandrolone | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S1 | | Norethisterone (norethindrone) | Anabolic | Combipatch, Activella, Amabelz, Nortrel, Alyacen, Aranelle and multiple others (with estradiol). | | |

| HISA listed as | HISA status | Penalty subclassification (specified substances are designated with 'x') | Substance | Action | Commercial name(s) (developmental names) | Detection time | Screening limit* |
|---|---|---|---|---|---|---|---|
| BANNED | S0 | | Norfenefrine | Antihypotensive | Lacks FDA approval. | | |
| BANNED | S0 | | Norfenfluramine | Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Norfluoxetine (Seproxetine) | Antidepressant | Lacks FDA approval. | | |
| BANNED | S0 | | Norpseudoephedrine (cathine) | Stimulant | Lacks FDA approval. DEA Schedule IV. | | |
| BANNED | S0 | | Nortriptyline | Antidepressant | Pamelor. | | |
| BANNED | S0 | | Noscapine | Antitussive | Lacks FDA approval. | | |
| BANNED | S0 | | Nylidrin (buphenine) | Vasodilator | Lacks FDA approval. | | |
| BANNED | S0 | | Octopamine (Octopamine is a metabolite of ephedrine. If there is credible evidence that the presence of octopamine is a consequence of exposure to ephedrine, the classification of octopamine may be revised to S7(A).). | Stimulant | Lacks FDC approval. | | |
| BANNED | S0 | | Olanzapine | Antipsychotic | Zyprexa. | | |
| BANNED | S0 | | Oliceridine | Opioid agonist | Olinvk. DEA Schedule II. | | |
| BANNED | S0 | | Olmesartan | Antihypertensive | Benicar (with medoxomil). | | |
| BANNED | S3 | | Olodaterol | Beta-2 agonist-bronchodilator | Striverdi Respimat, Stiolto Respimat (with tiotropium bromide). | | |
| BANNED | S6 | | Olpadronate | Bisphosphonate | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Olsalazine | Anti-inflammatory | Diipentum. | | |
| CONTROLLED | S7 | C | Omeprazole | Anti-ulcer | Gastrogard | Restricted administration time: 24 hours. 2.2 g orally once daily for 4 doses (9 horses). | 10 ng/mL in serum or plasma as omeprazole sulfide. |
| BANNED | S0 | | Opipramol | Antidepressant | Lacks FDA approval. | | |
| CONTROLLED | S3 | | Orciprenaline (Metaproterenol) | Beta-2 agonist-bronchodilator | Generic. | | |
| BANNED | S0 | (x) | Oripavine | Opioid | Plant alkaloid. DEA schedule II. | | |
| BANNED | S0 | | Orphenadrine | Muscle relaxant | Generic. | | |
| BANNED | S4 | | Ospemifene | Selective Estrogen Receptor Modulator (SERM). | Osphena. | | |
| BANNED | S1 | | Ostarine (enobosarm) | Selective Androgen Receptor Modulator (SARM). | Lacks FDA approval. | | |
| BANNED | S1 | | Oxabolone | Anabolic | Lacks FDA approval. | | |
| BANNED | S0 | | Oxaflumazine | Psychosedative | Lacks FDA approval. | | |
| BANNED | S1 | | Oxandrolone | Anabolic | Generic. DEA Schedule III. | | |
| BANNED | S0 | | Oxaprozin | NSAID | Daypro. | | |
| BANNED | S0 | | Oxazepam (Oxazepam is a metabolite of diazepam. If there is credible evidence that the presence of oxazepam in a horse's sample is the consequence of exposure to diazepam, the classification of oxazepam may be revised to S7(A).). | Anxiolytic | Generic. DEA Schedule IV. | | |
| BANNED | S0 | | Oxazolam | Sedative/Anxiolytic | Lacks FDA approval. DEA Schedule IV. | | |
| BANNED | S0 | | Oxcarbazepine | Anticonvulsant | Generic. | | |
| BANNED | S0 | | Oxethazaine (Oxetacaine) | Local anesthetic | Lacks FDA approval. | | |
| BANNED | S0 | | Oxilofrine (hydroxyephedrine) | Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Oxolamine | Antitussive | Lacks FDA approval. | | |
| BANNED | S0 | | Oxprenolol | Antihypertensive | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Oxybuprocaine (Benoxinate, oxybucaine). | Local anesthetic | Atafluor Benox. | | |

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| BANNED | S0 | | Oxycodone | Opioid Analgesic | Oxycontin, Roxybond, Roxicodone, Oxaydo, Xtampza; Percocet, Percodan, Oxycet (with NSAID). DEA Schedule II. |
| BANNED | S1 | | Oxyguno | Anabolic | Lacks FDA approval. |
| BANNED | S1 | | Oxymesterone | Anabolic | Lacks FDA approval. DEA Schedule III. |
| CONTROLLED | S7 | B | Oxymetazoline | Nasal decongestant | Rhofade, Upneq, Visine. |
| BANNED | S1 | | Oxymetholone | Anabolic | Discontinued, no FDA-approved product commercially available. DEA Schedule III. |
| BANNED | S0 | | Oxymorphone | Opioid analgesic | Generic. DEA Schedule II. |
| BANNED | S0 | | Oxypertine | Antipsychotic | Lacks FDA approval. |
| BANNED | S0 | | Oxyphencyclimine | Anticholinergic | Discontinued, no FDA-approved product commercially available. |
| BANNED | S0 | | Oxyphenonium | Anticholinergic | Discontinued, no FDA-approved product commercially available. |
| CONTROLLED | S7 | B | Oxytocin | Uterine contraction | Pitocin. |
| BANNED | S0 | | Paliperidone | Antipsychotic | Invega. |
| BANNED | S0 | | Palmitoylethanolamid | Anti-inflammatory | Lacks FDA approval. |
| BANNED | S6 | | Pamidronate | Bisphosphonate | Generic. |
| CONTROLLED | S7 | A | Pancuronium | Muscle relaxant | Generic. |
| CONTROLLED | S7 | C | Pantoprazole | Anti-ulcer | Protonix. |
| BANNED | S0 | (x) | Papaverine | Vasodilator | Plant alkaloid. |
| BANNED | S0 | | Paraldehyde | Anticonvulsant | Lacks FDA approval. DEA Schedule IV. |
| BANNED | S0 | | Paramethadione | Anticonvulsant | Discontinued, no FDA-approved product commercially available. |
| BANNED | S0 | | Paramethasone | Corticosteroid | Discontinued, no FDA-approved product commercially available. |
| BANNED | S0 | (x) | Paraxanthine (Paraxanthine is a metabolite of caffeine. If there is credible evidence that the presence of paraxanthine in a horse's sample is the consequence of exposure to caffeine, the classification of paraxanthine may be revised to S7(B).). | Stimulant | Lacks FDA approval. |
| BANNED | S0 | | Parecoxib | NSAID | Lacks FDA approval. |
| BANNED | S0 | | Pargyline | Antihypertensive | Discontinued, no FDA-approved product commercially available. |
| BANNED | S0 | | Paroxetine | Antidepressant | Paxil. |
| BANNED | S2 | | Pegepoietin | Erythropoiesis | Micera. |
| BANNED | S2 | | Peginesatide | Erythropoiesis | Discontinued, no FDA-approved product commercially available. |
| BANNED | S0 | | Pemoline | Stimulant | Discontinued, no FDA-approved product commercially available. DEA Schedule IV. |
| BANNED | S0 | | Pempidine | Ganglion blocker/ antihypertensive. | Lacks FDA approval. |
| BANNED | S0 | | Penbutolol | Antihypertensive | Discontinued, no FDA-approved product commercially available. |
| BANNED | S0 | | Penfluridol | Antipsychotic | Lacks FDA approval. |
| BANNED | S0 | | Pentaerythritol tetranitrate | Vasodilator | Lacks FDA approval. |
| CONTROLLED | S7 | B | Pentazocine | Opiate analgesic | Generic (with naloxone hydrochloride). DEA Schedule IV. |
| BANNED | S0 | | Pentetrazol | Stimulant | Lacks FDA approval. |
| BANNED | S0 | | Pentifylline | Vasodilator | Lacks FDA approval. |
| CONTROLLED | S7 | A | Pentobarbital | Barbiturate | Nembutal. DEA Schedule II. |
| CONTROLLED | S7 | C | Pentoxyfylline | Vasodilator | Discontinued, no FDA-approved product commercially available. |
| BANNED | S0 | | Pentylenetetrazol | Stimulant | Lacks FDA approval. |
| BANNED | S2 | | Perfluorodecahydronophthalene | Oxygen transfer | Lacks FDA approval. |
| BANNED | S0 | | Perfluorodecalin (Octadecafluoronaphthalene). | Oxygen transport | Lacks FDA approval. |

| HISA listed as | HISA status | Penalty subclassification (specified substances are designated with 'x') | Substance | Action | Commercial name(s) (developmental names) | Detection time | Screening limit* |
|---|---|---|---|---|---|---|---|
| BANNED | S2 | | Perfluorooctyl bromide | Oxygen transfer | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S2 | | Perfluorotripropylamine | Oxygen transfer | Discontinued, no FDA-approved product commercially available. | | |
| CONTROLLED | S7 | B | Pergolide | Dopamine agonist | Prascend. | | |
| BANNED | S0 | | Periciazine | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S0 | | Perindopril | Antihypertensive | Generic, Prestalia (with amlodipine besylate). | | |
| BANNED | S0 | | Perlapine | Sedative/Hypnotic | Lacks FDA approval. | | |
| BANNED | S0 | | Perphenazine | Antipsychotic | Generic. | | |
| BANNED | S0 | | Phenacemide | Anticonvulsant | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Phenaglycodol | Sedative/Anxiolytic | Lacks FDA approval. | | |
| BANNED | S0 | | Phenazocine | Opioid analgesic | Lacks FDA approval. DEA Schedule II. | | |
| BANNED | S0 | | Phenazone | NSAID | Lacks FDA approval. | | |
| CONTROLLED | S7 | A | Phenazopyridine | Local anesthetic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Phencyclidine (PCP) | Dissociative hallucinogen | Lacks FDA approval. DEA Schedule I. | | |
| BANNED | S0 | | Phendimetrazine | Stimulant | Bontril. DEA Schedule III. | | |
| BANNED | S0 | | Phenelzine | Antidepressant | Nardil. | | |
| BANNED | S0 | | Phenibut | Anxiolytic | Lacks FDA approval. | | |
| BANNED | S0 | | Phenindamine | Antihistamine | Lacks FDA approval. | | |
| BANNED | S0 | | Phenindione | Anticoagulant | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Pheniramine | Antihistamine | Bromfed-DM (with dextromethorphan and pseudoephedrine). | | |
| BANNED | S0 | | Phenmetrazine | Stimulant | Discontinued, no FDA-approved product commercially available. | | |
| CONTROLLED | S7 | A | Phenobarbital | Barbiturate | predates FDA, grandfathered. DEA schedule IV. | | |
| BANNED | S0 | | Phenoxybenzamine | Antihypertensive | Dibenzyline. | | |
| BANNED | S0 | | Phenprocoumon | Anticoagulant | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Phenpromethamine | Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Phensuximide | Anticonvulsant | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Phentermine | Stimulant | Adipex-P, Lomaira, Qsymia. DEA Schedule IV. | | |
| CONTROLLED | S7 | B | Phentolamine | Vasodilator | Oraverse. | | |
| CONTROLLED | S7 | C | Phenylbutazone | NSAID (3 NSAIDs (Flunixin, Ketoprofen, Phenylbutazone) are associated with a Detection Time of 48 hours. Only one of the three may be administered using a Withdrawal Interval based on the 48 hour Detection Time. To avoid a stacking violation (detection of more than 1 NSAID in a blood sample) the following secondary Detection Times should be applied for the following NSAIDs: Flunixin: 144 hours; Ketoprofen: 96 hours; Phenylbutazone: 168 hours.). | Butazolidin, Butatron, EquiBute, Phen Buta Vet, Bizolin, Butequine, Superiorbute, Pributazone. | Detection Time: 48 hours. 4.4 mg/kg single IV dose. (17 horses). | 0.2 mcg/mL in serum or plasma. *Note:* The detection of more than one NSAID in a horse's post-Race or post-Official Workout blood and sample constitutes a Stacking Violation. |
| CONTROLLED | S7 | B | Phenylephrine | Stimulant | Biorphen. | | |

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|---|---|---|---|---|---|---|---|
| BANNED | S0 | | Phenylpiracetam (Carphedon) | Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Phenylpropanolamine | Stimulant | Proin. | | |
| BANNED | S0 | | Phenyltoloxamine | Antihistamine | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Phenytoin | Anti-convulsant | Dilantin, Phenytek. | | |
| BANNED | S0 | | Pholcodine | Opioid antitussive | Lacks FDA approval; DEA Schedule I. | | |
| BANNED | S0 | | Pholedrine | Stimulant | Lacks FDA approval. | | |
| CONTROLLED | S7 | A | Physostigmine | Acetylcholinesterase inhibitor | Antilirium. | | |
| BANNED | S0 | | Picrotoxin | Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Piminodine | Opioid analgesic | Lacks FDA approval. DEA Schedule II. | | |
| BANNED | S1 | | Pimobendan | Cardiac stimulant | Vetmedin. | | |
| BANNED | S0 | | Pimozide | Antipsychotic | Generic. | | |
| BANNED | S0 | | Pinazepam | Anxiolytic | Lacks FDA approval. DEA Schedule IV. | | |
| BANNED | S0 | | Pinazepam | Sedative/Anxiolytic | Lacks FDA approval. | | |
| BANNED | S0 | | Pindolol | Antihypertensive | Generic. | | |
| BANNED | S0 | | Pipamazine | Anti-emetic | Lacks FDA approval. | | |
| BANNED | S0 | | Pipamperone | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S0 | | Pipecuronium | Muscle relaxant | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Pipequaline | Anxiolytic | Lacks FDA approval. | | |
| BANNED | S0 | | Piper Methysticum (kava) | Anxiolytic/Anti-inflammatory | Lacks FDA approval. | | |
| BANNED | S0 | | Piperacetazine | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S0 | | Piperidione | Sedative | Lacks FDA approval. | | |
| BANNED | S0 | | Piperidolate | Antispasmodic | Lacks FDA approval. | | |
| BANNED | S0 | | Piperocaine | Local anesthetic | Lacks FDA approval. | | |
| BANNED | S0 | | Piperoxan | Antihistamine/Antihypertensive | Lacks FDA approval. | | |
| BANNED | S0 | | Pipotiazine | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S0 | | Pipradrol | Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Piquindone | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S0 | | Piracetam | Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Pirbuterol | Beta-2 agonist-bronchodilator | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Pirenzepine | Anticholinergic | Lacks FDA approval. | | |
| BANNED | S5 | | Piretanide | Diuretic | Lacks FDA approval. | | |
| BANNED | S0 | | Piritramide | Synthetic opioid analgesic | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Piroxicam | NSAID | Feldene. | | |
| BANNED | S0 | | Pirprofen | NSAID | Lacks FDA approval. | | |
| BANNED | S6 | | Pitcher Plant Extract | Analgesic | Sarapin. | | |
| BANNED | S0 | | Pizotifen (Pizotylline) | Antimigraine | Lacks FDA approval. | | |
| BANNED | S2 | | Platelet-Derived Growth Factor (PDGF). | Growth Hormone. | | | |
| BANNED | S5 | | Polythiazide | Diuretic | Discontinued, no FDA-approved product commercially available. | | |
| CONTROLLED | S7 | A | Potassium Bromide | Anti-convulsant/anxiolytic | KBroVet-CA1. | | |
| BANNED | S0 | | Practolol | Antiarrhythmic | Lacks FDA approval. | | |
| BANNED | S2 | | Pralmorelin | Growth Hormone | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Pramoxine | Topical anesthetic | Epifoam (with hydrocortisone acetate), Pramosone (with hydrocortisone acetate). | | |
| BANNED | S1 | | Prasterone (dehydroepiandrosterone, DHEA, 3βhydroxyandrost-5-en17-one). | Anabolic | Intrarosa. | | |
| BANNED | S0 | | Prazepam | Sedative/Anxiolytic | Discontinued, no FDA-approved product commercially available. DEA Schedule IV. | | |
| BANNED | S0 | | Prazosin | Antihypertensive | Minipress. | | |
| CONTROLLED | S7 | C | Prednisolone | Corticosteroid | Endogenous subtance (urine only) per IFHA. | | Threshold: 0.01 mcg/mL free prednisolone in urine. |
| CONTROLLED | S7 | C | Prednisone | Corticosteroid | Rayos. | | |
| CONTROLLED | S7 | A | Pregabalin | Anticonvulsant/Analgesic | Lyrica. DEA Schedule V. | | |
| BANNED | S0 | | Prenylamine | Vasodilator | Lacks FDA approval. | | |
| BANNED | S0 | | Pridinol | Anticholinergic | Lacks FDA approval. | | |

| HISA listed as | HISA status | Penalty subclassification (specified substances are designated with 'x') | Substance | Action | Commercial name(s) (developmental names) | Detection time | Screening limit* |
|---|---|---|---|---|---|---|---|
| BANNED | S0 | | Prifinium Bromide | Antispasmodic | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Prilocaine | Local | Emla (with lidocaine), Oraqix (with lidocaine), Citanest (with epinephrine). | | |
| CONTROLLED | S7 | B | Primidone | Anticonvulsant | Mysoline. | | |
| BANNED | S5 | | Probenecid | Anti-gout | Probalan. | | |
| CONTROLLED | S7 | B | Procainamide | Antiarrhythmic | Generic. | | |
| CONTROLLED | S7 | B | Procaine | Local anesthetic | (with Penicillin G) | 17 mg (~17,000 IU) per kg IM. | 25 ng/mL in serum or plasma. |
| BANNED | S0 | | Procarbazine | Antineoplastic | Matulane. | | |
| BANNED | S3 | | Procaterol | Beta-2 agonist-bronchodilator | Lacks FDA approval. | | |
| BANNED | S0 | | Prochlorperazine | Anti-nausea | Compro, Procomp, Compazine. | | |
| BANNED | S0 | | Procyclidine | Anticholinergic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Proglumide | Anti-ulcer | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Promazine | Sedative/Antipsychotic | Promazine Granules. | | |
| CONTROLLED | S7 | B | Promethazine | Antihistamine | Promethegan. *Note:* Component of multiple OTC cough/cold formulations. | | |
| BANNED | S0 | | Pronethalol | Antiarrhythmic | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Propafenone | Antiarrhythmic | Rythmol. | | |
| BANNED | S0 | | Propallylonal | Sedative/Hypnotic | Lacks FDA approval. | | |
| BANNED | S0 | | Propanidid | Anesthetic | Lacks FDA approval. | | |
| BANNED | S0 | | Propantheline | Anticholinergic | Discontinued, no FDA-approved product commercially available. | | |
| CONTROLLED | S7 | C | Proparacaine (Proxymetacaine) | Local anesthetic | Alcane. | | |
| BANNED | S0 | | Propentophylline (propentofylline). | Phosphodiesterase inhibitor | Lacks FDA approval. | | |
| BANNED | S0 | | Propiomazine | Antipsychotic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Propionylpromazine | Sedative | Lacks FDA approval. | | |
| BANNED | S0 | | Propiram | Opioid analgesic | Lacks FDA approval. DEA Schedule I. | | |
| CONTROLLED | S7 | A | Propofol | Anesthetic | PropoFlo, Rapanofal. | | |
| BANNED | S0 | | Propoxycaine | Local anesthetic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Propoxyphene | Opioid analgesic | Discontinued, no FDA-approved product commercially available. | | |
| CONTROLLED | S7 | A | Propranolol | Antiarrhythmic/Antihypertensive | Inderal, Hemangeol. | | |
| BANNED | S0 | | Propylhexedrine | Stimulant | Benzedrex. | | |
| BANNED | S0 | | Propyphenazone | NSAID | Lacks FDA approval. | | |
| BANNED | S0 | | Proquazone | NSAID | Lacks FDA approval. | | |
| BANNED | S1 | | Prostanazol | Anabolic | Lacks FDA approval. DEA Schedule III.F1166. | | |
| BANNED | S0 | | Prothipendyl | Anxiolytic/Antihistamine | Lacks FDA approval. | | |
| BANNED | S0 | | Protokylol | Bronchodilator | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Protriptyline | Antidepressant | Generic. | | |
| BANNED | S0 | | Proxibarbital | Sedative/Anxiolytic | Lacks FDA approval. | | |
| BANNED | S0 | | Proxyphylline | Bronchodilator | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Pseudoephedrine | Stimulant | Sudafed. | | |
| BANNED | S0 | | Psilocin (Psilocyn) | Hallucinogen | Lacks FDA approval; DEA Schedule I. | | |
| CONTROLLED | S7 | B | Pyridostigmine | Cholinesterase Inhibitor | Mestinon, Regonol. | | |
| CONTROLLED | S7 | B | Pyrilamine | Antihistamine | Histavet-P. | | |
| BANNED | S0 | | Pyrithyldione | Sedative/Hypnotic | Lacks FDA approval. | | |
| BANNED | S0 | | Pyrrobutamine | Antihistamine | Lacks FDA approval. | | |
| BANNED | S0 | | Quazepam | Sedative | Doral.DEA Schedule IV. | | |
| BANNED | S0 | | Quetiapine | Antipsychotic | Lacks FDA approval. | | |

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|---|---|---|---|---|---|---|---|
| BANNED | S0 | | Quinapril, Quinaprilat | Antihypertensive | Accuretic. | | |
| BANNED | S1 | | Quinbolone | Anabolic | Lacks FDA approval. | | |
| BANNED | S5 | | Quinethazone | Diuretic | Discontinued, no FDA-approved product commercially available. | | |
| CONTROLLED | S7 | B | Quinidine | Anti-arrhythmic | Generic. | | |
| BANNED | S0 | | Quinisocaine | Local anesthetic | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Rabeprazole | Anti-ulcer | Aciphex. | | |
| BANNED | S0 | | Racemethorphan | Anti-Alzheimer's | Lacks FDA approval. DEA Schedule II. | | |
| BANNED | S0 | | Racemorphan | Opioid agonist | Lacks FDA approval. DEA Schedule II. | | |
| BANNED | S0 | | Raclopride | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S1 | (x) | Ractopamine | Anabolic | Paylean, Optaflexx, Topmax. | | |
| BANNED | S4 | | Raloxifene | Selective Estrogen Receptor Modulator (SERM). | Evista. | | |
| BANNED | S4 | | Ramatercept (ACE–031) | Myostatin inhibitor | Lacks FDA approval. | | |
| BANNED | S0 | | Ramifenazone (Isopyrin) | NSAID | Lacks FDA approval. | | |
| BANNED | S0 | | Ramipril, metabolite Ramiprilat | Antihypertensive | Altace. | | |
| CONTROLLED | S7 | C | Ranitidine | Anti-ulcer | Generic | Restricted administration time: 24 hours. 8 mg/kg orally twice daily for 7 doses. (9 horses). | 40 ng/mL in serum or plasma. |
| BANNED | S0 | | Regadenoson | Cardiac stimulant | Lexiscan. | | |
| BANNED | S0 | | Remifentanil | Synthetic opioid analgesic | Ultiva. DEA Schedule II. | | |
| BANNED | S0 | | Remimazolam | Anesthetic | Byfavo. DEA schedule IV. | | |
| BANNED | S0 | | Remoxipride | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S3 | | Reproterol | Beta-2 agonist-bronchodilator | Lacks FDA approval. | | |
| CONTROLLED | S7 | A | Reserpine | Antihypertensive/Depressant | Serpasil. | | |
| BANNED | S0 | | Rilmazafone | Sedative/Hypnotic | Lacks FDA approval. | | |
| BANNED | S3 | | Rimiterol | Beta-2 agonist-bronchodilator | Lacks FDA approval. | | |
| BANNED | S6 | | Risedronate | Bisphosphonate | Actonel. | | |
| BANNED | S0 | | Risperidone | Antipsychotic | Perseris Kit, Risperdal Consta, Risperdal. | | |
| BANNED | S0 | | Ritanserin | Antidepressant | Lacks FDA approval. | | |
| BANNED | S3 | | Ritodrine | Beta-2 agonist | Lacks FDA approval. | | |
| BANNED | S0 | | Rivastigmine | Cholinesterase Inhibitor | Exelon. | | |
| BANNED | S0 | | Rizatriptan | Selective Serotonin Receptor Agonist. | Maxalt. | | |
| CONTROLLED | S7 | A | Rocuronium | Muscle relaxant | Generic. | | |
| BANNED | S0 | | Rofecoxib | NSAID | Discontinued, no FDA-approved product commercially available. | | |
| CONTROLLED | S7 | B | Romifidine | Sedative | Sedivet | Detection Time: 60 hours. 80 mcg/kg single IV dose (6 horses). | 1 ng/mL in urine. |
| CONTROLLED | S7 | A | Ropivacaine | Local anesthetic | Naropin. | | |
| BANNED | S2 | | Roxadustat (FG–4592) | Erythropoiesis | Lacks FDA approval. | | |
| BANNED | S0 | | Salicylamide | Analgesic | Lacks FDA approval. | | |
| CONTROLLED—when administered via inhalation. | S7 | B | Salmeterol | Beta-2 agonist-bronchodilator | Serevent, Advair (with fluticasone), Airduo (with fluticasone), Wixela (with fluticasone). | | |
| BANNED | S1 | | SARM YK–11 | Anabolic | Lacks FDA approval. | | |
| CONTROLLED | S7 | C (x) | Scopolamine (Hyoscine) | Anticholinergic | Transdermal Scop; Dietary substance per IFHA. | | 60 ng/mL total (free and conjugated) in urine. |
| CONTROLLED | S7 | A | Secobarbital (Quinalbarbitone) | Sedative/Hypnotic | Discontinued, no FDA-approved product commercially available. DEA Schedule II. | | |
| BANNED | S0 | | Selegiline | Antidepressant | Emsam, Zelapar. | | |
| BANNED | S2 | | Sermorelin | Growth Hormone | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Sertraline | Antidepressant | Zoloft. | | |
| BANNED | S0 | | Sibutramine | Stimulant | Discontinued, no FDA-approved product commercially available. DEA Schedule IV. | | |
| BANNED | S0 | | Sildenafil | Phosphodiesterase inhibitor | Viagra. | | |
| BANNED | S6 | | Snake Venoms | Neurotoxin | Lacks FDA approval. | | |
| BANNED | S2 | | Somatrem | Growth Hormone | Protropin. | | |

| HISA listed as | HISA status | Penalty subclassification (specified substances are designated with 'x') | Substance | Action | Commercial name(s) (developmental names) | Detection time | Screening limit* |
|---|---|---|---|---|---|---|---|
| BANNED | S2 | | Somatrogon | Growth Hormone | Lacks FDA approval. | | |
| BANNED | S2 | | Somatropin | Growth Hormone | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Sotalol | Antiarrhythmic | Betapace, Sorine, Sotylize. | | |
| BANNED | S2 | | Sotatercept | Growth Hormone | Lacks FDA approval. | | |
| BANNED | S0 | (x) | Sparteine | Antiarrhythmic | Lacks FDA approval. | | |
| BANNED | S0 | | Spiperone | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S0 | | Spirapril, metabolite Spiraprilat | Antihypertensive | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S5 | | Spironalactone | Diuretic | Aldactazide, Caarospir, Aldactone. | | |
| BANNED | S4 | | Stamulumab (Myo-29) | Myostatin inhibitor | Lacks FDA approval. | | |
| BANNED | S1 | | Stanozolol | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S1 | | Stenbolone | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S0 | | Strychnine | CNS stimulant | Lacks FDA approval. (Has anetodal use as contituent of unregulated appetite stimulants and leg paints. Extreme caution is advised when using these products.). | | |
| BANNED | S0 | | Styramate | Muscle relaxant | Lacks FDA approval. | | |
| CONTROLLED | S7 | A | Succinylcholine | Muscle relaxant | Anectine, Quelicin. | | |
| BANNED | S0 | | Sufentanil | Opioid analgesic | Sufenta, Dsuvia. DEA Schedule II. | | |
| CONTROLLED | S7 | C | Sulfasalazine | Disease-modifying anti-rheumatic. | Azulfadine. | | |
| BANNED | S0 | | Sulfondiethylmethane | Sedative/Hypnotic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S0 | | Sulfonmethane | Sedative/Hypnotic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S0 | | Sulforidazine | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S0 | | Sulindac | NSAID | Generic. | | |
| BANNED | S0 | | Sulpiride | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S0 | | Sultopride | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S0 | | Sumatriptan | Selective Serotonin Receptor Agonist. | Imitrex, Treximet [with naproxen]. | | |
| CONTROLLED | S7 | C | Suprofen | NSAID | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Suxibuzone | NSAID | Lacks FDA approval. | | |
| BANNED | S0 | (x) | Synephrine | Stimulant | Lacks FDA approval. | | |
| BANNED | S4 | | T3 (triiodothyronine) | Metabolic hormone | Lacks FDA approval. | | |
| BANNED | S4 | | T4 (tetraiodothyronine/thyroxine). | Metabolic hormone | Thyro-Tabs Canine, Thyrokare. | | |
| BANNED | S2 | | Tabimorelin | Growth Hormone | Lacks FDA approval. | | |
| BANNED | S0 | | Tadalafil | Phosphodiesterase inhibitor | Cialis. | | |
| BANNED | S0 | | Talbutal | CNS depressant | Discontinued, no FDA-approved product commercially available. DEA Schedule III. | | |
| BANNED | S4 | | Tamoxifen | Selective Estrogen Receptor Modulator (SERM). | Soltamox. | | |
| BANNED | S0 | | Tandospirone | Anxiolytic | Lacks FDA approval. | | |
| BANNED | S0 | | Tapentadol | Opioid analgesic | Nucynta. DEA Schedule II. | | |
| BANNED | S0 | | Telmisartan | Antihypertensive | Micardis. | | |

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|---|---|---|---|---|---|---|---|
| CONTROLLED | S7 | B | Temazepam (Temazepam is a major metabolite of diazepam. If there is credible evidence that the presence of temazepam in a horse's sample is the consequence of exposure to diazepam, the classification of temazepam may be revised to S7(B).). | Anxiolytic | Restoril. DEA Schedule IV. | | |
| BANNED | S0 | | Tenoxicam | NSAID | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Tepoxalin | NSAID | Zubrin. | | |
| BANNED | S0 | | Terazosin | Antihypertensive | Generic. | | |
| BANNED | S3 | | Terbutaline | Bronchodilator | Brethine. | | |
| BANNED | S0 | | Terfenadine | Antihistamine | Lacks FDA approval. | | |
| BANNED | S2 | | Tesamorelin | Growth Hormone | Egrifta. | | |
| BANNED | S4 | | Testolactone | Aromatase inhibitor | Teslac. DEA Schedule III. | | |
| BANNED | S2 | | Testolone | Selective Androgen Receptor Modulator (SARM). | Lacks FDA approval. | | |
| BANNED—Fillies and Mares (unless in foal). | S1 | | Testosterone | Anabolic | Androderm, Testm, Vogelxo, Testopel, Aveed, Kyzatrex, Jatenzo, Xyosted. DEA Schedule III. | | Threshold: 55 ng/mL total (free and conjugated) testosterone in urine OR 0.1 n/mL free testosterone in serum or plasma. |
| BANNED—Geldings | S1 | | Testosterone | Anabolic | Androderm, Testm, Vogelxo, Testopel, Aveed, Kyzatrex, Jatenzo, Xyosted. DEA Schedule III. | | Threshold: 20 ng/mL total (free and conjugated) testosterone in urine OR 0.1 ng/mL free testosterone in serum or plasma. |
| BANNED | S0 | | Tetrabenazine (deutetrabenazine). | Neurotransmitter modulator | Xenazine, Austedo. | | |
| CONTROLLED | S7 | B | Tetracaine | Local anesthetic | Pliaglis [with lidocaine], Synera [with lidocaine], Kovanze [with oxymetazoline]. | | |
| BANNED | S1 | | Tetrahydrogestrinone | Anabolic | Lacks FDA approval. DEA Schedule III. | | |
| CONTROLLED | S7 | B | Tetrahydrozoline | Topical Decongestant | Visine. | | |
| BANNED | S0 | | Tetrazepam | Anxiolytic | Lacks FDA approval. DEA Schedule IV. | | |
| BANNED | S1 | | THC (tetrahydrocannabinol) | Psychoactive | Lacks FDA approval. DEA Schedule I. | | |
| BANNED | S0 | (x) | Thebaine | Opioid analgesic | Lacks FDA approval. DEA Schedule II. | | |
| CONTROLLED | S7 | B (x) | Theobromine | Bronchodilator/Vasodilator | Lacks FDA approval; Dietary substance per IFHA. | | Threshold: mcg/mL (free and conjugated) in urine OR 0.3 mcg/mL in serum or plasma. |
| CONTROLLED | S7 | B (x) | Theophylline | Bronchodilator | Generic; Dietary subtance per IFHA. | | Threshold: 250 ng/mL (free and conjugated) in urine. |
| BANNED | S0 | | Thialbarbital | Sedative/Hypnotic | Lacks FDA approval. | | |
| CONTROLLED | S7 | A | Thiamylal | Sedative/Hypnotic | Surital, Biotal, Anestatal. DEA Schedule III. | | |
| BANNED | S0 | | Thiethylperazine | Antipsychotic | Discontinued, no FDA-approved product commercially available. | | |
| CONTROLLED | S7 | A | Thiopental (pentothal) | Anesthetic | Combuthal Powder, Xylamed. DEA Schedule III. | | |
| BANNED | S0 | | Thiopropazate | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S0 | | Thioproperazine | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S0 | | Thioridazine | Antipsychotic | Generic. | | |
| BANNED | S0 | | Thiothixene | Antipsychotic | Generic. | | |
| BANNED | S0 | | Thiphenamil (tifenamil) | Antispasmodic/Local anesthetic | Lacks FDA approval. | | |
| BANNED | S0 | | Thonzylamine | Antihistamine/anticholinergic | Lacks FDA approval. | | |
| BANNED | S0 | | Thozalinone | Antidepressant | Lacks FDA approval. | | |
| BANNED | S2 | | Thymosin | Peptide hormone | Lacks FDA approval. | | |

| HISA listed as | HISA status | Penalty subclassification (specified substances are designated with 'x') | Substance | Action | Commercial name(s) (developmental names) | Detection time | Screening limit* |
|---|---|---|---|---|---|---|---|
| BANNED | S0 | | Tiapride | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S0 | | Tiaprofenic acid | NSAID | Lacks FDA approval. | | |
| BANNED | S1 | | Tibolone | Anabolic | Lacks FDA approval. | | |
| BANNED | S6 | | Tildronate (Tiludronic Acid) | Bisphosphonate | Tildren. | | |
| CONTROLLED | S7 | A | Tiletamine | Anesthetic | Telazol [with zolazepam]. DEA Schedule III. | | |
| BANNED | S0 | | Timiperone | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S3 | | Timolol | Antihypertensive | Istalol, Betimol, Timoptic. | | |
| CONTROLLED | S7 | B | Tiotropium | Bronchodilator | Spiriva. | | |
| BANNED | S0 | | Tocainide | Antiarrhythmic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Tofenacin | Antidepressant | Lacks FDA approval. | | |
| BANNED | S0 | | Tofisopam | Anxiolytic | Lacks FDA approval. | | |
| CONTROLLED | S7 | A | Tolazoline | Vasodilator | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Tolfenamic Acid | NSAID | Lacks FDA approval. | | |
| BANNED | S0 | | Tolmetin | NSAID | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S5 | | Tolvaptan | Diuretic | Jynarque, Samsca. | | |
| BANNED | S0 | | Tolycaine | Local anesthetic | Lacks FDA approval. | | |
| BANNED | S0 | | Topiramate | Anticonvulsant | Topamax, Qsymia (with phentermine hydrochloride). | | |
| BANNED | S4 | | Toremifene | Selective Estrogen Receptor Modulator (SERM). | Fareston. | | |
| BANNED | S5 | | Torsemide (Torasemide) | Diuretic | Soaanz. | | |
| CONTROLLED | S7 | B | Tramadol | Opioid Analgesic | Ultram. DEA Schedule IV. | | |
| BANNED | S0 | | Tramazoline | Sympathomimetic | Lacks FDA approval. | | |
| BANNED | S0 | | Trandolapril (and metabolite, trandolaprilat). | Antihypertensivle | Generic. | | |
| CONTROLLED | S7 | C | Tranexamic acid | Antifibrinolytic | Cykokapron. | | |
| BANNED | S0 | | Tranylcypromine | Antidepressant | Parnate. | | |
| BANNED | S0 | | Trazodone | Antidepressant | Generic. | | |
| BANNED | S1 | | Trenbolone (trendione) | Anabolic | Finaplix; Revalor, Synovex (with Estradiol); Component (with estradiol and tylosin). DEA Schedule III. | | |
| BANNED | S1 | | Trendione | Anabolic | Lacks FDA approval. | | |
| BANNED | S0 | | Trestolone | Anabolic | Lacks FDA approval. | | |
| BANNED | S3 | | Tretoquinol (trimetoquinol) | Beta-2 agonist-bronchodilator | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Triamcinolone | Corticosteroid | Vetalog, Kenalog | | 0.5 ng/mL in urine |
| BANNED | S5 | | Triamterene | Diuretic | Dyrenium. | | |
| BANNED | S0 | | Triazolam | CNS depressant | Halcion. DEA Schedule IV. | | |
| BANNED | S0 | | Tribromoethanol | Anesthetic | Lacks FDA approval. | | |
| BANNED | S0 | | Tricaine methanesulfonate | Anesthetic | Syncaine. | | |
| CONTROLLED | S7 | C | Trichlormethiazide | Diuretic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Trichloroethanol | Sedative/Hypnotic | Lacks FDA approval. | | |
| BANNED | S0 | | Trichloroethylene | Anesthetic | Lacks FDA approval. | | |
| BANNED | S0 | | Triclofos | Sedative | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Tridihexethyl | Anticholinergic | No FDA-approved product. | | |
| BANNED | S0 | | Triflumeprazine | Sedative | Lacks FDA approval. | | |
| BANNED | S0 | | Trifluoperazine | Antipsychotic | Generic. | | |
| BANNED | S0 | | Trifluoromethylphenyl piperazine | Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Trifluperidol | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S0 | | Triflupromazine | Antipsychotic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Triflupromazine | Antipsychotic | Discontinued, no FDA-approved product commercially available. | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| BANNED | S0 | | Trihexyphenidyl | Anticholinergic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Trimecaine | Local anesthetic | Lacks FDA approval. | | |
| BANNED | S0 | | Trimeprazine (alimemazine) | Antihistamine | Temaril-P [with prednisolone]. | | |
| BANNED | S4 | | Trimetazidine | Angina treatment | Lacks FDA approval. | | |
| BANNED | S0 | | Trimethadione | Anticonvulsant | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Trimethaphan | Antihypertensive/Anesthetic | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Trimipramine | Antidepressant | Generic. | | |
| CONTROLLED | S7 | B | Tripelennamine | Antihistamine | Re-Covr. | | |
| BANNED | S0 | | Triprolidine | Antihistamine | Triacin-C (with codeine phosphate and pseudoephedrine hydrochloride). | | |
| BANNED | S2 | | Triptorelin | Reproductive hormone modulator. | Triptodur, Trelstar. | | |
| BANNED | S0 | | Trometamol (Tris hydroxymethylaminomethane [THAM]. | Alkalinizing agent | Discontinued, no FDA-approved product is commercially available. | | |
| CONTROLLED | S7 | B | Tropicamide | Ophthalmic Anticholinergic | Mydriacyl. | | |
| BANNED | S0 | | Tuaminoheptane | Stimulant | Lacks FDA approval. | | |
| BANNED | S0 | | Tubocurarine (Curare) | Muscle relaxant | Plant alkaloid. Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S3 | | Tulobuterol | Beta-2 agonist-bronchodilator | Lacks FDA approval. | | |
| BANNED | S0 | | Tybamate | Anxiolytic | Lacks FDA approval. | | |
| BANNED | S0 | | Valdecoxib | NSAID | Discontinued, no FDA-approved product commercially available. | | |
| CONTROLLED | S7 | A | Valerenic acid | Sedative | Plant derived. | | |
| BANNED | S0 | | Valnoctamide | Sedative/Hypnotic | Lacks FDA approval. | | |
| BANNED | S0 | | Valproate Sodium | Anticonvulsant | Discontinued, no FDA-approved product commercially available. | | |
| BANNED | S0 | | Valsartan | Antihypertensive | Diovan, Entresto (with sacubitril). | | |
| BANNED | S0 | | Vardenafil | Phosphodiesterase inhibitor | Levitra. | | |
| BANNED | S2 | | Vascular-Endothelial Growth Factor (VEGF). | Growth Hormone. | | | |
| CONTROLLED | S7 | A | Vecuronium | Muscle relaxant | Generic. | | |
| BANNED | S0 | | Vedaprofen | NSAID | Lacks FDA approval. | | |
| BANNED | S0 | | Venlafaxine | Antidepressant | Pristiq. | | |
| BANNED | S0 | | Veralipride | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S0 | | Verapamil | Antihypertensive | Verelan, Calan. | | |
| BANNED | S3 | | Vilanterol | Beta-2 agonist-bronchodilator | Trelegy, Ellipta. | | |
| BANNED | S0 | | Viloxazine | Antidepressant | Qelbree. | | |
| BANNED | S0 | | Vinbarbital | Hypnotic | Lacks FDA approval. DEA Schedule III. | | |
| BANNED | S0 | | Vinylbital | Sedative/Hypnotic | Lacks FDA approval. | | |
| CONTROLLED | S7 | C | Warfarin | Anticoagulant | Coumadin, Jantoven. | | |
| BANNED | S2 | | Xenon | HIF activating agent. | | | |
| BANNED | S5 | | Xipamide | Diuretic | Lacks FDA approval. | | |
| CONTROLLED | S7 | B | Xylazine | Sedative/Analgesic | Rompun, Anased | Detection Time: 72 hours. 200 mg single IV dose. | SL: 10 ng/mL U (as 4–OH xylazine); 0.05 ng/mL B. |
| BANNED | S0 | | Xylometazoline | Stimulant | Afrin, Vicks Sinex. | | |
| CONTROLLED | S7 | B | Yohimbine | Stimulant | Antagonil. | | |
| BANNED | S0 | | Zafirlukast | Asthma prevention | Accolate. | | |
| BANNED | S0 | | Zaleplon | CNS depressant | Sonata. DEA Schedule IV. | | |
| BANNED | S1 | | Zeranol | Anabolic | Ralgro. | | |
| BANNED | S6 | | Ziconotide | Neurotoxin | Prialt. | | |
| BANNED | S0 | | Zileuton | Asthma prevention | Zyflo. | | |
| BANNED | S1 | (x) | Zilpaterol hydrochloride | Anabolic | Zilmax, Heifermax. | | |
| BANNED | S0 | | Zimeldine | Antidepressant | Lacks FDA approval. | | |
| BANNED | S0 | | Ziprasidone | Antipsychotic | Geodon. | | |
| CONTROLLED | S7 | A | Zolazepam | Sedative/Anxiolytic | Telazol [with tiletamine]. | | |
| BANNED | S6 | | Zoledronic acid | Bisphosphonate | Reclast. | | |
| BANNED | S0 | | Zolmitriptan | Selective Serotonin Receptor Agonist. | Zomig. | | |

| HISA listed as | HISA status | Penalty subclassification (specified substances are designated with 'x') | Substance | Action | Commercial name(s) (developmental names) | Detection time | Screening limit * |
|---|---|---|---|---|---|---|---|
| BANNED | S0 | | Zolpidem | Sedative/Hypnotic | Ambien. DEA Schedule IV. | | |
| BANNED | S0 | | Zomepirac | Anticonvulsant | Lacks FDA approval. | | |
| BANNED | S0 | | Zonisamide | Anticonvulsant | Zonegran. | | |
| BANNED | S0 | | Zopiclone | Sedative/Hypnotic | Lunesta. DEA Schedule IV. | | |
| BANNED | S0 | | Zotepine | Antipsychotic | Lacks FDA approval. | | |
| BANNED | S0 | | Zuclopenthixol | Antipsychotic | Lacks FDA approval. | | |

*(Unless otherwise designated as a Threshold). Where no value is listed for serum or plasma the substance is controlled by Laboratory Limit of Detection. Unless otherwise specified, urine values are in *hydrolyzed* urine.

*5000. Equine Testing and Investigations Standards*

5010. Purpose

(a) The Equine Testing and Investigations Standards have been developed pursuant to the Act and the Protocol.

(b) The first purpose of the Testing and Investigations Standards is to plan for intelligent and effective Testing, both in- and out-of-competition, and to maintain the integrity and identity of the Samples collected from the point of notification of a Covered Horse's selection for Sample collection, to the point the Samples are delivered to a Laboratory for analysis. To that end, these Testing and Investigations Standards establish protocols for test planning, notification of a Covered Horse's selection for Sample collection, preparing for and conducting Sample collection, security/post-test administration of Samples and documentation, and transport of Samples to Laboratories for analysis.

(c) The second purpose of the Testing and Investigations Standards is to establish rules for the efficient and effective gathering, assessment, and use of anti-doping and medication control intelligence, and for efficient and effective investigations into possible anti-doping and medication control rule violations.

5020. Definitions

Unless specified otherwise, capitalized terms used in these Testing and Investigations Standards have the meanings given to them in Rule 1020.

*5100. Standards for Testing*

5110. Planning Effective Testing

(a) The Agency is required to plan and implement intelligent and effective Testing on Covered Horses over which it has authority, and that is proportionate to the risk of doping and the misuse of medication, and effective to detect and to deter such practices. The objective of this Rule is to explain the steps that form part of a Risk Assessment to inform Testing plans in a way that best ensures clean competition and protects the health and welfare of Covered Horses.

(b) The Agency shall ensure that Covered Persons with a conflict of interest in the outcome of the Testing being contemplated are not involved in test planning or in the process of selection of Covered Horses for Sample collection.

(c) The Agency should monitor, evaluate, and update its Risk Assessment during the year or cycle in light of changing circumstances and in implementing its Testing plans.

5120. Risk Assessment

The Risk Assessment shall be conducted in good faith, reviewed and updated as required (at the discretion of the Agency), and should take into account (if available) the following information:

(a) discipline and individual factors that may result in a higher potential for adopting doping behavior or misuse of medication;

(b) available statistics and research on doping trends and misuse of medication, practices, and methods;

(c) reliable information received and intelligence developed on possible doping practices and misuse of medication;

(d) outcomes of previous test planning cycles, including past testing strategies;

(e) optimal times to apply specific test types (including analysis) to maximize opportunities for detecting and deterring doping;

(f) given the structure of the racing season (including generic racing schedules and training patterns), the time during the year a horse is most likely to be administered Banned Substances or be subjected to Banned Methods (to enhance or impair performance or impact welfare or soundness); and

(g) any Risk Assessment carried out by a State Racing Commission or racing authority in another country and provided to the Agency for the purposes of enhancing its Risk Assessment.

5130. Prioritizing Between Covered Horses, Types of Testing, and Samples

(a) The Agency should consider various factors in prioritizing the allocation of Testing resources. In addition, the Agency will use Target Testing to focus Testing resources where they are most needed within the overall pool of Covered Horses.

(b) Factors relevant to determining which Covered Horses should be the subject of Target Testing may include, but are not limited to, the following:

(1) Covered Horses serving a period of Ineligibility or a Provisional Suspension;

(2) Covered Horses who were high priority for Testing before retirement and are now returning from retirement to active participation;

(3) Covered Horses' testing history, including any abnormal Sample data (*e.g.,* an Atypical Finding reported by a Laboratory);

(4) Covered Persons' prior anti-doping and medication control rule violations and testing history, including any abnormal Sample data (*e.g.,* an Atypical Finding reported by a Laboratory);

(5) performance history, performance pattern, or high performance (*e.g.,* Trainer strike rate) without a commensurate testing record;

(6) repeated failure to meet whereabouts requirements;

(7) suspicious whereabouts filing patterns;

(8) moving to or training in a remote location;

(9) suspicious withdrawal or absence from expected Covered Horserace(s);

(10) association with a third party (such as a Trainer, Veterinarian, or Owner) with a history of involvement in doping or misuse of medication;

(11) injury;

(12) age and stage of career;

(13) financial incentives for improved or degraded performance, such as purse size, unusual betting patterns, or upcoming Claiming Race; or

(14) reliable information from a third party, or intelligence developed by or shared with the Agency.

(c) Target Testing is a priority because random Testing, or even weighted random Testing, does not ensure that all of the appropriate Covered Horses will be sufficiently tested. Covered Horses may be tested at any time and at any place where they are located (*e.g.,* Racetrack, Training Facility, private facility). The Protocol does not impose any reasonable suspicion or probable cause requirement for Target Testing or Testing.

(d) Testing that is not Target Testing should be determined based on the Risk Assessment. Testing should be conducted using a documented system for such selection, such as weighted testing (where Covered Horses are ranked using pre-determined criteria to increase or decrease the chances of selection) or random testing (where no pre-determined criteria are considered, and Covered Horses are chosen arbitrarily from a list or pool of names). Testing that is weighted should be prioritized and conducted according to defined criteria which may take into account the risk factors to ensure that a greater percentage of at risk Covered Horses are selected.

(e) Based on the Risk Assessment and prioritization process described above, the Agency should determine to what extent each of the following types of Testing is required to effectively detect and deter doping and misuse of medication within the sport:

(1) TCO2 and Post-Race Sample collection on Race Day;

(2) Post-Work Sample collection following Timed and Reported Workouts;

(3) Out-of-competition Sample collection;
(4) Sample matrices to be considered:
(i) urine;
(ii) hair;
(iii) blood; or
(iv) other matrices or methodologies, as available.

5140. Sample Analysis, Retention Strategy, and Further Analysis

(a) Laboratories shall analyze Samples for an Analytical Testing menu directed by the Agency. The Agency may also consider undertaking more extensive Sample analysis for Prohibited Substances or Prohibited Methods based on the assessed risk or any intelligence that the Agency may receive (*e.g.,* specific Prohibited Substances, gene doping).

(b) The Agency should develop a system for retention of Samples and related documentation to enable the Further Analysis of such Samples at a later date in accordance with Rule 3138. Such a system should comply with the requirements of the Laboratory Standards and should take into account the purposes of Sample analysis set out in Rule 3137, as well as (without limitation) the following elements:

(1) Laboratory recommendations (when available);

(2) new relevant detection methods to be introduced in the future;

(3) collected Samples that meet some or all of the criteria set out at Rule 5130; or

(4) the Agency determining based on available information or random selection that long-term storage or Further Analysis of the Samples is appropriate.

5150. Coordinating With State Racing Commissions and Other Entities

(a) In accordance with Rule 3132, the Agency may delegate Testing (or aspects thereof) to State Racing Commissions, subject to the applicable State Racing Commission electing to enter into an agreement with the Agency. For example, the Agency may utilize Sample Collection Personnel employed or designated by a State Racing Commission to collect Samples. Any state rule, law, or regulation preventing sample collection personnel employed or designated by a State Racing Commission from contracting with the Agency to collect Samples is pre-empted by this rule, which expressly permits such arrangements. Regardless of who collects a Sample, only the Agency shall receive the results of Sample analysis directly from the Laboratory.

(b) The Agency may delegate Testing (or aspects thereof) to qualified third parties, *e.g.,* by contracting a third-party sample collection service provider to collect Samples on behalf of the Agency.

(c) State Racing Commissions, Racetracks, Race Organizers, and other third parties may (at their own cost) contract with the Agency to collect additional Samples on Covered Horses in a manner that is consistent with the Act and the Protocol.

*5200. Notification*

5210. Requirements Prior to Notification

(a) Testing without advance notice should be the method for Sample collection except in circumstances where advance notice is required to facilitate the Testing. If the Responsible Person is with the Covered Horse at the time of notification, the Responsible Person should be the first Person notified that the Covered Horse has been selected for Sample collection. In order to ensure that Testing is conducted on a without advance notice basis, the Agency shall ensure Testing selection decisions are only disclosed in advance of Testing to those who need to know in order for such Testing to be conducted. Any notification to a third party shall be conducted in a secure and confidential manner to minimize the risk that the Responsible Person or other Covered Person will receive any advance notice of a Covered Horse's selection for Sample collection.

(b) The Agency shall appoint DCOs, BCOs, Chaperones, and other Sample Collection Personnel sufficient to facilitate Testing without advance notice and to ensure continuous observation of the Covered Horse and confirmation that the Covered Horse is in a secure location (a stall, for example) throughout the Sample collection process. Sample Collection Personnel must be trained for their assigned responsibilities, must not have a conflict of interest with respect to the performance or outcome of the Sample collection, and must be 18 or older. See Rule 5450 for more information on Sample Collection Personnel requirements.

(c) Sample Collection Personnel shall have official documentation provided by the Agency, evidencing their authority to collect a Sample from the Covered Horse.

(d) Information provided in the Covered Horse's whereabouts filing and registration with the Authority, or other equally reliable form of identification, shall be used by Sample Collection Personnel to confirm the identity of the Covered Horse. Confirmation of the Covered Horse's identity by any other method or failure to confirm the identity of the Covered Horse shall be documented, including through photographs, and reported to the Agency.

(e) The DCO or BCO shall establish the location of the selected Covered Horse and plan the approach and timing of notification, taking into consideration the specific circumstances of the location, schedule, and the situation in question (*e.g.,* Covered Horserace, Timed and Reported Workout, Vets' List Workout).

5220. Requirements for Notification

(a) Out-of-competition Sample collection.

(1) The Sample Collection Personnel will seek to locate the Covered Horse based on available data regarding Racetracks and Training Facilities or based on whereabouts information.

(2) If the Sample Collection Personnel are able to locate the Covered Horse, notification of out-of-competition Sample collection shall ordinarily take place in person, but may, if necessary, take place by telephone, text message, or email using the contact details provided by the Responsible Person upon registration with the Authority.

(3) If the Sample Collection Personnel are not able to locate the Covered Horse based on available data or whereabouts information, notification of out-of-competition Sample collection shall take place by telephone, text message, or email, using the contact details provided by the Responsible Person upon registration with the Authority.

(4) In accordance with Rule 3215, the Responsible Person shall ensure that the Covered Horse is produced for Sample collection immediately upon notification by a duly authorized person in accordance with the Agency's procedures if the Covered Horse is present at the location where notification is attempted. If the Covered Horse is not present at the location where notification is attempted (including due to a Whereabouts Failure), the Responsible Person shall ensure that the Covered Horse is produced for Sample collection within 6 hours of notification by a duly authorized Person in accordance with the Agency's procedures, except that the Agency may extend the 6-hour period if it considers that extenuating circumstances justify doing so.

(5) At the time of notification, the Sample Collection Personnel shall inform the Responsible Person or Nominated Person:

(i) that the Covered Horse is required to undergo Sample collection;

(ii) that immediate access to the Covered Horse shall be granted, and (if

that is not possible because the Covered Horse is not present at the location), the Responsible Person has 6 hours to produce the Covered Horse for Sample collection, failing which significant Consequences may apply in accordance with Rule 3215;

(iii) that the Sample collection process shall start immediately, unless there are valid reasons for a delay (as determined by the DCO or BCO);

(iv) that the Sample collection process shall take place in a secure location determined suitable by the DCO or BCO (*e.g.,* the horse's stall);

(v) of the responsibilities of the Responsible Person or Nominated Person with respect to the Covered Horse, including the requirement to:

(A) ensure that the Covered Horse remains under continuous observation of Sample Collection Personnel at all times until the completion of the Sample collection procedure;

(B) not leave the Covered Horse unattended once the Responsible Person or Nominated Person is notified and contact is made with the Covered Horse until the completion of the Sample collection procedure;

(C) produce on request identification for himself or herself and the Covered Horse. Identification for the Responsible Person or Nominated Person should include his or her Authority registration number or (if not available) valid photo identification. The Sample Collection Personnel may take photographs of the individual(s) and the Covered Horse if identification is not provided;

(D) comply and cooperate with Sample collection procedures and processes (the Responsible Person or Nominated Person should also be advised of the possible Consequences of failure to comply, including pursuant to Rule 3215 and 3510); and

(E) ensure that the Covered Horse is not administered any medications or supplements from notification of Sample collection until completion of Sample collection, unless there is a medical emergency, as determined by a Regulatory Veterinarian or (if not available) a Veterinarian.

(6) The Sample Collection Personnel shall have the Responsible Person or Nominated Person sign an appropriate form to acknowledge and accept the notification of Sample collection. If the Responsible Person or Nominated Person refuses to sign the form, or evades notification, the Sample Collection Personnel should, if possible, inform the Responsible Person or Nominated Person of the Consequences of a failure to comply, and the Sample Collection Personnel (if not the DCO) shall immediately report all relevant facts to the DCO or BCO. When possible, the Sample Collection Personnel shall continue the Sample collection. The DCO shall document the facts in a detailed report and report the circumstances to the Agency.

(7) A Nominated Person may be replaced by another Nominated Person during the Sample collection process upon reasonable request to the Sample Collection Personnel so long as the new Nominated Person (i) falls within the scope of the definition of Nominated Person, (ii) completes the relevant portions of the Sample collection paperwork, and (iii) does not interfere with the Sample collection process. Any changes of Nominated Person during the Sample collection process shall be documented by the Sample Collection Personnel.

(b) Post-Race Sample collection.

(1) Pursuant to Rule 1020, a Post-Race Sample includes any Sample collected by or on behalf of the Agency from a Covered Horse where notification of such Sample collection takes place no more than 1 hour after the end of a Covered Horserace in which a Covered Horse participates or is entered, or the end of a Vet's List Workout in which a Covered Horse participates.

(2) A member of the Sample Collection Personnel will tag or otherwise identify a Covered Horse selected for Sample collection (ordinarily in the unsaddling area) within one (1) hour of the end of the Covered Horserace or Vets' List Workout and chaperone the Covered Horse, to the extent possible, from the point of tagging/notification until the end of the Sample Collection Session. Such notification should inform the Responsible Person or Nominated Person:

(i) that the Covered Horse is required to undergo Sample collection;

(ii) that the Covered Horse must report to the Test Barn as soon as practicable, unless there are valid reasons for a delay (as determined by the DCO or BCO);

(iii) of the location of the Test Barn;

(iv) of the responsibilities of the Responsible Person or Nominated Person with respect to the Covered Horse, including the requirement to:

(A) ensure that the Covered Horse remains under observation of Sample Collection Personnel, to the extent possible, until the completion of the Sample Collection Session;

(B) not leave the Covered Horse unattended once the Responsible Person or Nominated Person is notified and contact is made with the Covered Horse until the Sample Collection Session is completed;

(C) produce on request identification for himself or herself (which shall include his or her Authority registration number) and the Covered Horse. The Sample Collection Personnel may take photographs of the individual(s) and the Covered Horse if no identification is provided;

(D) comply and cooperate with Sample collection procedures and processes (the Responsible Person or Nominated Person should be advised of the possible Consequences of a failure to comply, including pursuant to Rule 3215 and 3510);

(E) ensure that the Covered Horse is not administered any medications or supplements (or similar items) from notification of Sample collection until completion of the Sample Collection Session, unless there is a medical emergency, as determined by the Test Barn Veterinarian or a Regulatory Veterinarian; and

(F) confirm that the water bucket of the Covered Horse is clean and acceptable and ensure that it is only used for that Covered Horse during the Sample Collection Session.

(3) The Sample Collection Personnel shall notify the Responsible Person or Nominated Person and document the time and the individual notified (*e.g.,* by taking a photograph or by having the Responsible Person or Nominated Person sign an appropriate form or through such other reasonable and appropriate measure under the circumstances), and the Responsible Person or Nominated Person must sign an appropriate form to acknowledge and accept the notification no later than once in the Test Barn or other secure location. If the Responsible Person or Nominated Person refuses to sign the form, or evades the notification, the Sample Collection Personnel should, if possible, inform the Responsible Person or Nominated Person of the Consequences of a failure to comply, and the Sample Collection Personnel (if not the DCO or BCO) shall immediately report all relevant facts to the DCO or BCO. When possible, the Sample Collection Personnel shall continue the Sample collection. The DCO or BCO shall document the facts in a detailed report and report the circumstances to the Agency.

(4) From the time that a Covered Horse is tagged or identified for Sample collection until the end of the Sample collection process, the Sample Collection Personnel shall keep the Covered Horse under observation or ensure the Covered Horse is in a secure location (a stall, for example).

(5) A Nominated Person may be replaced by another Nominated Person

during the Sample collection process upon reasonable request to the Sample Collection Personnel, so long as the new Nominated Person (i) falls within the scope of the definition of Nominated Person, (ii) completes the relevant portions of the Sample collection paperwork, and (iii) does not interfere with the Sample collection process. Any changes of Nominated Person during the Sample collection process shall be documented by the Sample Collection Personnel.

(c) Pre-race Sample collection.

Blood samples may be collected before a Covered Horserace or Vets' List Workout for purposes of TCO2 testing in accordance with Rule 5430. Sample Collection Personnel shall provide notification of Sample collection in accordance with paragraph (a) or (b) above depending on the circumstances.

(d) Post-Work Sample collection.

Samples may be collected after a Timed and Reported Workout in accordance with Rule 5400. All Banned Substances and any Controlled Medication Substances specifically identified on the Prohibited List as prohibited during Timed and Reported Workouts are prohibited from being present in a Post-Work Sample. Sample Collection Personnel shall provide notification of Sample collection in accordance with paragraph (a) and (b) above depending on the circumstances.

5230. Requests for Delay

(a) The DCO or BCO may consider any reasonable request from the Responsible Person or Nominated Person or third party for permission to delay beginning the Sample collection process following acknowledgment and acceptance of notification. The DCO or BCO may grant such permission only if the Covered Horse can remain under continuous observation of Sample Collection Personnel at all times until the completion of the Sample collection procedure. The DCO or BCO shall otherwise reject a request for delay, unless there is a medical emergency (as determined by a Test Barn Veterinarian or Regulatory Veterinarian or, if not available for an out-of-competition Sample collection, a Veterinarian) or other circumstances so require it (as determined by the DCO or BCO).

(b) For Race Day Sample collection, delayed reporting to the Test Barn may be permitted in accordance with paragraph (a) on account of:

(1) participation in the winner's circle;

(2) obtaining necessary medical treatment if there is a medical emergency, as determined by a Regulatory Veterinarian or Test Barn Veterinarian; or

(3) any other reasonable circumstances, as determined by the DCO or BCO, taking into account any instructions of the Agency.

(c) For out-of-competition Sample collection, delayed reporting for Sample collection may be permitted in accordance with paragraph (a) on account of:

(1) completing a training session or a cool down;

(2) receiving necessary medical treatment if there is a medical emergency, as determined by a Regulatory Veterinarian or (if not available) a Veterinarian; or

(3) any other reasonable circumstances, as determined by the DCO or BCO, taking into account any instructions of the Agency.

(d) Sample Collection Personnel shall document any reasons for delay in reporting for Sample collection.

(e) If immediate access to the Covered Horse is not granted, the DCO or BCO shall report to the Agency a possible failure to comply. If at all possible, the DCO or BCO shall proceed with collecting a Sample.

*5300. Preparing for the Sample Collection Session*

5310. General Requirements

(a) The Agency should establish a system for obtaining all of the information necessary to ensure that the Sample Collection Session can be conducted effectively.

(b) For Race Day Sample collection, a Test Barn should be used that, where possible, is used solely as a Test Barn for the duration of all Sample Collection Sessions. Unauthorized persons should not be permitted access to the Test Barn. Should the DCO or BCO determine the Test Barn is unsuitable, he or she shall seek an alternative location.

(1) Unless otherwise approved by the Agency, the Test Barn should be equipped with:

(i) an enclosed area for Covered Horses to walk in or adjacent to the Test Barn that is large enough to accommodate several horses and allow for continuous observation of the Covered Horses;

(ii) sufficient enclosed stalls for the number of Sample collections that permit observation of the collection process and provide for the protection of Covered Horses undergoing Sample collection and space for Sample Collection Personnel and up to two (2) Covered Persons per Covered Horse;

(iii) facilities and equipment for the collection, identification, and storage of Samples, including one refrigerator or cooler that can be locked or otherwise secured, and one freezer that can be locked or otherwise secured;

(iv) an area and appropriate facilities for a Covered Horse to be bathed;

(v) a table or other suitable surface;

(vi) access to hot and cold running water;

(vii) clean water buckets for each Covered Horse; and

(viii) a security officer to ensure no unauthorized person is permitted in the Test Barn.

(2) The Test Barn Veterinarian shall be responsible for managing horse welfare in the Test Barn. For example, this includes determining when and how to manage congestion in the Test Barn, when to release Covered Horses from the Test Barn, and whether (if necessary) to permit treatment of a Covered Horse. A Covered Horse in the Test Barn may receive medical treatment only with the prior authorization of the Test Barn Veterinarian or a Regulatory Veterinarian.

(c) For out-of-competition Sample collection, the DCO or BCO will determine a suitable location to be used for the Sample Collection Session. If at a stable, by default the Covered Horse's own stall should be used.

5320. Sample Collection Equipment

(a) General. Sample Collection Personnel should ensure that they have and use Sample Collection Equipment provided by or approved by the Agency.

(b) Minimum requirements. Sample Collection Equipment should, at a minimum:

(1) have a unique numbering system for all bottles, containers, tubes, security bags, bar code labels, or other items used to seal and transport the Samples;

(2) have a Tamper Evident sealing system;

(3) not reveal the identities of the Responsible Person and Covered Horse on the equipment (*i.e.,* only the unique numbering system shall be used on the equipment);

(4) be clean and sealed prior to use;

(5) be constructed of a material and sealing system approved by the Agency that should:

(i) be able to withstand the handling conditions and environment in which the equipment will be used or subjected to, including, but not limited to, transportation, Laboratory analysis, and long-term storage;

(ii) maintain the integrity (chemical and physical properties) of the Sample for Laboratory analysis;

(iii) if the Sample will be transported or stored frozen, withstand temperatures

of up to −80 °C and a minimum of three (3) freeze/thaw cycles;

(iv) be transparent or translucent so the Sample is visible;

(v) have a sealing system that allows verification by the Responsible Person or Nominated Person and the DCO or BCO that the Sample is correctly sealed in the bottles or containers;

(vi) be designed to prevent leakage during transportation (including by air);

(vii) have been manufactured under the internationally recognized ISO 9001 certified process which includes quality control management systems; and

(viii) be able to be resealed after initial opening by a Laboratory to maintain the integrity of the Sample and Chain of Custody in accordance with the requirements for long-term storage and Further Analysis; and

(6) include a transport device or packaging that is suitable to the Sample at issue.

(c) Additional requirements applicable to urine Samples. In addition to the requirements of paragraph (b) of this Rule 5320, Sample Collection Equipment used in the collection of urine Samples shall include:

(1) a collection vessel with the capacity to contain a minimum of 50 mL volume of urine;

(2) A and B bottles with the capacity to contain a minimum 25 mL volume of urine; and

(3) visual markings on the A and B bottles and the collection vessel, indicating the minimum volume of urine required and the maximum volume levels that allow for expansion when frozen without compromising the bottle, container, or sealing system.

(d) Specific requirements applicable to blood Samples. In addition to the requirements of paragraph (b) of this Rule 5320, Sample Collection Equipment used in the collection of blood Samples shall include:

(1) a needle for blood sampling; and

(2) blood collection tubes, each with a capacity to contain a minimum of 8 mL of blood, to ensure a minimum total of 30 mL of blood is collected (except for TCO2 testing, where a lesser volume may be collected at the discretion of the Agency).

(e) Specific requirements applicable to Hair Samples and other Samples. Sample Collection Personnel should ensure that they have the necessary equipment for hair Sample collection and any other approved Testing matrices or methodologies, in accordance with any procedures or guidance issued by the Agency.

*5400. Conducting the Sample Collection Session*

5410. Collection of Samples

(a) The Agency shall be responsible for the overall conduct of the Sample Collection Session, with specific responsibilities delegated to the DCO or BCO. Sample collection may be performed only by Sample Collection Personnel approved by the Agency. The Agency may issue supplemental procedures or guidance regarding Sample collection procedures as it considers necessary.

(b) The following Persons may be authorized or required to be present during the Sample Collection Session:

(1) Sample Collection Personnel sufficient to notify, chaperone, and collect the required Samples must be present during the Sample Collection Session;

(2) the Responsible Person or Nominated Person should be present during the Sample Collection Session. If the Responsible Person or Nominated Person is not present, this will be documented by the DCO or BCO;

(3) no more than two (2) Covered Persons (including the Responsible Person or Nominated Person) may be present during the Sample collection for a Covered Horse, except in exceptional circumstances, as determined by the DCO or BCO; and

(4) any Person authorized by the Agency (*e.g.,* a person who is involved in the training or supervision of Sample Collection Personnel) may be present during the Sample Collection Session.

(c) The Sample Collection Personnel will coordinate with the Test Barn security officer to ensure that no unauthorized person is permitted in the Test Barn.

(d) For Race Day Sample collection, the Covered Horse shall remain in the Test Barn through to the end of the Sample collection when the Covered Horse is released from the Test Barn by the DCO.

(e) Samples shall be collected in a manner that ensures:

(1) the Sample is of a quality and quantity that meets the relevant Sample suitability and analytical requirements;

(2) the Sample has not been contaminated or otherwise tampered with in any way at the time of collection;

(3) the Sample is clearly and accurately identified; and

(4) the Sample is securely sealed in a Tamper Evident kit.

(f) The Sample Collection Personnel shall collect the Sample from the Covered Horse according to the following protocol(s) for the specific type of Sample collection:

(1) Rule 5420: Collection of urine Samples;

(2) Rule 5430: Collection of blood Samples; and

(3) Rule 5440: Collection of hair Samples.

(g) Except for Samples collected for TCO2 testing (see Rule 5430(p) below), each Sample collected shall be split into an A and a B Sample at the time of collection.

(h) In general, the relevant Sample Collection Personnel should wear a new pair of disposable gloves when handling the Sample collection vessel/tubes and when sealing Samples.

(i) The following information shall be recorded at a minimum on the Sample collection documentation for a Sample Collection Session:

(1) date and time of notification, and name and signature of notifying Sample Collection Personnel;

(2) the arrival time of the Covered Horse to the Test Barn (for Race Day Sample collection) or secure location (for out-of-competition Sample collection);

(3) the name of the Responsible Person and Nominated Person;

(4) any changes in the Nominated Person during the Sample Collection Session;

(5) the contact information of the Responsible Person or Nominated Person(s), if requested;

(6) the name of the Covered Horse;

(7) the sex of the Covered Horse (intact male, mare, gelding);

(8) the color of the Covered Horse;

(9) the means by which the Covered Horse's identity is validated (*e.g.,* microchip number, or branding);

(10) the name and signature of the Sample Collection Personnel involved in the Sample collection process for the Covered Horse;

(11) the name of additional Covered Persons (if any) present during the Sample Collection Session;

(12) the Sample code number(s);

(13) the date and time of sealing of each Sample collected and date and time of completion of entire Sample Collection Session;

(14) the location at which the Sample Collection Session took place;

(15) the type of the Sample collected (*e.g.,* urine, blood, hair);

(16) the type of test, *e.g.,* Race Day (TCO2 or Post-Race Sample), Post-Work, or out-of-competition;

(17) whether furosemide was administered to the Covered Horse within 48 hours before Post-Time;

(18) any required Laboratory information on the Sample (*e.g.,* for

urine or blood Sample, its volume; for hair Sample, mane/tail and pulled/cut);

(19) for a blood Sample, the information to be recorded by the DCO or BCO as outlined in Rule 5430;

(20) any irregularities in procedures (*e.g.,* if advance notice was provided, if there were any delays in arriving to the Test Barn or secure location, or any anomalous behavior by those present at the collection);

(21) any comments or concerns from the Responsible Person or Nominated Person regarding the conduct of the Sample Collection Session; and

(22) acknowledgement by the Responsible Person or Nominated Person of the processing of Sample collection data and a description of such processing.

(j) At the conclusion of the Sample Collection Session the Responsible Person or Nominated Person and DCO or BCO shall sign appropriate documentation to indicate their satisfaction (or otherwise) that the documentation accurately reflects the details of the Covered Horse's Sample Collection Session. The DCO (or BCO) shall also provide the Responsible Person or Nominated Person the opportunity to document any concerns he or she may have concerning the manner in which Sample Collection Session was conducted.

(k) The Agency may require the Sample Collection Personnel to complete supplemental documentation regarding the Sample Collection Session. For example, any anomalous behavior by the Responsible Person, Nominated Person, or other Covered Persons or Persons associated with the Covered Horse or Responsible Person, or behavior with the potential to compromise the Sample collection shall be recorded in detail by the Sample Collection Personnel. If the Covered Horse requires any emergency medical treatment, that shall be recorded in detail by the Sample Collection Personnel.

(l) Only the DCO or BCO is authorized to end a Sample Collection Session and so release a Covered Horse from the Test Barn or Sample collection location. Only the DCO or BCO, in consultation with the Test Barn Veterinarian for any Race Day Sample collection, is authorized to temporarily release a Covered Horse from the Test Barn or Sample collection location.

(m) Subject to Rule 5200, no photography or audio or video recording of the Sample Collection Session is permitted. Instead, the Sample collection documentation will be the definitive record of the Sample Collection Session, and any comments regarding the Sample Collection Session must be recorded on the Sample collection documentation. If a Covered Person insists on photographing or recording the Sample Collection Session (in whole or in part) in violation of this Rule, the Sample Collection Session should continue, but a case may be brought against the Covered Person under Rule 3510. If the conduct of the Covered Person results in the Sample Collection Session being discontinued, a case may be brought against the Covered Person (on its own or in the alternative) for an Anti-Doping Rule Violation under Rule 3215 or Rule 3216. For the avoidance of doubt, any conduct by a Nominated Person or other Person or employee, agent, or associate of the Responsible Person in relation to a Sample Collection Session may in appropriate circumstances be imputed to the Responsible Person for these purposes.

(n) If the Agency collects any Sample(s) from a deceased horse:

(1) Sample collection shall not interfere with any life-saving treatment.

(2) Sample(s) should ordinarily be collected from the Covered Horse before it is removed from the relevant venue where it suffered a fatal condition, but otherwise may be collected at the location where the Covered Horse is transported to (*e.g.,* veterinary clinic).

(3) The Agency shall afford the Responsible Person and Nominated Person the opportunity to waive attendance at the Sample collection if such attendance would cause undue distress.

(4) The Sample collection shall proceed in accordance with the applicable Sample collection procedures, amended as necessary to account for the specific circumstances.

5420. Collection of Urine Samples

(a) Urine Samples may be collected and analyzed for any anti-doping analytical matrix or methodology, as determined by the Agency, and in accordance with the Prohibited List and related Technical Documents.

(b) The relevant Sample Collection Personnel will retain control of the Sample collection vessel.

(c) The Responsible Person or Nominated Person will be instructed to examine the Sample collection vessel to ensure that it will not affect the integrity of the urine Sample.

(d) The relevant Sample Collection Personnel will then open and use the selected Sample collection vessel to collect the urine Sample.

(e) The relevant Sample Collection Personnel shall ensure as unobstructed a view as possible of the Sample leaving the Covered Horse's body and shall continue to observe the Sample after provision until the Sample is securely sealed.

(f) When the Covered Horse passes urine, the collection vessel should be positioned to collect as much urine as possible.

(g) The volume of urine required for a full Sample is a minimum of 25 mL for each of the A Sample and B Sample (minimum of 50 mL in total). If during the initial attempt less than 50 mL is obtained, the relevant Sample Collection Personnel should try to collect additional urine.

(h) The Test Barn Veterinarian (or a Regulatory Veterinarian), in consultation with the DCO, shall determine if a Covered Horse is intractable, and (if so) when the urine Sample Collection Session should be terminated. If a urine Sample is not collected because the Covered Horse is intractable, a blood Sample should be collected (in addition to any other Sample, *e.g.,* hair). The Sample Collection Personnel should record the reasons for terminating any Sample collection on the Sample collection documentation.

(i) Once the volume of urine provided by the Covered Horse is deemed sufficient, the relevant Sample Collection Personnel will bring the Sample to the designated processing area.

(j) The relevant Sample Collection Personnel will select the Sample collection kit and will open, inspect, and confirm Sample codes numbers within the kit match and ask the Responsible Person or Nominated Person to confirm the same.

(k) If the Responsible Person or Nominated Person is not satisfied with the chosen Sample Collection Equipment, this shall be recorded by the DCO. If the DCO does not agree with the Responsible Person or Nominated Person that the equipment is unsatisfactory, the DCO shall inform the Responsible Person or Nominated Person that the Sample Collection Session is proceeding. If the DCO agrees with the Responsible Person or Nominated Person that the equipment is unsatisfactory, the DCO shall use other available equipment that the DCO determines is satisfactory. If no such equipment is available, the DCO shall terminate the Sample Collection Session, and the termination and its specific reason shall be recorded by the DCO.

(l) Once the Sample collection kit has been selected, the relevant Sample Collection Personnel will pour and split the urine Sample into A and B Sample

collection bottles within the view of the Responsible Person or Nominated Person.

(m) The relevant Sample Collection Personnel will seal the A and B bottles within the view of the Responsible Person or Nominated Person. Once closed, the relevant Sample Collection Personnel will check that the bottles have been properly sealed.

(n) The Sample Collection Personnel will complete all the required Sample collection documentation and provide the Responsible Person a copy for his or her records.

(o) Urine should only be discarded when both the A and B bottles or containers have been filled to the maximum amount they can hold and have been sealed. Any excess urine should be disposed of into a drain (ground drain or sink) or into a bin or waste pile, if necessary. The Responsible Person or Nominated Person shall be given the option to observe the disposal of any residual urine not sent to the Laboratory for analysis.

5430. Collection of Blood Samples

(a) Blood collection shall be conducted by the BCO.

(b) Blood Samples may be collected and analyzed for any anti-doping analytical matrix or methodology, as determined by the Agency, and in accordance with the Prohibited List and related Technical Documents.

(c) The DCO or BCO will select a Sample collection kit containing a sufficient number of blood collection tubes (two or three of which will be paired together as the A Sample, and the third or fourth of which will constitute the B Sample), and the other necessary equipment needed to collect a blood Sample.

(d) If the Responsible Person or Nominated Person is not satisfied with the chosen Sample Collection Equipment, this shall be recorded by the DCO or BCO. If the DCO or BCO does not agree with the Responsible Person or Nominated Person that the equipment is unsatisfactory, the DCO or BCO shall inform the Responsible Person or Nominated Person that the Sample Collection Session is proceeding. If the DCO or BCO agrees with the Responsible Person or Nominated Person that the equipment is unsatisfactory, the DCO or BCO shall use other available equipment that the DCO or BCO determines is satisfactory. If no such equipment is available, the DCO or BCO shall terminate the Sample Collection Session, and this termination and its specific reason shall be recorded by the DCO or BCO.

(e) Once the Sample collection kit has been selected, the BCO or DCO will open, inspect, and confirm Sample codes numbers within the kit match and ask the Responsible Person or Nominated Person to confirm the same.

(f) The BCO will determine the most suitable location of venipuncture;

(g) The BCO shall safely dispose of used blood sampling equipment not required to complete the Sample Collection Session.

(h) Subject to paragraph (l) below, the BCO will collect the amount of blood that will adequately satisfy the relevant analytical requirements for the Sample analysis to be performed. The minimum total volume requirement is 30 mL whole blood, plasma, or serum, with each collection tube containing a minimum of 8 mL.

(i) If the amount of blood that can be removed from the Covered Horse at the first attempt is insufficient, the BCO shall repeat as necessary and appropriate (taking horse welfare into account) to try to obtain the minimum total volume for a blood Sample. If the BCO is unable to collect a sufficient amount of blood, the BCO or DCO may terminate the blood Sample Collection Session and record the reasons for such termination. Other matrices should be considered for collection.

(j) Once a complete blood Sample is obtained, the Sample Collection Personnel will properly seal the A and B tubes.

(k) The Sample Collection Personnel will complete all the required Sample collection documentation and provide the Responsible Person a copy for his or her records.

(l) Total carbon dioxide (TCO2):

(1) In addition to the collection of a Post-Race Sample, blood Sample(s) may also be collected from a Covered Horse prior to a Covered Horserace or Vets' List Workout for the purpose of testing for TCO2. The Prohibited List specifies the TCO2 levels that will be considered prima facie evidence of alkalinization or administration of an alkalinizing agent, *i.e.,* a Controlled Medication Method.

(2) A blood Sample collected for TCO2 analysis may have a total volume below 24 mL, at the Agency's discretion. Any volume of blood collected for TCO2 analysis will be transported to the Laboratory.

(3) The Responsible Person or Owner of a Covered Horse selected for TCO2 testing may request that a duplicate Sample be taken. Such request must be made prior to the collection of the official Sample. The costs related to obtaining, handling, shipping, and analyzing the duplicate Sample shall be the responsibility of the Responsible Person or Owner who requested such Sample.

(4) The duplicate sample shall not constitute a B Sample. Accordingly:

(i) the provisions in the Protocol addressing the splitting of Samples for analysis purposes shall not apply to blood samples collected for TCO2 testing.

(ii) the provisions of Rule 5430 apply to blood Samples collected for TCO2 testing, except that any references to A and B Samples or tubes shall not apply, as there shall be only one official Sample.

(5) The official Sample and any duplicate Sample shall be analyzed by the same Laboratory. If the Agency, in its discretion, determines that the duplicate Sample cannot be analyzed within 5 days after the Sample is collected, the findings of the official Sample shall be final.

(6) Blood Samples collected for TCO2 testing may be subject to Further Analysis if a Post-Race Sample collected from the same Covered Horse returns an Atypical Finding or an Adverse Analytical Finding.

5440. Collection of Hair Samples

Sample Collection Personnel should collect hair Samples in accordance with the following requirements:

(a) hair should (to the extent possible) be completely dry and free of visible dirt, debris, or foreign substances;

(b) mane hair should be collected unless tail hair is specifically requested. If, for a particular reason, a mane Sample cannot be obtained (*e.g.,* due to a hogged mane), tail hair may be collected;

(c) an adequate Sample of hair should be obtained for each of the A and B Samples;

(d) if the mane is less than 10 cm, an additional Sample of hair may be required to ensure a suitable volume is obtained for analysis;

(e) the Sample should be secured tightly with an elastic band, or equivalent, and oriented to clearly mark the ends cut or pulled from the Covered Horse; and

(f) hair shafts should remain aligned so that the hair does not become knotted.

5450. Sample Collection Personnel Requirements

(a) Minimum requirements. The Agency shall establish the necessary eligibility and qualification requirements for the positions of DCO, BCO, and Chaperone. At a minimum:

(1) Sample Collection Personnel shall be 18 years or older;

(2) Sample Collection Personnel shall agree to undergo screening required by

the Agency (*e.g.,* background checks, conflicts of interest); and

(3) The BCO shall be a Veterinarian or veterinary technician with the practical skills and knowledge to perform blood collection from a vein on a horse.

(b) Conflicts.

(1) The Agency may require all Sample Collection Personnel to sign an agreement regarding conflicts of interest, confidentiality, and an appropriate code of conduct.

(2) The Agency shall not assign any Sample Collection Personnel to a Sample Collection Session where they have an interest in the performance or outcome of the Sample collection process. At a minimum, Sample Collection Personnel are deemed to have such an interest if they:

(i) are related to, employed or otherwise engaged by, or otherwise affiliated with any Equine Constituencies, excluding State Racing Commissions and Racetracks, if the Sample Collection Personnel have met the other requirements set forth by the Agency;

(ii) have a financial interest in or are involved in any way with the care or training or ownership of the Covered Horse at issue;

(iii) are engaged in business with, have a financial interest in, or have a personal stake in a Covered Horserace; or

(iv) appear to have private or personal interests that detract from their ability to perform their duties with integrity and in an independent and purposeful manner.

(c) Training.

(1) The Agency shall establish or approve written training materials for Sample Collection Personnel that outline their respective responsibilities and that provide adequate training for their roles.

(2) The Agency shall ensure that DCOs and BCOs have completed the necessary training program and are familiar with the requirements before issuing them a credential or other authorization documentation.

(3) The training program for DCOs and BCOs should include, at a minimum:

(i) comprehensive theoretical training in the activities relevant to the DCO or BCO position (as applicable);

(ii) observation of the activities that are the responsibility of the DCO or BCO as set out in these Testing and Investigations Standards, preferably on-site; and

(iii) the satisfactory performance of one complete Sample Collection Session on-site under observation by a qualified DCO, BCO, or similar personnel.

(4) The training program for Sample Collection Personnel responsible for the collection of blood Samples shall also include standard precautions in veterinary settings.

(5) The Agency should ensure that Sample Collection Personnel are adequately trained to carry out their responsibilities in a manner respectful of any Covered Persons who are of a different race, religion, sex, national origin, sexual orientation, age, citizenship, disability, gender identity, or Veteran status.

(d) Credentialing.

(1) The Agency shall establish a system for credentialing and re-credentialing DCOs and BCOs. DCOs and BCOs shall have either a credential including their name, photograph, and date of expiration, or a letter of authority from the Agency and a Federal or State issued identification. The Agency may determine what information or authorization documentation to require for other Sample Collection Personnel.

(2) Only Sample Collection Personnel who have been authorized by the Agency are permitted to conduct Doping Control and Medication Control activities on behalf of the Agency.

(3) DCO and BCO credentials shall be valid for a maximum of 2 years. DCOs and BCOs should be subject to an assessment (theoretical or practical) before being re-credentialed.

(4) The Agency will take steps to develop a system to monitor the performance of DCOs and BCOs.

(5) The Agency will maintain records of conflicts of interest and training of all Sample Collection Personnel.

*5500. Storage and Transportation*

5510. Storage and Custody of Samples Prior to Analysis

(a) After Sample collection, the DCO or BCO shall store Samples in a manner that protects the integrity, identity, and security, prior to transport to the Laboratory.

(b) If a urine or blood Sample is not transported to the Laboratory on the day of collection:

(1) the DCO shall store the urine Sample in a secure freezer; and

(2) the DCO or BCO shall store the blood Sample in a secure refrigerator;

(3) and, in each case, shall document in the Chain of Custody the location and time in and time out of the urine or blood Sample.

(c) The DCO or BCO shall document who has custody of the Samples or who is permitted access to the Samples.

(d) The Agency shall develop a system for recording the Chain of Custody of Samples and receiving Sample Collection Session documentation to ensure that each Sample is securely handled and the documentation for each Sample is completed.

5520. Transport of Samples and Documentation

(a) Samples should be transported to the Laboratory as soon as reasonably practicable after the conclusion of the Sample Collection Session. Samples collected on a weekend or over consecutive days may be stored and shipped together in batches (*e.g.,* Samples collected on a race weekend may be stored and sent to the Laboratory on the next Monday), provided that the Samples are stored in accordance with the requirements of these Testing and Investigations Standards.

(b) Samples shall be transported securely via a transportation or shipping service authorized by the Agency. The Agency shall authorize a transport system that ensures Samples and related documentation are transported in a manner that protects their integrity, identity, and security, and which minimizes the potential for Sample degradation due to factors such as delays and extreme temperature variations. Blood samples must be transported in a manner that maintains a cool and constant environment.

(c) State Racing Commissions may select a Laboratory at which the A Samples (or official TCO2 Samples) collected in its state shall be analyzed. If specific analysis requested by the Agency cannot be performed at the selected Laboratory, the Agency may have the Sample sent to another Laboratory that can conduct the requested analysis. Each year the State Racing Commissions must make their Laboratory designation for all Samples collected within its state on or before September 30th of the year prior to the designation taking effect. If a State Racing Commission fails to select a Laboratory by this deadline, the Agency shall select the Laboratory for that particular state. The Agency may allow for a State Racing Commission to change its selection of Laboratory outside of the time-period set forth above if a reasonable request is made (as determined by the Agency).

(d) A and B Samples (and official and duplicate TCO2 Samples) will be shipped together to the Laboratory conducting the A Sample analysis. If the B sample analysis is requested, the B Sample will be shipped to the B Sample Laboratory selected by the Agency.

(e) The Agency will have the ability to confirm, if necessary, that Samples

and related documentation arrived at the Laboratory. The Laboratory shall report any irregularities to the Agency with respect to the condition of Samples upon arrival in accordance with the Laboratory Standards.

(f) The Agency shall develop a system to ensure that, where required, instructions for the type of analysis to be conducted are provided to the Laboratory that will be conducting the analysis. In addition, the Agency shall provide the Laboratory with information as required for result reporting and statistical purposes, including whether long-term storage is required.

(g) Documentation identifying the Covered Horse and Responsible Person or Nominated Person shall not be included with the Samples or documentation sent to the Laboratory that will be analyzing the Samples.

(h) If the Samples or related documentation are not received by the Laboratory, or if a Sample's integrity or identity was compromised during transport, the Agency will consider whether the Samples should be voided. The decision to void a Sample is in the sole discretion of the Agency.

5530. Ownership and Retention of Samples and Retention of Documentation

(a) Samples collected from a Covered Horse are owned by the Authority. Samples shall be retained by Laboratories in accordance with the requirements of Rule 6319.

(b) Documentation related to a Sample Collection Session or an Anti-Doping Rule Violation or Controlled Medication Rule Violation shall be stored by the Agency in accordance with the Agency's record retention policy.

*5600. Standards for Intelligence Gathering*

5610. Purpose

The Agency shall ensure that it is able to: obtain, assess, and process anti-doping and medication control intelligence from all available sources to help deter and detect doping and misuse of medication and inform effective, intelligent, and proportionate test planning; plan Target Testing; and conduct investigations as required by the Protocol. The objective of this Rule is to establish standards for the efficient and effective gathering, assessment, and processing of such intelligence for these purposes.

5620. Gathering Intelligence

(a) The Agency should make every reasonable effort to ensure that it is able to obtain or receive anti-doping and medication control intelligence from all available sources, including, but not limited to: Covered Persons, including through Substantial Assistance; members of the public (*e.g.,* by means of a confidential whistleblower platform); Sample Collection Personnel (whether via mission reports, incident reports, or otherwise); Laboratories; pharmaceutical companies; the Authority; law enforcement (authorized by any government, including Federal, State, or international); State Racing Commissions; Racetracks; Race Organizers; anti-doping organizations; equine regulatory bodies; other relevant regulatory or disciplinary authorities; and the media (in all its forms).

(b) The Agency shall ensure that anti-doping and medication control intelligence obtained or received from a confidential source or in a non-public fashion is handled securely and confidentially, that sources of intelligence are protected, that the risk of leaks or inadvertent disclosure is properly addressed, and that intelligence shared with the Agency in a matter intended to be confidential is processed, used, and disclosed only for any legitimate legal, law enforcement, regulatory, anti-doping, medication control, integrity, disciplinary, horse welfare, or safety purposes.

(c) The Agency shall facilitate, encourage, and seek to protect whistleblowers.

(d) The Agency may consult or coordinate with the Authority, law enforcement (authorized by any government, including Federal, State, or international), State Racing Commissions, Racetracks, Race Organizers, Training Facilities, Laboratories, anti-doping organizations, equine regulatory bodies, or other relevant regulatory or disciplinary authorities in obtaining, developing, or sharing information and intelligence that may be useful for the implementation or enforcement of the Protocol or the Act or for any legitimate legal, law enforcement, regulatory, anti-doping, medication control, integrity, disciplinary, horse welfare, or safety purposes (*e.g.,* the Agency may share information with other entities investigating the possible commission of a crime, regulatory offense, or breach of other rules of conduct; in particular, for example, the Agency may share the results of Sample analyses with the Authority for purposes of enforcing the Racetrack Safety Program).

5630. Assessment and Analysis of Intelligence

(a) The Agency should ensure that it is able to assess all anti-doping and medication control intelligence upon receipt for relevance, reliability, and accuracy, taking into account the nature of the source and the circumstances in which the intelligence has been captured or received.

(b) All relevant anti-doping and medication control intelligence obtained or received by the Agency should be collated and analyzed to establish patterns, trends, and relationships that may assist the Agency in developing an effective anti-doping and medication control strategy and in determining (where the intelligence relates to a particular case) whether there is reasonable suspicion that an Anti-Doping Rule Violation or Controlled Medication Rule Violation may have been committed, such that further investigation is warranted.

5640. Intelligence Outcomes

Anti-doping and medication control intelligence may be used for the following purposes (without limitation):

(a) developing, reviewing, and revising test distribution planning;

(b) determining when to conduct Target Testing; or

(c) creating targeted intelligence files to be referred for investigation.

*5700. Standards for Investigations*

5710. Purpose

(a) The objective of this Rule is to establish standards for the efficient and effective conduct of investigations under the Protocol, including, but not limited to:

(1) the investigation of Sample abnormalities reported by Laboratories;

(2) the investigation of any other analytical or non-analytical information or intelligence where there is reasonable suspicion to suspect that an Anti-Doping Rule Violation or Controlled Medication Rule Violation may have been committed;

(3) the investigation of the circumstances surrounding or arising from an Adverse Analytical Finding to gain further intelligence concerning the Responsible Person or other Covered Persons associated with the Covered Horse whose Sample is the subject of the Adverse Analytical Finding, including to determine if any other methods are involved in doping or medication abuse; and

(4) where a Covered Person is alleged to have committed an Anti-Doping Rule Violation or Controlled Medication Rule Violation, the investigation into whether any other Covered Persons were complicit or otherwise involved in that violation.

(b) In each case, the purpose of the investigation is to achieve one of the following:

(1) to rule out a possible violation or involvement in an Anti-Doping Rule Violation or Controlled Medication Rule Violation;

(2) to develop evidence that supports an Anti-Doping Rule Violation or Controlled Medication Rule Violation proceeding or the initiation of such a proceeding in accordance with the Protocol; or

(3) to provide evidence of a violation of any other provisions of the Protocol or related Rule Series, or applicable law or regulation.

5720. Investigating Possible Violations

(a) The Agency shall conduct, direct, and manage all investigations under the Protocol, unless it specifically delegates an investigation (or aspects of an investigation) to a State Racing Commission (subject to the applicable State Racing Commission electing to enter into an agreement with the Agency).

(b) The Agency and any State Racing Commission to which the Agency delegates investigatory tasks shall ensure that investigations are conducted confidentially.

(c) The Agency will seek to investigate any analytical or non-analytical information or intelligence that indicates that there is reasonable suspicion that an Anti-Doping Rule Violation or Controlled Medication Rule Violation may have been committed or that further inquiry might lead to the discovery of admissible evidence of such violation.

(d) The Agency should gather and record all relevant information and documentation as soon as possible.

(e) The Agency shall ensure that investigations are conducted fairly, objectively, and impartially at all times. The conduct of investigations, the evaluation of information and evidence identified in the course of that investigation, and the outcome of the investigation, should be fully documented.

(f) Covered Persons are required under the Protocol to cooperate with investigations conducted by the Agency (or a State Racing Commission, if the investigation is delegated by the Agency). If they fail to do so, the Agency may bring proceedings against them for failure to cooperate (in accordance with Rule 3510(b)). If their conduct amounts to subversion of the investigative process (*e.g.,* by providing false, misleading, or incomplete information, or by destroying potential evidence), the Agency may also bring proceedings against them for the Anti-Doping Rule Violation of Tampering or Attempted Tampering.

(g) It shall not be a defense in a proceeding involving an Anti-Doping Rule Violation or Controlled Medication Rule Violation that an investigation should have been conducted more quickly or that any aspect of the Testing and Investigations Standards was not followed by the Agency or State Racing Commission, except as provided in Rule 3122.

5730. Obtaining Investigative Information

(a) General. The Agency should make use of all investigative resources reasonably available to it to conduct its investigation. These resources may include: obtaining information and assistance from other entities pursuant to Rule 5620(d); investigative powers conferred under applicable rules (including inspection, examination, and seizure, production of documents, subpoenas, and interviews); and the power to suspend a period of Ineligibility imposed on a Covered Person in return for Substantial Assistance in accordance with the Protocol. Without limitation, the Agency may utilize the investigative tools set forth in paragraphs (b) through (f) of this Rule in relation to investigations and inquiries of possible violations of the Protocol.

(b) Inspection, examination and seizure.

(1) The Agency shall have access to the books, records, offices, racetrack facilities, and other places of business of Covered Persons that are used in the care, treatment, training, or racing of Covered Horses.

(2) The Agency may seize any medication, drug, substance, or paraphernalia in violation or suspected violation of any provision of the Act or any rules approved by the Commission pursuant to the Act, and any object or device reasonably believed to have been used in furtherance of the violation or suspected violation.

(c) Return of seized property. Upon final resolution of a violation, the Agency shall return seized property, including, but not limited to, phones, computers and other repositories of electronic data, the possession of which is not specifically prohibited by the Act or the rules of the Authority.

(d) Production of documents and information.

(1) The Agency may require a Covered Person to provide any information, documents, or records in such form as the Agency may require, which are held by the Covered Person or are within his or her power to obtain, and that are used in the care, treatment, training, or racing of Covered Horses.

(2) The Agency may require production of any mobile phones, computers, tablets, other electronic devices, books, documents and records (including telephone or financial records whether currently in the direct possession of a Covered Person or a third person who may be directed by the Covered Person to provide the information) that may be relevant to any investigation, inquiry, hearing, or proceeding, and that are used in the care, treatment, training, or racing of Covered Horses.

(e) Subpoenas. The Agency may request that the Authority issue a subpoena to a Person to appear or to answer questions or produce evidence related to anti-doping and medication control matters. A subpoena may direct the witness to: appear at a specific time and place to testify; produce designated evidence by a specific time; or permit the Agency to inspect premises at a specific time. A subpoena must be issued under the signature of a designated person from the Authority. If the Covered Person fails to comply with a subpoena, the Agency or Authority may seek enforcement of the subpoena in any of the district courts of the United States within the jurisdiction of which such inquiry is being conducted. Additionally, the arbitrator(s), IAP member(s), administrative law judge, or Commission considering a case arising under the Protocol may draw an adverse inference against a Covered Person who fails to comply with a valid subpoena, regardless of whether a court has been required to enforce the subpoena or has found the Covered Person in contempt.

(1) This issuance of a subpoena and compliance therewith is independent of the Agency's powers to inspect and obtain evidence without a subpoena and a Covered Persons' duty to cooperate under the Protocol. In addition to a rule violation for refusal to cooperate, a refusal to cooperate can result in imposition of an adverse inference against a Covered Person by the arbitrator(s), IAP member(s), administrative law judge, or Commission.

(2) The following considerations should be taken into account by the Agency in determining whether a subpoena should be requested to be issued by the Authority:

(i) the availability of, and success in, using alternative methods for obtaining the information in a timely manner;

(ii) the indispensability of the information to the success of the

investigation or establishing a violation; and

(iii) the need to protect against the destruction of records or information that may be necessary to investigate and prosecute violations of the Protocol.

(f) Interviews.

(1) Covered Persons shall comply with a request to be interviewed by the Agency.

(2) If the Agency requires a Covered Person to submit to an interview under oath, the Covered Person may request a delay of the interview to seek legal advice. However, such delay shall only encompass the time reasonably necessary to contact and retain legal counsel and shall in no case exceed 7 days, unless agreed otherwise by the Agency.

(3) An authorized Person may administer an oath or affirmation to a Covered Person appearing for an interview under oath.

(4) The only basis for refusing to answer a question in an interview is an assertion of the attorney-client privilege or the Fifth Amendment privilege against self-incrimination.

5740. Investigation Outcomes

(a) The Agency shall determine without undue delay whether proceedings should be initiated against a Covered Person or Responsible Person in relation to a Covered Horse for an Anti-Doping Rule Violation or Controlled Medication Rule Violation.

(b) If the Agency concludes based on the results of its investigation that proceedings should be initiated against a Covered Person or a Responsible Person independently or in relation to a Covered Horse, asserting commission of an Anti-Doping Rule Violation or Controlled Medication Rule Violation, it shall give notice of that decision in the manner set out in the Protocol.

(c) If the Agency concludes, based on the results of its investigation, that proceedings asserting commission of an Anti-Doping Rule Violation or Controlled Medication Rule Violation should not be initiated against a Covered Person or a Responsible Person independently or in relation to a Covered Horse, the Agency shall consider whether any of the intelligence obtained or lessons learned during the investigation should be used for test distribution planning, Target Testing, or whether it should be shared with any other Person or included in any report in accordance with these Testing and Investigations Standards.

(d) The Agency may include information from its investigations in reports made to the Authority, Congress, State Racing Commissions, or other appropriate bodies, regardless of whether the information relates to one or more rule violations. The fact that information was included in such a report shall not be a defense in any proceeding involving a potential rule violation.

*6000. Equine Standards for Laboratories and Accreditation*

Rule 6010. Equine Standards for Laboratories and Accreditation

(a) The main purpose of these Laboratory Standards is to ensure that Laboratories report valid test results based on reliable evidentiary data and to facilitate harmonization in Analytical Testing of Samples by Laboratories.

(b) The Laboratory Standards set out the requirements to be followed by Laboratories that wish to demonstrate that they are technically competent, operate within an effective Management System, and can produce forensically valid results. The Laboratory Standards include, inter alia, requirements for obtaining and maintaining HISA Equine Analytical Laboratory (HEAL) accreditation, operating standards for the performance of Laboratories, and a description of the accreditation and approval processes. The Laboratory Standards also set out requirements and guidance in relation to Sample custody and storage, Analytical Testing, and some aspects of Results Management.

(c) Compliance with the Laboratory Standards in effect at the time of Sample analysis (as opposed to another alternative standard, practice, or procedure) shall be sufficient to conclude that the procedures covered by the Laboratory Standards were performed properly. A failure by a Laboratory to follow a requirement in effect at the time of Analytical Testing, which has subsequently been eliminated from these Laboratory Standards or applicable Technical Document(s) or Technical Letter(s) at the time of a hearing, shall not serve as a defense to an Anti-Doping Rule Violation.

(d) Otherwise undefined capitalized terms used in these Laboratory Standards have the meanings given to them in Rule 1020.

Rule 6020. Technical Documents

(a) Technical Documents may be drafted by the Laboratory Expert Group or Agency and circulated for stakeholder consultation before being finalized. Technical Documents will be approved by the Agency, and Authority (where appropriate), and published on the Agency website. Once approved, a relevant Technical Document becomes an integral part of the Laboratory Standards and supersedes any previous publication on a similar topic, including Technical Letter(s) or the Laboratory Standards.

(b) Implementation of the requirements detailed in a Technical Document may occur prior to the effective date for implementation specified in the Technical Document in accordance with this Rule 6020 and shall occur no later than the effective date.

(c) A failure by a Laboratory to implement a Technical Document or Technical Letter by the effective date may result in the imposition of an Analytical Testing Restriction against the Laboratory for that Analytical Testing Procedure, or remediation requirements. In exceptional circumstances, a suspension of the Laboratory's HEAL accreditation may be warranted, as determined by the Agency.

(d) If a Laboratory is not able to implement a new Technical Document by its effective date, it shall inform the Agency as soon as possible. The Laboratory shall send a written request to the Agency for an extension beyond the applicable effective date, providing the reason(s) for the delayed implementation of the Technical Document, any measures taken to ensure that Samples received in the Laboratory will be subject to Analytical Testing in compliance with the new Technical Document (for example, by subcontracting the analysis to another Laboratory as applicable), as well as plans for the implementation of the new Technical Document.

(e) The implementation of the Technical Documents' requirements into the Laboratory's Management System is mandatory for obtaining and maintaining HEAL accreditation or approval, respectively, and for the application of the relevant Analytical Testing Procedure(s) to the analysis of Samples.

(f) In cases when a newly approved version of a Technical Document lowers a Threshold for a Threshold Substance, a Minimum Reporting Level for a Non-Threshold Substance, or any other limit, as applicable, the revised limits specified in the new Technical Document shall not be applied to the reporting of analytical results for Samples collected before the effective date of the Technical Document.

(g) Where the above revised limit specification does not apply, Laboratories may implement a Technical Document as soon as it is approved by the Agency, and Authority (where appropriate), provided that the

requirements of the Technical Document have been implemented and documented appropriately by the Laboratory.

(h) The most recently approved Technical Document shall be applied to the Analytical Testing of Samples prior to the effective date if it would lead to a result that benefits the Covered Person and Covered Horse (*e.g.,* increase of the Threshold for a Threshold Substance or of the Minimum Reporting Level for a Non-Threshold Substance, or any other limit, establishment of more stringent identification criteria for chromatographic-mass spectrometric or other Confirmation Procedures). Therefore, in the case where an analytical finding does not meet the reporting criteria defined in the new Technical Document, it shall be reported as a Negative Finding.

Rule 6030. Technical Letters

(a) Technical Letters may be issued in letter format on an ad-hoc basis to provide direction to the Laboratories on particular issues on the analysis, interpretation and reporting of results for specific Prohibited Substance(s) or Prohibited Method(s) or on the application of specific Laboratory procedures. Technical Letters are modified or withdrawn by the Agency, as appropriate.

(b) Technical Letters will be drafted and approved by the Agency, and Authority (where appropriate), in consultation with relevant scientific experts, and published on the Agency's website. Technical Letters become effective immediately, unless otherwise specified by the Agency. Technical Letters may require actions (*e.g.,* validation of new Analytes or modifications to Analytical Testing Procedures, the procurement of Reference Material(s) or Reference Collection(s)), which may justify that its application cannot be immediate. In such cases, the Agency shall make a time provision for implementation and specify an effective date for the Technical Letter.

(c) Once approved, a relevant Technical Letter becomes an integral part of the Laboratory Standards and supersedes any previous publication on a similar topic, including Technical Document(s) or the Laboratory Standards.

(d) The implementation of the requirements of relevant Technical Letters into the Laboratory's Management System is mandatory for obtaining and maintaining HEAL accreditation or approval, respectively, and for the application of the relevant Analytical Testing Procedure(s) to the analysis of Samples.

Rule 6040. Laboratory Guidelines

(a) Laboratory Guidelines may be issued to provide direction to the Laboratories on new Analytical Methods or procedures approved by the Agency. Laboratory Guidelines will be modified or deleted by the Agency, as appropriate.

(b) Laboratory Guidelines will be approved by the Laboratory Expert Group (LabEG). Laboratory Guidelines are provided to Laboratories only and are not published on the Agency website.

(c) Implementation of Laboratory Guidelines is not mandatory. However, Laboratories are encouraged to follow, to the fullest extent possible, the recommendations of best practice included in relevant Laboratory Guidelines.

Rule 6050. Technical Notes

(a) Technical Notes may be issued to Laboratories to provide detailed technical guidance on the performance of specific Analytical Methods or procedures.

(b) Technical Notes will be approved by the LabEG. Technical Notes are provided to Laboratories only and are not published on the Agency website.

(c) Implementation of the recommendations detailed in Technical Notes is not mandatory. However, Laboratories are encouraged to follow, to the fullest extent possible, the technical guidance included in Technical Notes.

Rule 6060. Sample Analysis

(a) Sample analysis is part of the Analytical Testing process and involves the detection, identification, and, in some cases, demonstration of the presence above a Threshold of Prohibited Substance(s) or their Metabolite(s), or Marker(s) of Use of Prohibited Substances or Prohibited Methods in an equine Sample.

(b) Laboratories may accept samples for other forms of analysis, subject to the provisions of the Code of Ethics, which are not under the scope of HEAL accreditation. Any such analysis shall not be covered by the Laboratory's HEAL accreditation and, therefore, shall not be subject to the requirements of the Laboratory Standards, Technical Documents, or Technical Letters. Test reports or other documentation or correspondence from Laboratories shall not declare or represent that any such analysis is covered under their HEAL accreditation status.

Rule 6070. Racing Medication and Testing Consortium Accredited Laboratories

(a) These Laboratory Standards will replace current Racing Medication and Testing Consortium (RMTC) accreditation, although a transition phase which may include RMTC conducting the accreditation program may be agreed between the Agency and RMTC.

(b) Where a laboratory has current RMTC accreditation, any information required as part of the HEAL application process that has already been provided as part of its RMTC accreditation, and that the laboratory checks to confirm it is still current and valid may, with the agreement of the parties, be provided to the Agency.

*6100. Laboratory Accreditation and Operating Standards*

Rule 6110. Process and Requirements for HEAL Laboratory Accreditation

(a) Applicant laboratory for HEAL accreditation. Only a laboratory that satisfies the criteria in this Rule 6110 may apply to become a candidate laboratory for HEAL accreditation.

(1) The applicant laboratory shall submit a completed application form, provided by the Agency, duly signed by the laboratory Director (or equivalent position) and, if relevant, by the Director (or equivalent position) of the host organization (*e.g.,* university or public institution).

(2) Provision of business plan. The Agency shall request the applicant laboratory to submit a business plan summary, which shall include market considerations (clients, number of Samples, maintenance costs, etc.), facility, instrumental, staffing and training needs, and shall make a reasonable guarantee of the long-term provision of adequate financial and human resources to the laboratory.

(b) Candidate laboratory for HEAL accreditation. The application shall be evaluated by the Agency to determine whether the applicant laboratory will be granted candidate laboratory status by the Agency and thereby continue within the HEAL accreditation process. Additional supporting documentation may be requested by, and at the discretion of, the Agency.

(1) Description of the candidate laboratory. Once approved by the Agency, the candidate laboratory shall complete a detailed questionnaire and submit it to the Agency. The questionnaire will include, but is not limited to, the following:

(i) Staff list and their qualifications, including description of any relevant

anti-doping experience and a list of relevant scientific publications by laboratory staff;

(ii) Relevant memberships and engagement with professional societies, such as the Association of Official Racing Chemists (AORC), World Association of Anti-Doping Scientists (WAADS), Society of Forensic Toxicologists (SOFT), and The International Association of Forensic Toxicologists (TIAFT);

(iii) Description of the physical laboratory facilities, including a description of the security considerations for Samples and records. The laboratory facilities shall include ample analytical and administrative space to allow separate, restricted and dedicated areas for analytical and administrative operations;

(A) Physical security. Specific measures to maintain secure and restricted access to the laboratory facility and a controlled internal laboratory environment (*e.g.,* dedicated and restricted Sample storage areas, CCTV monitoring);

(B) IT security. Implementation of firewalls and other cyber security measures consistent with best practice and any applicable governmental regulations;

(C) Information Technology (IT) infrastructure. Implementation of a data and information management system (*e.g.,* LIMS) and a central server/intranet which allows secure data handling.

(iv) List of actual and proposed instrumental resources and equipment, including year of purchase and conditions for technical support (*e.g.,* contract/access to instrument manufacturer maintenance services);

(v) List of validated Initial Testing Procedures and Confirmation Procedures, including target Analytes and Limits of Detection (LODs), Limits of Identification (LOIs) and, where applicable, Limits of Quantification (LOQs) and estimates of Measurement Uncertainty (MU);

(vi) Status of method development and validation, including, at minimum, all mandatory Analytical Methods and method validation reports (if completed and currently in use);

(vii) List of available Reference Materials and Reference Collections, or plans to acquire Reference Materials or obtain Reference Collections;

(viii) Plans to ensure compliance with laboratory independence and impartiality requirements before receiving HEAL accreditation (and if this requirement is covered by other accreditation, such as ISO/IEC 17025, the laboratory may refer to it);

(ix) Status and scope of ISO/IEC 17025 accreditation; and

(x) A description of how the principles of the Code of Ethics is integrated into the laboratory Management System. A letter of compliance with the Code of Ethics signed by the laboratory Director shall be provided.

(xi) The Agency may require an update of this documentation during the process of accreditation.

(2) Payment of initial accreditation fee. Prior to entering the probationary period, the candidate laboratory shall pay the Agency a one-time non-refundable fee to cover the costs related to the initial accreditation process. This fee shall be determined by the Agency and disclosed to the laboratory prior to the accreditation process commencing. The accreditation process will not commence until the fee is agreed upon.

(3) Compliance with the Code of Ethics. The candidate laboratory shall implement and comply with the provision(s) of the Code of Ethics. Candidate laboratories shall not accept Samples directly from individual Covered Persons or from individuals or organizations acting on his or her behalf (unless approved in writing and in advance by the Agency and on the condition that Samples will be treated as a Sample under the Protocol, and proceedings may be brought against the relevant Covered Person(s) if evidence of an Anti-Doping Rule Violation or a Controlled Medication Rule Violation emerges).

(4) Pre-probationary testing and on-site assessment. If this is covered by another accreditation, such as ISO/IEC 17025, the laboratory may refer to this paragraph (4).

(i) Prior to entering the probationary accredited period, the Agency shall conduct a pre-probationary testing (PPT) and on-site assessment of the candidate laboratory at the candidate laboratory's expense. The purpose of this assessment is to obtain information about different aspects of the laboratory's competence and to clarify any issues regarding the accreditation process, which are relevant for the HEAL accreditation.

(ii) As part of the PPT, the candidate laboratory shall be required to analyze at least 10 blind EQAS samples arranged by the Agency. The general composition and content of the blind EQAS samples and the evaluation of laboratory EQAS results are described in the Rule 6200 and 6400 Series, respectively.

(iii) The candidate laboratory shall report the results for the PPT blind EQAS samples to, and in a form designated by, the Agency (in compliance with paragraph (e) of Rule 6260) within 6 weeks, unless otherwise requested by the candidate laboratory and agreed to by the Agency.

(A) Upon request, the candidate laboratory shall provide the Agency with a Laboratory Documentation Package for selected EQAS samples for which there is an Adverse Analytical Finding. Additional data may be required upon the Agency's request. This documentation shall be submitted within 10 days of the request or as otherwise indicated by the Agency.

(B) For selected EQAS samples with Negative Findings, the Agency may request all, or a portion of, the Initial Testing Procedure data.

(iv) After receiving the PPT EQAS results, the Agency shall inform the candidate laboratory of the evaluation of its performance and provide guidance for improvement. Corrective actions, if any, shall be conducted and reported by the candidate laboratory to the Agency within 30 days, or as otherwise indicated by the Agency.

(v) In addition, the Agency shall provide an assessment report regarding the outcomes of the on-site assessment, including any identified nonconformities, to allow the candidate laboratory to implement the necessary improvements. Corrective actions, if requested, shall be conducted, and reported by the candidate laboratory to the Agency within 30 days, or as otherwise indicated by the Agency.

(vi) The nonconformities identified in the Agency assessment report shall be satisfactorily addressed and the recommendations for improvement shall be implemented before the candidate laboratory can be accepted as an Agency probationary laboratory. The candidate laboratory's performance in the PPT and on-site assessment will be considered in the overall review of the candidate laboratory's application and may affect the timeliness of the candidate laboratory's entry into the probationary phase of accreditation.

(5) ISO/IEC 17025 accreditation.

(i) ISO/IEC 17025 accreditation is a critical and mandatory precondition for HEAL accreditation.

(ii) The Agency will consider a candidate laboratory application for HEAL accreditation only if the laboratory has obtained (or is in the process of obtaining) ISO/IEC 17025 accreditation. ISO/IEC 17025 accreditation must be conferred prior to an applicant receiving full HEAL accreditation.

(iii) The accreditation body, which may be specified by the Agency, shall be an International Laboratory Accreditation Cooperation (ILAC) full member that is a signatory to the ILAC

Mutual Recognition Arrangement (ILAC MRA) for testing activities as defined in ISO/IEC 17025.

(iv) The candidate laboratory shall (in a timely manner) send to the Agency a summary of the assessment report and any corrective or preventive action documentation addressing nonconformities.

(6) Analytical Testing Procedures. Before the Agency grants accreditation, candidate laboratories shall provide documentation to the Agency demonstrating that all mandatory Test Methods have been validated and included in the Laboratory's scope of ISO/IEC 17025 accreditation.

(7) Laboratory independence and impartiality. Before the Agency grants accreditation, probationary laboratories shall provide documentation to the Agency demonstrating compliance with the requirements of Laboratory independence and impartiality established in paragraph (c) of Rule 6130.

(8) Professional liability insurance coverage. Before the Agency grants accreditation, probationary laboratories shall provide documentation to the Agency demonstrating that they have adequate provisions for self-insuring, or professional liability risk insurance coverage has been obtained to cover liability of no less than $5,000,000 annually.

Rule 6120. The Agency Accredited Laboratory; Obtaining HEAL Accreditation

(a) The Agency probationary HEAL accreditation.

(1) Upon satisfactory completion of the candidate laboratory requirements (as per Rule 6110), as determined by the LabEG, a candidate laboratory can be considered for entry to the probationary phase of HEAL accreditation as an Agency probationary laboratory. Once the Agency has determined that the laboratory has successfully completed the requirements of a candidate laboratory, the Agency can grant the laboratory probationary accreditation status.

(2) A probationary laboratory must comply with the requirements of accredited laboratories, including the requirements for maintaining accreditation.

(3) The probationary period is 2 years or following the analysis of 2,500 Samples, whichever comes later. In circumstances where the laboratory was previously accredited by the RMTC, the Agency may exercise its discretion to reduce or eliminate the probationary period.

(b) The Agency pre-final accreditation.

(1) Once the Agency has determined that the laboratory has successfully completed the requirements of the probationary period, the laboratory can be granted final accreditation status. At the Agency's discretion, as part of the final accreditation process, a Final Accreditation Test (FAT) or on-site assessment may be conducted by the Agency. Costs associated with the Agency on-site assessment and FAT shall be disclosed and agreed to with the probationary laboratory.

(2) As part of the FAT, the probationary laboratory shall analyze a minimum of 15 blind EQAS samples selected from the routine EQAS program. The general composition and content of the blind EQAS samples and the evaluation of laboratory EQAS results are described in Rules 6200 and 6400, respectively.

(3) Compliance with the scope of ISO/IEC 17025 accreditation, the Laboratory Standards, and other procedures required by the Agency (*e.g.,* Technical Documents, Technical Letters) will be assessed. The FAT shall assess both the scientific competence and the capability of the probationary laboratory to manage multiple Samples.

(4) The probationary laboratory shall successfully report the results for the blind EQAS samples in the FAT to the Agency in accordance with paragraph (e) of Rule 6260 within 6 weeks of receipt the samples, unless otherwise specified by the Agency or otherwise requested by the laboratory and agreed to by the Agency.

(5) Upon request, the probationary laboratory shall provide the Agency with a Laboratory Documentation Package for selected EQAS samples for which there is an Adverse Analytical Finding. Additional data may be required upon the Agency's request. This documentation shall be submitted within 10 days of the Agency request, or as otherwise indicated by the Agency.

(6) For EQAS samples with Negative Findings, the Agency may request all or a portion of the Initial Testing Procedure data.

(7) After receiving the FAT EQAS results, the Agency shall inform the probationary laboratory of the evaluation of its performance. Corrective actions, if any, shall be conducted and reported by the probationary laboratory to the Agency within 30 days, or as otherwise indicated by the Agency.

(8) The Agency shall provide an assessment report with the outcomes of the accreditation assessment, including any identified nonconformities, for the probationary laboratory to implement the necessary improvements. Corrective actions, if any, shall be conducted and reported by the probationary laboratory to the Agency within 30 days, or as otherwise indicated by the Agency. The nonconformities identified in the FAT EQAS and the assessment report shall be satisfactorily addressed by the laboratory and the recommendations for improvement shall be implemented before accreditation will be granted.

(c) The Agency recommendation for accreditation.

(1) Based on the relevant documentation received from the probationary laboratory, the assessment report(s) from the Agency and from the relevant accreditation body, the Agency shall evaluate the probationary laboratory's progress in meeting all the requirements outlined in Rules 6110 and 6120.

(2) Once, as determined by the Agency (in the Agency's sole discretion), all accreditation requirements have been satisfactorily met by the probationary laboratory, the Agency will grant accreditation to the laboratory.

(3) However, if following the FAT and on-site assessment, and the review of any resulting Corrective Action Reports submitted by the probationary laboratory, the Agency determines that the probationary laboratory shall not be accredited, the laboratory will have a maximum of 6 additional months to correct and improve any pending nonconformities. The provision of documentation, the analysis of additional EQAS samples, or an additional assessment (on-site, remotely, or as a documentary audit, as determined by the Agency) may be required and, if so, will be conducted at the probationary laboratory's expense. A probationary laboratory that fails to provide satisfactory improvements after 6 months, as determined by the Agency, may be required to renew its candidacy as described in Rule 6110 or to restart the probationary phase of accreditation in accordance with paragraph (a) of this Rule 6120.

(d) Issuing and publishing of HEAL accreditation certificate. An accreditation certificate signed by a duly authorized representative of the Agency shall be issued in recognition of the HEAL accreditation. It shall specify probationary or final accreditation status. Such accreditation certificate shall specify the name of the Laboratory and the period for which the accreditation certificate is valid. Accreditation certificates may be issued after the effective date, with retroactive effect. A list of HEAL accredited

laboratories, together with internationally approved laboratories, shall be published on the Agency's website.

Rule 6130. Maintaining HEAL Accreditation

(a) Maintain ISO/IEC 17025 accreditation. The Laboratory shall maintain accreditation to ISO/IEC 17025, with primary reference to the analysis of Samples, granted by an accreditation body, which may be specified by the Agency, and which shall be an International Laboratory Accreditation Cooperation (ILAC) full member that is a signatory to the ILAC Mutual Recognition Arrangement (ILAC MRA) for testing activities as defined in ISO/IEC 17025. Flexible scope of accreditation must be included in the Laboratory's scope of accreditation.

(b) Participation in the Agency EQAS program. Laboratories are required to participate in the Agency EQAS on a continuous basis and meet the performance requirements of the EQAS as described in the Rule 6200 Series.

(c) Laboratory independence and impartiality.

(1) The Laboratory shall be administratively and operationally independent from any organization or person(s) that could exert undue pressure on the Laboratory and affect the impartial execution of its tasks and operations. Laboratories shall comply with these requirements of administrative and operational independence by January 1, 2023, unless otherwise approved by the Agency.

(2) In order to be operationally independent, the Laboratory shall manage its own affairs without hindrance, interference, or direction from any Person, except in accordance with the Laboratory Standards. The Laboratory shall, without limitation, control: the allocation of its budget; the procurement of equipment and other resources; Laboratory personnel decisions; the research conducted by the Laboratory; and all Sample Analytical Testing and reporting of results. The Laboratory shall not accept money from any Covered Person.

(3) The Laboratory shall have a dedicated budget allowing the implementation of an efficient approval process for the timely procurement of necessary Reference Materials, reagents, consumables and essential equipment, as well as independent Laboratory management decisions concerning the recruitment, retention and training of staff, participation in scientific meetings and symposia, and other relevant scientific decisions. This does not prevent the Laboratory from receiving research grants or other financial support from its host organization (*e.g.,* university, public institution), anti-doping organizations, sport organizations, governments, or other sponsors, while following applicable accounting regulations in connection with the receipt and management of those funds.

(d) Document compliance with the Code of Ethics.

(1) The Laboratory shall comply with the provisions of the Code of Ethics.

(2) The Laboratory shall annually provide to the Agency a letter of compliance with the provisions of the Code of Ethics, signed by the Laboratory Director. All staff employed at the Laboratory, permanent or temporary, shall also read, agree to, and sign documentation to indicate their agreement to the Code of Ethics. The Laboratory may be asked to provide documentation of compliance with the provisions of the Code of Ethics.

(3) The Laboratory shall establish a system requiring Laboratory staff to report any alleged breaches of the Code of Ethics to the Laboratory Director, which the Laboratory Director shall promptly report to the Agency. However, if Laboratory staff suspect that the Laboratory Director may have breached the Code of Ethics, the Laboratory staff shall promptly report the alleged breaches of the Code of Ethics directly to the Agency. The Laboratory Director or the Agency, as applicable, shall immediately and thoroughly investigate any alleged breach of the Code of Ethics.

(4) If the Laboratory's investigation determines that a breach of the Code of Ethics occurred, the Laboratory Director shall immediately inform the Agency of the results of the investigation and the disciplinary actions taken. The Agency may also impose penalties as a result of its own investigations. Penalties may range from a personal reprimand to the expulsion of the implicated Laboratory staff member(s), the reporting of the breach to the pertinent authorities (*e.g.,* law enforcement), the suspension or revocation of the Laboratory's HEAL accreditation, or any other follow-up measures the Agency determines to be appropriate.

(e) Document implemented research and development activities.

(1) The Laboratory shall develop and maintain a plan for research and development in the field of anti-doping science. The research activities can either be conducted by the Laboratory alone or in cooperation with other Laboratories or other research organizations.

(2) The Laboratory shall supply an annual progress report to the Agency documenting research and development results in the field of anti-doping science. The Laboratory shall also relate research and development plans for the following year.

(3) The annual research summary will be evaluated and scored by the LabEG. The Laboratory must, except where otherwise agreed by the Agency, achieve the minimum requirement to meet accreditation research requirements in Rule 6620.

(f) Document implemented sharing of knowledge.

(1) The Laboratory shall demonstrate its willingness and ability to share knowledge with other Laboratories. The Laboratory shall disseminate the results of its research and development activities to other Laboratories. The Laboratory is encouraged to make at least one annual contribution to an anti-doping symposium or conference. Laboratories are encouraged to: participate in collaborative research projects with other Laboratories; exchange experience and protocols with other Laboratories; arrange for visits of specialists with other Laboratories; and provide training to other Laboratories and probationary laboratories in specific areas of Analytical Testing.

(2) The Laboratory shall supply a report on sharing of knowledge with other Laboratories to the Agency, if requested. A description of sharing of knowledge is provided in the Code of Ethics.

(g) Maintain professional liability insurance coverage. Laboratories shall provide documentation to the Agency including evidence that professional liability risk insurance coverage is maintained of no less than $5,000,000 annually (for example, evidence of timely payment of applicable fees and premiums).

(h) Maintain minimum number of Samples.

(1) To maintain proficiency in Analytical Testing, Laboratories are required to analyze a minimum of 2,500 Samples provided annually by the Agency. To determine the minimum number of Samples, each urine Sample and blood Sample analyzed by the Laboratory (excluding Samples submitted for TCO2 analysis only), regardless of whether they are collected as a ''paired'' Sample, shall count as an individual Sample. The Agency will monitor the number of Samples tested by the Laboratory. Except where the Agency fails to send the minimum annual number of Samples to the Laboratory, if the number of Samples falls below the minimum, the

Laboratory's HEAL accreditation may be suspended in accordance with Rule 6510.

(2) It is recognized that specific circumstances may affect a Laboratory's ability to analyze the minimum Samples annually, such as when the Laboratory is not operational for the full calendar year. In such cases, the Agency shall require that the Laboratory implement measures to maintain proficiency in Analytical Testing, for example, by strengthening its internal Quality Assurance Scheme (iQAS) and internal audits program. The Agency may also provide additional EQAS samples, conduct a documentary audit, or an on-site or remote (online) assessment, at its discretion, to assess the status of the Laboratory's operations.

(i) Laboratory Analytical Testing Procedures and services. Laboratories shall provide to the Agency an up-to-date list of Analytical Testing Procedures and services, to assist the Agency in developing test distribution plans. Upon request, Laboratories shall cooperate with the Agency by providing other relevant information regarding Testing plans (*e.g.,* Laboratory analytical capabilities).

(j) Participating in the Agency/accreditation body re-assessments and continuous assessments during the accreditation cycle.

(1) The assessment team shall include at least one Laboratory Standards-trained assessor selected by the accreditation body for the assessment/re-assessment.

(2) The Laboratory shall (in a timely manner) send to the Agency a summary of the assessment report and any corrective or preventive action documentation addressing nonconformities.

(3) The Laboratory shall provide the Agency with an updated copy of the ISO/IEC 17025 certificate and scope of ISO/IEC 17025 accreditation as soon as it is obtained from the accreditation body.

(4) The Agency Laboratory assessment. The Agency reserves the right to conduct documentary audits, as well as inspect and assess the Laboratory, through on-site or remote (online) assessments at any time, at the Agency's expense. The notice of the Agency assessment will be made in writing to the Laboratory Director. In exceptional circumstances, and at the Agency's discretion, the assessment may be unannounced.

(5) As part of an announced or unannounced Laboratory assessment, the Agency retains the right to request copies of Laboratory documentation or request Further Analysis of selected A or B Samples, either on-site or in any Laboratory selected by the Agency.

Rule 6140. The Agency Monitoring of Accreditation Status

(a) The Agency shall regularly review the compliance of Laboratories with the requirements listed in the Laboratory Standards and related Technical Documents and Technical Letters. In addition, the Agency shall also conduct an annual review of EQAS results and of relevant routine Analytical Testing issues to assess the overall performance of each Laboratory and to decide its accreditation status.

(b) Maintenance of HEAL accreditation. Compliance with all the requirements established in Rule 6130, including satisfactory performance by a Laboratory in the EQAS and in routine Analytical Testing, as determined by the Agency, is a critical requirement for the maintenance of the Laboratory's HEAL accreditation.

(c) Issuing and publication of accreditation certificate. On an annual basis, when maintenance of accreditation is approved by the Agency, the Laboratory shall receive a HEAL accreditation certificate, signed by a duly authorized representative of the Agency, which is issued in recognition of such accreditation. The accreditation certificate shall specify the name of the Laboratory and the period for which the accreditation certificate is valid. HEAL accreditation certificates may be issued after the effective date, with retroactive effect. The list of the HEAL-accredited Laboratories is maintained on the Agency's website.

*6200. The Agency External Quality Assessment Scheme*

Rule 6210. The Agency External Quality Assessment Scheme

The Agency regularly distributes External Quality Assessment Scheme (EQAS) samples to Laboratories and, when applicable, to probationary laboratories. The Agency EQAS is designed to continually monitor the capabilities of the Laboratories and probationary laboratories, to evaluate their proficiency, and to improve test result uniformity between Laboratories. EQAS samples are used to assess Laboratory routine analytical capacity and performance, reporting turn-around times, and overall compliance with the Agency Laboratory standards (*e.g.,* Laboratory Standards, Technical Documents and Technical Letters), as well as other, non-analytical performance criteria. At the same time, the EQAS also represents, via its educational components, a source of continuous improvement for the effectiveness of the Analytical Testing Procedures.

Rule 6220. Types of EQAS

(a) Blind EQAS. The Laboratory will be aware that the sample is an EQAS sample since it is delivered by the Agency's EQAS sample provider. However, the Laboratory will not know the content of the sample.

(b) Double-blind EQAS. The Laboratory will not be aware that the sample is an EQAS sample since it is delivered by the Agency and is indistinguishable from routine Samples.

(c) Educational EQAS.

(1) Educational EQAS samples may be provided as open (in which case the content of the EQAS sample is known), blind or double-blind samples. This approach is used for educational purposes or for data gathering.

(2) As part of the educational EQAS, the Agency may provide Laboratories with new Reference Materials, Reference Collections, or quality control (QC) samples for a prompt implementation of existing or new Analytical Testing Procedures.

(3) The Agency may require the successful participation of Laboratories in an educational EQAS for the Agency-specific Analytical Testing Procedures for Laboratories to seek an extension of the Laboratory's scope of ISO/IEC 17025 accreditation by an accreditation body before the subsequent application of the Analytical Testing Procedure to the routine analysis of Samples.

Rule 6230. Number of EQAS Samples

(a) The actual composition and number of EQAS samples supplied to different Laboratories may vary; however, within any calendar year, all Laboratories participating in the EQAS are expected to have analyzed the minimum total number of EQAS samples.

(b) Each year, the EQAS program will consist of:

(1) At least 15 blind EQAS samples, distributed by the Agency in multiple rounds;

(2) At least 5 double-blind EQAS samples, distributed by the Agency in multiple rounds; and

(3) At least 3 of the above EQAS samples will contain Threshold Substances.

(c) As part of the Agency's Laboratory monitoring activities, and with the main purpose of assisting Laboratories in their continuous improvement of performance, the Agency may increase the number of annual EQAS samples (mainly for educational purposes) for

certain Laboratories, according, but not limited, to the following criteria:

(1) Monitoring the effectiveness of corrective action implementation after questionable or unsatisfactory performance in the Agency EQAS or in routine Analytical Testing;

(2) Substantiated intelligence information received by the Agency indicating questionable or unsatisfactory Laboratory performance;

(3) Laboratories which do not receive enough Samples (<100 annual Samples) for a specific Analytical Testing Procedure, which is not part of the Laboratory's routine Analytical Testing menu; and

(4) As part of the Agency's Laboratory assessments.

Rule 6240. Composition of EQAS Samples

(a) EQAS samples may or may not contain Prohibited Substance(s) or Metabolite(s) of Prohibited Substance(s) or Marker(s) of Prohibited Substance(s) or Prohibited Method(s).

(b) Blank EQAS samples. Blank EQAS samples do not contain Prohibited Substance(s) or Metabolite(s) of Prohibited Substance(s) or Marker(s) of Prohibited Substance(s) or Prohibited Method(s).

(c) Adulterated EQAS samples. Adulterated EQAS samples are those which have been deliberately adulterated by the spiking of non-characteristic Metabolite(s) or by the addition of extraneous substances designed to dilute or concentrate the sample, or to degrade or mask the Analyte prior to or during the analytical determination. Adulterated EQAS samples may also be obtained from the controlled administration or the addition of non-prohibited substances, which share common Metabolite(s) with Prohibited Substance(s).

(d) EQAS samples containing Prohibited Substance(s), their Metabolite(s) or Marker(s), or the Marker(s) of Prohibited Method(s).

(1) The concentration(s) of selected Analyte(s) are those that may be encountered in the urine or blood after Use of Prohibited Substance(s) or Prohibited Method(s). For some Analytes, the EQAS sample may contain the parent Prohibited Substance or its Metabolite(s) or its Marker(s).

(2) EQAS samples may be spiked with Prohibited Substance(s) or their Metabolite(s) or Marker(s) but, where appropriate, may be prepared from controlled administration studies. The EQAS sample composition shall reflect as closely as possible the expected target Analyte Metabolite pattern and concentrations usually found in Samples.

(3) An EQAS sample may contain more than one Prohibited Substance, Metabolite(s), or Marker(s) of a Prohibited Substance or Prohibited Method. It may also contain multiple Metabolites or Markers of a single Prohibited Substance or Markers of a Prohibited Method, which would represent the presence of a single Prohibited Substance or the Use of a single Prohibited Method.

(4) Double-blind EQAS samples shall be representative of Samples. Therefore, to the extent possible (in consideration, for example, of technical or ethical constraints, availability of the pharmaceutical grade substance), double-blind EQAS samples containing Prohibited Substance(s) or Metabolite(s) of Prohibited Substance(s) or Marker(s) of Prohibited Substance(s) or Prohibited Method(s) shall be prepared from controlled administration studies performed in equine subjects. However, if this is not possible, then the double-blind EQAS sample(s) may be prepared by spiking expected target Analyte(s) in the Sample matrix in consideration of the representative metabolic profile(s).

(5) For Non-Threshold Substances, the concentration in the EQAS sample will be guided by, but not limited to, one of the following criteria: concentrations of the Prohibited Substance or its Metabolite(s) or Marker(s) equal to or greater than (≥) the applicable MRPL; concentrations of the Prohibited Substance or its Metabolite(s) or Marker(s) between 50% of the MRPL and the MRPL (applicable only to Non-Threshold Substances prohibited at all times and with no Minimum Reporting Levels); Non-Threshold Substances with Minimum Reporting Levels or other limits controlling them (*e.g.,* substances prohibited in a Post-Race Sample only), will normally be present in estimated concentrations greater than (≤) 120% of the applicable Minimum Reporting Level; or concentrations of the Prohibited Substance or its Metabolite(s) or Marker(s) below (<) 50% of the applicable MRPL (for Non-Threshold Substances prohibited at all times with no Minimum Reporting Levels, for educational purposes).

(6) For Threshold Substances, the concentration in the EQAS sample will be guided by, but not limited to, one of the following criteria: greater than (≤) 10% of the Threshold as established in any relevant Technical Document(s) or Laboratory Guidelines; or less than (<) 50% of the Threshold for those Threshold Substances whose presence shall be reported if detected in the presence of diuretics or masking agents.

Rule 6250. Laboratory Analytical Testing Procedures Used in EQAS

All procedures associated with the Analytical Testing of the EQAS samples by the Laboratory are to be conducted in a manner substantially similar to that applied to routine Samples, unless otherwise specified by the Agency. No effort shall be made to optimize instrument (*e.g.,* change multipliers or chromatographic columns) or method performance prior to analyzing the EQAS samples, unless it is a scheduled maintenance activity. Only validated, Fit-for-Purpose Analytical Testing Procedures described in the Laboratory's Standard Operating Procedures are to be employed in the analysis of EQAS samples (*i.e.,* using the Initial Testing Procedures and Confirmation Procedures applied in routine Analytical Testing).

Rule 6260. Reporting of EQAS Results

(a) The purpose of the EQAS program is to ensure that all Laboratories maintain proficiency in the performance of their Analytical Testing Procedures and report valid results to the Agency in a timely manner.

(b) In the spirit of the EQAS program, a Laboratory shall not communicate with other Laboratories regarding the identity or content of substances present in or absent from blind EQAS samples prior to the submission of EQAS results to the Agency. This prohibition also applies to Laboratory requests for second opinions, which shall not be requested for blind EQAS samples.

(c) Contact between Laboratories regarding any aspect of blind EQAS analysis (including the results obtained) prior to reporting by all Laboratories to the Agency will be considered an attempt to circumvent the quality control assessment.

(d) For double-blind EQAS samples, which are indistinguishable from routine Samples, consultation between Laboratories before reporting such EQAS results to the Agency may occur. However, such consultation shall not involve identifying the sample as an Agency double-blind EQAS sample (in cases when, for any reason, the Laboratory identifies the EQAS nature of the sample).

(e) Reporting blind EQAS results.

(1) The Laboratory shall report the results of blind EQAS samples to the Agency in the same manner as specified for routine Samples (see Rule 6316) unless otherwise notified by the Agency. For some blind EQAS samples or sample sets, additional information may be requested from the Laboratory (*e.g.,* LODs, LOQs, MU estimations).

(2) The results of the blind EQAS shall be submitted to the Agency on or before the specified reporting date, unless an extension is granted by the Agency. Failure to report results of blind EQAS samples will be considered a false Negative Finding(s).

(f) Reporting double-blind EQAS results.

(1) The Laboratory shall report the results of double-blind EQAS samples as per Rule 6316.

(2) Reporting of double-blind EQAS results shall occur within the same timeframe as specified for routine Samples, unless an extension is granted by the Agency.

(3) Failure to report double-blind EQAS results within this timeframe or, subject to an extension of this deadline granted by the Agency pursuant to subparagraph (2) above, within the agreed or the Agency-approved deadline, will be considered a false Negative Finding(s).

(g) Reporting educational EQAS results.

(1) The Laboratory shall report the results of open or blind educational EQAS samples on or before the specified reporting deadline and in a format specified by the Agency. Results received after the deadline will not be included in the assessment of EQAS results or in the subsequent educational EQAS report and will be considered a false Negative Finding(s).

(2) For open educational and blind EQAS samples, the Laboratory shall report the LODs of the identified Non-Threshold Substance(s) or Metabolite(s) or Marker(s), or of the identified Marker(s) of Prohibited Method(s), as estimated during method validation of the Initial Testing Procedure.

(h) Reporting results for EQAS samples containing Non-Threshold Substances. Unless otherwise specified by the Agency (for example, for an educational EQAS), the report of EQAS results for Non-Threshold Substances shall include all the Analytes whose presence in the EQAS sample has been confirmed by the Laboratory, including the Prohibited Substance(s) (*e.g.,* parent compound(s), if applicable) and all identified Metabolite(s) or Marker(s) of the Prohibited Substances or Marker(s) of Prohibited Method(s). The Agency may also require that the Laboratory report the estimated concentrations of the confirmed Analyte(s).

(i) Reporting results for EQAS samples containing Threshold Substances.

(1) For educational and blind EQAS samples, the report of EQAS results for Threshold Substances shall include the values measured for each aliquot analyzed, whenever the measured mean value of all replicates is greater than or equal to (≥) 50% of the applicable Threshold.

(2) For double-blind EQAS samples, the Laboratory shall report the quantitative results to, and in a form designated by, the Agency for routine Samples, in accordance with any relevant Technical Document(s), Technical Letter(s) or Laboratory Guidelines.

*6300. Analysis of Samples*

Rule 6301. Application of ISO/IEC 17025 to the Analysis of Samples

(a) Introduction and scope. This section of the Laboratory Standards is intended as an extension of the application of ISO/IEC 17025 and ILAC–G7 to the field of Doping Control. Any aspect of Analytical Testing or management not specifically discussed in this document or in any relevant Technical Documents, Technical Letters or Laboratory Guidelines shall be governed by ISO/IEC 17025. The application focuses on the specific parts of the processes that are critical with regard to the quality of the laboratory's performance as a Laboratory and are, therefore, significant in the evaluation and accreditation process.

(b) This section introduces the specific performance standards for a Laboratory, as applicable. The conduct of Laboratory Analytical Testing is considered a process within the definitions of ISO 17000. Performance standards are defined according to a process model where the Laboratory practice is structured into 3 main categories of processes:

(1) structural and resource requirements;

(2) process requirements; and

(3) management requirements.

Rule 6302. Subcontracting Analysis

(a) A Laboratory may subcontract an analysis to another Laboratory, in consultation with, and following written approval from, the Agency. The conditions that justify subcontracting include, for example:

(1) A specific technology or Analyte(s) that are not within the Laboratory's scope of ISO/IEC 17025 accreditation;

(2) An Analytical Testing Restriction decision;

(3) Other valid explanations, such as a need for higher sensitivity or specific equipment or expertise, temporary workload or technical incapacity;

(4) In exceptional circumstances, the Agency may elect to grant specific authorization to subcontract analyses using specific methods to an ISO/IEC 17025-accredited laboratory approved by the Agency, which has the necessary technique within its scope of ISO/IEC 17025 accreditation (for example, DNA analysis or genomic profiling);

(5) Other specific investigations, such as, without limitation, forensic examinations which need to be performed in the course of the Analytical Testing process may also be subcontracted by the Laboratory.

(b) In all such cases, the Laboratory subcontracting the analysis is only responsible for the maintenance of the appropriate Chain of Custody up to Sample reception by the subcontracted Laboratory. Such arrangements shall be clearly recorded as part of the Sample's documentation and included in the Laboratory Documentation Package, if applicable.

Rule 6303. Samples With Irregularities

(a) The Laboratory shall observe and document conditions that exist at the time of Sample reception or registration that may adversely impact on the integrity of a Sample or on the performance of Analytical Testing Procedures. Only unusual conditions shall be recorded.

(b) Irregularities to be noted by the Laboratory may include, but are not limited to:

(1) Sample transport conditions (*e.g.,* delivery time, temperature), which may impact the integrity of the Sample for Analytical Testing, as determined by the Laboratory;

(2) Sample collection information (including Sample identification Protocol), which is necessary to conduct the Analytical Testing menu requested by the Agency, is not provided (*e.g.,* missing or incomplete Sample collection documentation);

(3) Sample identification is questionable. For example, if the number on the Sample container does not match the Sample identification number on the Sample collection documentation;

(4) Covered Person or Covered Horse information is visible on the Laboratory copy of the Sample collection documentation or any other document transferred to the Laboratory;

(5) Sample identification numbers are different between the A and the B Sample containers of the same Sample;

(6) Tampering or adulteration of the Sample is evident;

(7) Sample is not sealed with Tamper Evident device or not sealed upon receipt;

(8) Sample volume does not meet the suitable volume for analysis or is otherwise inadequate to perform the

Analytical Testing menu requested by the Agency;

(9) The Sample contains foreign objects, such as insects; or

(10) The Sample condition(s) is unusual (*e.g.,* color, odor, presence of turbidity or foam in a urine Sample, color, hemolysis, freezing or clotting of a blood Sample, or unusual differences in Sample appearance (such as color or turbidity) between the A and the B Samples).

(c) When an analysis on a Sample with documented irregularities is performed, the Laboratory shall record the irregularities in the test report.

Rule 6304. Sample Splitting Procedure

(a) In cases when either the A or B Sample is not suitable for the performance of the analyses (*e.g.,* there is insufficient Sample volume, the Sample container has not been properly sealed or has been broken, the Sample's integrity has been compromised in any way, the Sample is heavily contaminated, the A or B Sample is missing), the Laboratory shall notify and consult with the Agency regarding whether it is appropriate to split the other Sample container (A or B, as applicable), provided that it is properly sealed. The Agency should inform the Laboratory of its decision in writing within 3 days of notification by the Laboratory. If the Agency decides not to proceed with the Sample splitting procedure, then the Laboratory shall report the Sample as ''not analyzed,'' including the noted Sample irregularities and the documented reasons if provided by the Agency.

(b) The first fraction of the split Sample shall be considered as the A Sample and shall be used for the Initial Testing Procedure(s), unless the Initial Testing Procedure(s) have already been performed, and the A Confirmation Procedure(s), if necessary. The second fraction, considered as the B Sample, shall be resealed and stored frozen for the B Confirmation Procedure(s), if necessary.

(c) The process of opening and splitting the Sample and resealing of the remaining second fraction shall be conducted in accordance with Rule 6312 for a customary B Sample opening.

(d) When the splitting procedure concerns blood Samples, which have been collected for Analytical Testing on the blood serum/plasma fraction, the sealed, intact (A or B) Sample shall be centrifuged as soon as practicable after Laboratory reception to obtain the serum or plasma fraction. The centrifuged Sample shall be stored frozen in the sealed Sample collection tube according to established protocols until the Sample opening/splitting procedure can be conducted. The opening of the Sample for the splitting of the serum/plasma fraction and resealing of the second fraction shall be carried out as described immediately above.

Rule 6305. Initial Storage and Sample Aliquoting for Analysis

(a) The Aliquot preparation procedure for any Initial Testing Procedure or Confirmation Procedure shall minimize the risk of contamination of the Sample or Aliquot. The Laboratory shall use new material(s) (*e.g.,* new test tubes, disposable pipettes or pipettes with disposable, non-reusable tips) to take Aliquots for Confirmation Procedures.

(b) Urine Samples. In order to maintain the stability and integrity of the urine Samples, the Laboratory shall implement Sample storage procedures that minimize storage time at room and refrigerated temperatures, as well as Sample freeze/thaw cycles.

(1) For urine Samples, the Laboratory shall obtain, following proper homogenization of the Sample, an initial Aliquot containing enough Sample volume for all analytical procedures (*i.e.,* all Initial Testing Procedures or all intended Confirmation Procedures, as applicable), by decanting the Aliquot from the urine Sample container into a secondary container (*e.g.,* a Falcon tube). Procedure-specific Aliquot(s) shall then be taken from the secondary container.

(2) The Laboratory shall measure the pH and specific gravity of urine Samples once, using one Aliquot, during the Initial Testing Procedure and the Confirmation Procedure(s) (A and B Samples). Other tests that may assist in the evaluation of adulteration or manipulation may be performed, if deemed necessary by the Laboratory.

(3) Urine A Samples shall be frozen after Aliquots are taken for the Initial Testing Procedure(s) to minimize risks of Sample microbial degradation. Urine B Samples shall be stored frozen after reception until analysis, if applicable.

(c) Blood Samples. The Laboratory shall follow any applicable Agency procedures, Technical Document(s), and Technical Letter(s) for handling and storing blood Samples.

Rule 6306. Selection and Validation of Analytical Testing Procedures

(a) The Laboratory shall select, validate, and document Analytical Testing Procedures, which are Fit-for-Purpose for the analysis of representative target Analytes of Prohibited Substances and Prohibited Methods.

(b) Validation results for Analytical Testing Procedures shall be summarized in a validation report and supported by the necessary documentation and analytical data. The validation report shall indicate whether the Analytical Testing Procedure is Fit-for-Purpose and shall be included in a Laboratory scope of accreditation.

(c) The Laboratory shall define and document the conditions that would trigger the revalidation of an Analytical Testing Procedure (*e.g.,* change of internal standard, modified extraction procedure or chromatographic methodology, change in detection technique) or a partial re-assessment of the validation process (*e.g.,* replacement or upgrade of instrument, addition of new Analyte to the Analytical Method).

(d) Validation of Analytical Testing Procedures for Non-Threshold Substances. The Laboratory shall develop, as part of the method validation process, appropriate standard solutions for detection or identification and estimation of the concentration of Non-Threshold Substances. In the absence of suitable Reference Materials, Reference Collections may be used for detection and identification.

(1) Validation of Initial Testing Procedures for Non-Threshold Substances.

(i) The Laboratory shall validate the Selectivity, carryover, reliability of detection at the MRPL and Limit of Detection (LOD) for the Initial Testing Procedure from the analysis of an adequate number of representative samples prepared in the appropriate matrix of analysis. For chromatographic-mass spectrometric Analytical Methods, the Initial Testing Procedure shall allow the detection of each Non-Threshold Substance or its representative Metabolite(s) or Marker(s) at 50% or less of the Minimum Required Performance Levels (MRPL).

(ii) For Non-Threshold Substances with Minimum Reporting Levels (MRL), the Laboratory shall validate and document the estimated concentration levels that will require a Confirmation Procedure.

(iii) If there is no available Reference Material, an estimate of the detection capability of the Initial Testing Procedure (*i.e.,* the LOD) for the Non-Threshold Substance or its representative Metabolite(s) or Marker(s) may be provided by assessing a representative substance from the same class of Prohibited Substances with a similar chemical structure.

(2) Validation of Confirmation Procedures for Non-Threshold Substances. Factors to be investigated in the method validation procedure to

demonstrate that a Confirmation Procedure for Non-Threshold Substances is Fit-for-Purpose include, but are not limited to:

(i) Selectivity: The ability of the Confirmation Procedure to detect and identify the Analyte of interest, taking into account interference(s) from the matrix or from other substance(s) present in the Sample. Selectivity shall be determined and documented from the analysis of an adequate number of representative samples prepared in the matrix of Sample analysis, in compliance with any applicable Agency procedures, Technical Document, Technical Letter, or Laboratory Guidelines. The Confirmation Procedure shall be able to discriminate between Analytes of closely related structures;

(ii) Limit of Identification (LOI): When the analyses of Non-Threshold Substances are based on chromatographic-mass spectrometric techniques, the Laboratory shall determine the lowest concentration at which each Non-Threshold Substance or its representative Metabolite(s) or Marker(s), for which a Reference Material is available, is identified at no more than 5% false negative rate (in compliance with any applicable Agency procedures, Technical Document, Technical Letter, or Laboratory Guidelines). The LOI shall be lower than the applicable MRPL;

(iii) Robustness: The Confirmation Procedure shall be demonstrated to produce similar results with respect to minor variations in analytical conditions, which may affect the results of the analysis. Those conditions that are critical to ensuring reproducible results shall be considered; and

(iv) Carryover: The conditions required to eliminate carryover of the substance of interest from Sample to Sample during processing or instrumental analysis. Elimination of ''injection memory'' effect is demonstrated by injecting a blank control sample for the Analyte in question, prepared in the Sample matrix, immediately prior to the Sample of interest.

(3) Validation of Analytical Testing Procedures for Threshold Substances.

(i) As part of the validation process for chromatography-mass spectrometric Analytical Methods applied to the analysis of Threshold Substances, the Laboratory shall develop acceptable standard solutions for identification of Threshold Substances. For Confirmation Procedures, Certified Reference Materials shall be used for quantification, if available.

(ii) For the application of affinity-binding assays, or other methods as applicable, to the analysis of Threshold Substances, the Laboratory shall follow any applicable Agency procedures and Technical Document, and should follow any relevant Laboratory Guidelines.

(4) Validation of Initial Testing Procedures for Threshold Substances.

(i) The Laboratory shall validate Initial Testing Procedures that are Fit-for-Purpose, in accordance with any applicable Technical Document(s), Technical Letter(s), or Laboratory Guidelines.

(ii) For chromatographic-mass spectrometric Initial Testing Procedures, the Laboratory shall validate the Selectivity, LOD and dynamic range from the analysis of an adequate number of representative samples prepared in the appropriate matrix of analysis, unless otherwise specified.

(iii) Unless otherwise specified, the Laboratory shall validate and document the estimated concentration levels which will require quantitative Confirmation Procedure(s).

(iv) In order to account for a possible underestimation of concentrations of Threshold Substances during non-quantitative Initial Testing Procedures, the Laboratory shall establish and document in the Test Method's SOP criteria (*e.g.,* concentration levels) determined, during the Initial Testing Procedure method validation, to evaluate initial results as Presumptive Adverse Analytical Findings and ensure that all potentially positive Samples are subjected to quantitative Confirmation Procedures.

(v) The estimation of Measurement Uncertainty (MU) is not required during the validation of Initial Testing Procedures, unless otherwise specified.

(5) Validation of Confirmation Procedures for Threshold Substances. Factors to be investigated during the method validation to demonstrate that a quantitative Confirmation Procedure for a Threshold Substance is Fit-for-Purpose include, but are not limited to:

(i) Selectivity, LOI, robustness, and carryover;

(ii) Limit of Quantification (LOQ): The Laboratory shall demonstrate that a quantitative Confirmation Procedure has an established LOQ of no more than 50% of the Threshold value, in accordance with the LOQ values required in relevant Technical Document(s) or in consideration of Laboratory Guidelines;

(iii) Dynamic range: The range of the quantitative Confirmation Procedure shall be documented from at least 50% to 200% of the Threshold value;

(iv) Repeatability (sr): The quantitative Confirmation Procedure shall allow for the reliable repetition of the results over a short time, using a single operator and item of equipment. Repeatability at levels close to the Threshold shall be determined;

(v) Intermediate Precision (sw): The quantitative Confirmation Procedure shall allow for the reliable repetition of the results at different times and with different operators and instruments, if applicable, performing the assay. Intermediate Precision at levels close to the Threshold shall be determined;

(vi) Bias (b): The Bias of the measurement procedure shall be evaluated either using Certified Reference Materials or traceable Reference Materials, if available, or from comparison with a reference method or with the consensus values obtained from an inter-Laboratory comparison study or EQAS participation. Bias at the levels close to the Threshold shall be determined;

(vii) Measurement Uncertainty (MU): The MU associated with the results obtained with the quantitative Confirmation Procedure shall be estimated in accordance with any applicable Agency procedures, Technical Document(s), Technical Letter(s), or Laboratory Guidelines. At a minimum, MU at levels close to the Threshold shall be addressed during the validation of the quantitative Confirmation Procedure.

(e) Confirmation Procedure method validation data (including the estimation of MU) is evaluated during the assessment process for inclusion of the quantitative Confirmation Procedure within the Laboratory's scope of ISO/IEC 17025 accreditation. Therefore, for those Confirmation Procedures that are included within the Laboratory's scope of ISO/IEC 17025 accreditation, the Laboratory is not required to produce method validation data, SOPs, or other evidence of method validation in any legal proceeding.

Rule 6307. Sample Analysis

(a) Laboratories shall analyze Samples collected by or on behalf of the Agency using any Analytical Testing menu directed by the Agency to detect the presence of Prohibited Substances or Prohibited Methods only (as defined in the Prohibited List).

(b) Covered Persons and their representatives are not permitted to be present for any aspect of Sample analysis or processing described in the Laboratory Standards, Technical Documents, Technical Letters, Laboratory Guidelines, or Laboratory SOPs. In addition, Covered Persons are not permitted to have a Sample transferred to be tested at a laboratory.

(c) Laboratories may analyze Samples for the following, in which case the results of the analysis shall not be reported as an Atypical Finding or an Adverse Analytical Finding:

(1) Non-prohibited substances or methods that are included in the Agency monitoring program;

(2) Non-prohibited substances for results interpretation purposes (*e.g.,* non-prohibited substances that share Metabolite(s) or degradation products with Prohibited Substances), if applicable;

(3) Non-prohibited substances or methods requested as part of a Results Management process by an adjudicatory body or the Agency;

(4) Non-prohibited substances or methods requested by the Agency as part of its safety Protocol, Protocol of conduct or other regulations; or

(5) Additional analyses for quality assurance/quality improvement/method development or research purposes, in accordance with the requirements indicated in Rule 6320.

(d) At minimum, all Laboratories are required to implement all mandatory Analytical Testing Procedures, as determined by the Agency in compliance with any relevant Technical Document(s) and Technical Letter(s). Laboratories may implement additional methods for the analysis of particular Prohibited Substances or Prohibited Methods.

(e) Analytical Testing Procedure(s) included in the Laboratory's scope of ISO/IEC 17025 accreditation shall be considered as Fit-for-Purpose, and, therefore, the Laboratory shall not be required to provide method validation documentation, SOPs or EQAS performance data in support of an Adverse Analytical Finding.

(f) However, if the Analytical Testing Procedure has not been included yet in the Laboratory's scope of ISO/IEC 17025 accreditation, the Laboratory shall validate the procedure in compliance with the Laboratory Standards and any applicable Agency procedures, Technical Document(s), Technical Letter(s), or Laboratory Guidelines prior to its application to the analysis of Samples. In such cases, the Laboratory may be required to provide method validation documentation or EQAS performance data in support of an Adverse Analytical Finding.

(g) Laboratories may, on their own initiative and prior to reporting a test result, apply additional Analytical Testing Procedures to analyze Samples for Prohibited Substances or Prohibited Methods not included in the standard Analytical Testing menu requested by the Agency, provided that the additional work is authorized by the Agency, conducted at the Laboratory's expense, and does not significantly affect the possibility to submit the Sample to Further Analysis. Results from any such analysis shall be reported to, and in a form designated by, the Agency and have the same validity and Consequences as any other analytical result.

Rule 6308. Application of Initial Testing Procedures

(a) The objective of the Initial Testing Procedure is to obtain information about the potential presence of Prohibited Substance(s) or Metabolite(s) of Prohibited Substance(s), or Marker(s) of the Use of a Prohibited Substance or Prohibited Method. Results from Initial Testing Procedure(s) can be included as part of longitudinal studies (*e.g.,* endogenous steroid), provided that the method is Fit-for-Purpose.

(b) The Initial Testing Procedure(s) shall fulfill the following requirements:

(1) The Initial Testing Procedure shall be Fit-for-Purpose;

(2) The Initial Testing Procedure shall be performed on Aliquot(s) taken from the container identified as the A Sample (and if the A Sample cannot be used for the Initial Testing Procedure(s), see Rule 6304);

(3) The Initial Testing Procedure shall be recorded, as part of the Sample (or Sample batch) record, each time it is conducted;

(4) All batches undergoing an Initial Testing Procedure shall include appropriate negative and positive quality controls prepared in the matrix of analysis, unless otherwise specified by the Agency;

(5) The Initial Testing Procedures for Non-Threshold Substances shall include appropriate controls of representative substance(s) at or below the MRPL;

(6) The Initial Testing Procedures for Threshold Substances shall include appropriate controls close to the Threshold, unless otherwise specified by the Agency;

(7) Results from Initial Testing Procedures are not required to consider the associated MU, unless otherwise specified by the Agency; and

(8) The Laboratory shall establish criteria, based on its method validation and in accordance with its SOP, to evaluate results from an Initial Testing Procedure as a Presumptive Adverse Analytical Finding, which would trigger confirmation analyses.

Rule 6309. Application of Confirmation Procedures

(a) The objective of the Confirmation Procedure is to obtain a result, which supports or does not support the reporting of an Adverse Analytical Finding or Atypical Finding.

(b) A Confirmation Procedure for a Non-Threshold Substance with a Minimum Reporting Level or other control limit may also be performed if the result estimated from the Initial Testing Procedure is lower than the applicable Minimum Reporting Level, as determined by the Laboratory in accordance with the method's validation results, or as specifically required by the Agency.

(c) A result obtained in the Initial Testing Procedure for a Threshold Substance higher than the Threshold requires a Confirmation Procedure. A Confirmation Procedure may also be performed if the result obtained in the Initial Testing Procedure is lower than the Threshold, as determined by the Laboratory, or as specifically required by the Agency.

(d) Irregularities in the Initial Testing Procedure(s) shall not invalidate an Adverse Analytical Finding, which is adequately established by a Confirmation Procedure.

(e) The Confirmation Procedure(s) shall fulfill the following requirements:

(1) The Confirmation Procedure(s) shall be Fit-for-Purpose, including the estimation of the MU associated with a quantitative Confirmation Procedure;

(2) The Confirmation Procedure(s) shall be recorded, as part of the Sample (or Sample batch) record, each time it is conducted;

(3) The Confirmation Procedure shall have equal or greater Selectivity than the Initial Testing Procedure and shall provide accurate quantification results (applicable to Threshold Substances). The Confirmation Procedure shall incorporate, when possible and adequate, a different Sample extraction protocol or a different analytical methodology, unless otherwise specified by the Agency; and

(4) All batches undergoing a Confirmation Procedure shall include appropriate negative and positive quality controls prepared in the matrix of analysis.

Rule 6310. Confirmation Procedure Methods

Mass spectrometry (MS) coupled to chromatographic separation (*e.g.,* gas or liquid chromatography) is the analytical technique of choice for confirmation of most Prohibited Substances, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method. These are acceptable methods for both the Initial Testing Procedure and the Confirmation Procedure.

Rule 6311. A Confirmation Procedure

(a) Aliquots. The A Confirmation Procedure shall be performed using new Aliquot(s) taken from the container identified as the A Sample (and if the A Sample cannot be used for the Initial Testing Procedure(s), see Rule 6304). At this point, the link between the Sample external code, as shown in the Sample container, and the Laboratory internal Sample code shall be verified.

(b) Target Analyte(s). If the presence of more than one Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method is detected by the Initial Testing Procedure(s), the Laboratory shall confirm as many of the Presumptive Adverse Analytical Findings as reasonably possible (and such decision should consider the volumes available in the A and B Samples). The confirmation(s) shall prioritize the identification or quantification of the Prohibited Substance(s) or Prohibited Method(s) that carry the longest potential period of Ineligibility. The prioritization decision shall be made in consultation with the Agency and documented by the Laboratory.

(c) Repetition of the A Confirmation Procedure. The Laboratory may repeat the Confirmation Procedure for an A Sample, if appropriate, (*e.g.,* quality control failure, chromatographic peak interferences, inconclusive A confirmation results). In that case, the previous test result shall be nullified. Each repeat confirmation shall be performed using a new Aliquot(s) taken from the A Sample container and shall be recorded.

(d) A Confirmation Procedure for Non-Threshold Substances.

(1) For Non-Threshold Substances without Minimum Reporting Levels, Adverse Analytical Finding or Atypical Finding decisions for the A Sample shall be based on the identification of the Non-Threshold Substance or its characteristic Metabolite(s) or Marker(s), as applicable, in compliance with any relevant Technical Document(s) or Technical Letter(s) or in consideration of Laboratory Guidelines.

(2) For Non-Threshold Substances with Minimum Reporting Levels, Adverse Analytical Finding decisions for the A Sample shall be based on the identification of the Non-Threshold Substance or its characteristic Metabolite(s) or Marker(s), in compliance with any applicable Agency procedures or Technical Document, at an estimated concentration greater than the Minimum Reporting Level, unless there is valid justification for reporting the finding at levels below the Minimum Reporting Level (*e.g.,* if the analysis forms part of an ongoing investigation).

(e) A Confirmation Procedure for Threshold Substances.

(1) For Threshold Substances, Adverse Analytical Finding or Atypical Finding decisions for the A Sample shall be based on the confirmed identification (in accordance with any applicable Agency Procedures or Technical Document) of the Threshold Substance or its Metabolite(s) or Marker(s) and their quantitative determination in the Sample at a level exceeding the value of the relevant Decision Limit.

(2) Quantitative Confirmation Procedures for Threshold Substances shall be based on the determination of the mean of measured analytical values (*e.g.,* concentrations, chromatogram areas) or the ratio/score calculated from the mean(s) of the measured analytical values of 2 A Sample Aliquots, unless otherwise specified by the Agency. If there is not enough Sample volume to analyze 2 Aliquots, the maximum number of Aliquots that can be prepared shall be analyzed.

(3) By determining that the test result exceeds the Decision Limit, the quantitative Confirmation Procedure establishes that the Threshold Substance or its Metabolite(s) or Marker(s) is present in the Sample at a level greater than the Threshold, with a statistical confidence of at least 95%.

(4) For Threshold Substances, Markers of the ''biomarker profile'', or any other Prohibited Substance that may be produced endogenously at low levels, Adverse Analytical Finding decisions for the A Sample may also be based on the application of any Fit-for-Purpose Confirmation Procedure that establishes the exogenous origin of the Prohibited Substance or its Metabolite(s) or Marker(s). Atypical Findings may result from non-conclusive determinations of the origin (*i.e.,* endogenous vs. exogenous) of the Prohibited Substance or its Metabolite(s) or Marker(s).

Rule 6312. B Sample Procedure

(a) Testing Laboratory. If the B Sample procedure is to be performed, it will be performed in a different Laboratory from the A Sample analysis (with the choice of the Laboratory for the B Sample analysis determined exclusively by the Agency), except where the Agency considers it necessary for the same Laboratory to perform the B Sample procedure:

(1) due to reasonable concerns over Sample integrity or unstable analytes; or

(2) because no other Laboratory is available to perform the B Sample procedure within a reasonable period of time.

(b) Notification and timing of B Sample procedure.

(1) The B Sample procedure shall only be performed by the Laboratory upon request by the Agency.

(2) The Agency should inform the Laboratory, in writing, within 15 days following the reporting of an A Sample Adverse Analytical Finding by the Laboratory, whether the B Sample procedure shall be conducted. This includes situations when the Covered Person does not request the B Sample analysis or expressly or implicitly waives his or her right to the analysis of the B Sample, but the Agency decides that the B Sample procedure shall still be performed.

(3) If the B Sample procedure is to be performed, whether upon the request of the Covered Person in accordance with the Protocol or the Agency:

(i) as soon as reasonably practicable after the Agency so decides or the Covered Person so requests, the Agency should notify the Laboratory that performed the A Sample analysis, and the Laboratory that will perform the B Sample procedure, that the B Sample procedure will be performed;

(ii) within 5 days of receipt of the notice at Rule 6312(b)(3)(i), the Laboratory that performed the A Sample analysis should send the B Sample to the Laboratory that will perform the B Sample procedure; and

(iii) the Laboratory that will perform the B Sample procedure should perform the B Sample procedure as soon as reasonably practicable after receipt of the B Sample.

(4) The timing of the B Sample procedure may be strictly fixed within a very short period of time and without any possible postponement, if circumstances so justify it. This can notably and without limitation be the case when a postponement of the B Sample analysis could significantly increase the risk of Sample degradation or inadequately delay the decision-making process in the given circumstances (*e.g.,* and without limitation, during or in view of a Covered Horserace requiring rapid completion of the Sample analysis).

(c) Opening, Aliquoting and Resealing of B Sample.

(1) The B Sample procedure shall be performed using Aliquot(s) taken from the container defined as the B Sample (and if the B Sample cannot be used, see Rule 6304).

(2) If the B Sample container was not properly sealed or showed signs of

Tampering, or if the identifying numbers did not match those on the Sample collection documentation, the Laboratory shall not proceed with the B Sample procedure and will inform the Agency immediately to obtain instructions on how to proceed. In such cases, unless the entire case is dismissed, the B Sample procedure may have to be re-scheduled.

(3) The Laboratory shall ensure that the B Sample container is opened and Aliquots for the B Sample procedure are taken.

(4) The Laboratory shall also ensure that, after opening and taking Aliquots for the B Sample procedure, the B Sample is properly resealed.

(5) At a minimum, the Laboratory Director or representative shall sign another part of the Laboratory documentation attesting that the B Sample opening and aliquoting procedures occurred and that the B Sample was properly resealed.

(d) Target Analyte(s). If more than one Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method has been confirmed in the A Sample procedure, the Laboratory shall confirm as many of the Adverse Analytical Findings as possible given the B Sample volume available. The decision on the prioritization for the confirmation(s) shall be made to prioritize the analysis of the Prohibited Substance(s) or Prohibited Method(s) that carry the longest potential period of Ineligibility. The prioritization decision shall be made in consultation with the Agency and documented.

(e) Repetition of the B Sample procedure. The Laboratory may repeat the B Sample procedure, if appropriate, (*e.g.,* quality control failure, chromatographic peak interferences, inconclusive B confirmation results). In that case, the previous test result shall be nullified. The Laboratory may repeat the B Sample procedure using the remaining volume of the same Aliquot initially taken from the B Sample container. However, if there is not enough volume left of the initial Aliquot, then the Laboratory shall use a new Aliquot(s) taken from the re-sealed B Sample container. Each Aliquot used shall be documented.

(f) B confirmation with negative results. If the final B confirmation results are negative, the Analytical Testing result shall be considered a Negative Finding. The Laboratory shall notify the Agency immediately. If requested by the Agency, one or more Laboratories shall conduct an internal investigation of the causes of the discrepancy between the A and B Sample results. Target Analytes (*e.g.,* parent compound, Metabolite(s), and Marker(s)) used to conclude the presence of a given Prohibited Substance or Use of a Prohibited Method may differ between the A and B Confirmation Procedures. This does not mean that the B confirmation results are negative, as long as the Analyte(s) targeted allows the unequivocal and conclusive identification of the Prohibited Substance or Prohibited Method in the B Sample.

(g) B Sample procedure for Non-Threshold Substances and exogenous Threshold Substances. For Non-Threshold Substances (including those with Minimum Reporting Levels) and exogenous Threshold Substances, the B Sample results shall only confirm the presence of the Prohibited Substance(s) or its Metabolite(s) or Marker(s) identified in the A Sample (in compliance with any applicable Agency procedures or Technical Document) for the Adverse Analytical Finding to be valid, unless otherwise specified by the Agency. No quantification or estimation of concentrations of such Prohibited Substance, or its Metabolite(s) or Marker(s) is necessary.

(h) B Sample procedure for Threshold Substances.

(1) For Threshold Substances, Adverse Analytical Finding decisions for the B Sample results shall be based on the confirmed identification (in accordance with any applicable Agency procedures or Technical Document, applicable to B Sample procedures based on chromatography-mass spectrometry) of the Threshold Substance or its Metabolite(s) or Marker(s) and their quantitative determination in the Sample at a level exceeding the value of the relevant Threshold as specified in any applicable Agency procedures, Technical Document(s), or Laboratory Guidelines. Comparison of the measured value of the B Sample to the measured value of the A Sample is not necessary to establish B Sample confirmation. The B Sample value is only required to exceed the applicable Threshold (plus any Measurement Uncertainty).

(2) Quantitative B Sample procedures for Threshold Substances shall be based on the determination of the mean of measured analytical values (*e.g.,* concentrations, chromatogram areas) or the ratio/score calculated from the mean(s) of the measured analytical values of two (2) B Sample Aliquots, unless otherwise specified by the Agency. If there is not enough Sample volume to analyze two (2) Aliquots, the maximum number of Aliquots that can be prepared shall be analyzed.

(3) For Threshold Substances or any other Prohibited Substance that may be produced endogenously at low levels, Adverse Analytical Finding decisions for the B Sample results may also be based on the application of any Fit-for-Purpose Analytical Testing Procedure that establishes the exogenous origin of the Prohibited Substance or its Metabolite(s) or Marker(s). Atypical Findings may result from non-conclusive determinations of the origin (*i.e.,* endogenous vs. exogenous) of the Prohibited Substance or its Metabolite(s) or Marker(s).

Rule 6313. Further Analysis of Stored Samples

(a) Further Analysis of stored Samples shall, as a matter of principle, be aimed at detecting all the Prohibited Substance(s) or Metabolite(s) of Prohibited Substance(s), or Marker(s) of the Use of a Prohibited Substance or Prohibited Method included in the Prohibited List in force at the time of the collection of the Sample(s).

(b) Selection of Samples and Laboratories for Further Analysis.

(1) Stored Samples may be selected for Further Analysis at the discretion of the Agency or the Authority.

(2) The choice of which Laboratory will conduct the Further Analysis will be made by the Agency. Requests to the Laboratory for Further Analysis shall be made in writing and be recorded as part of the Sample's documentation.

(3) When a Sample has been reported as a Negative Finding or Atypical Finding, there is no limitation on the Agency to conduct Further Analysis on the Sample.

(4) Further Analysis may also be performed on stored Samples that were previously reported as Adverse Analytical Findings. Any Prohibited Substance or Prohibited Method detected, which was prohibited at the time of Sample collection, shall be reported.

(5) Previously acquired Initial Testing Procedure data may also be re-evaluated for the presence of Prohibited Substances or their Metabolite(s) or Marker(s) of Prohibited Substances or Prohibited Methods, at the initiative of the Agency or the Laboratory itself. The results of such re-evaluation, if suspicious, shall be communicated to the Agency, and may lead to Further Analysis.

(c) Analytical Testing Procedures for Further Analysis of stored Samples.

(1) Further Analysis of stored Samples shall be performed under the Laboratory Standards, Technical Documents, and Technical Letters in effect at the time the Further Analysis is performed. Any

Laboratory Guidelines may also be referenced.

(2) Further Analysis of stored Samples includes, notably, but without limitation, the application of newly developed or more sensitive Analytical Testing Procedures or the analysis of new target Analytes of Prohibited Substance(s) or Prohibited Method(s) (*e.g.,* Metabolite(s) or Marker(s)), which were not known or not included in the initial Analytical Testing of the Sample.

(3) Depending on the circumstances, and to ensure an effective and targeted use of the available Sample volume, priorities may be set, or the scope of the Further Analysis restricted to specific analyses (in particular, but without limitation, to analyses based on new or improved Analytical Testing Procedures).

(d) Further Analysis of stored Samples process.

(1) Use of the A Sample. The Agency may instruct the Laboratory to use the A Sample for both the Initial Testing Procedure(s) and the A Confirmation Procedure(s), to use it only for the Initial Testing Procedure(s), or not to use the A Sample for Further Analysis at all.

(i) If the Laboratory has been instructed to perform only the Initial Testing Procedure(s) on the A Sample, any suspicious analytical result obtained from the A Sample shall be considered as a Presumptive Adverse Analytical Finding, irrespective of the Analytical Testing Procedure applied, and shall be confirmed using the split B Sample.

(ii) When a Confirmation Procedure is performed on the A Sample and an Adverse Analytical Finding is reported on this basis, the B Sample procedure shall be applicable (as per Rule 6316).

(2) Use of the split B Sample. When the A Sample is used only for the Initial Testing Procedure(s) or is not used at all during Further Analysis, the B Sample shall be split and used for analysis. The B Sample shall be split into 2 fractions, in accordance with Rule 6304.

(i) In the event an Adverse Analytical Finding is notified based on the results of a B Sample procedure of the first fraction of the B Sample, the second split fraction of the B Sample shall be deemed as the B Sample. Since the first split fraction of the B Sample is considered as an A Sample, analysis of Aliquots taken from this Sample may include the performance of Initial Testing Procedure(s) and A Confirmation Procedures or A Confirmation Procedures only (if the Initial Testing Procedure(s) was/were already performed using the A Sample).

(ii) If applicable, a B confirmation shall be decided and performed in accordance with Rule 6316.

(e) Alternative biological matrices. Any negative Analytical Testing results obtained from hair, hoof, saliva or other biological material shall not be used to counter Adverse Analytical Findings or Atypical Findings from urine, blood (including whole blood, plasma or serum), or hair.

Rule 6314. Assuring the Validity of Analytical Results

(a) The Laboratory shall monitor its analytical performance and the validity of test results by operating quality control schemes, which are appropriate to the type and frequency of Analytical Testing performed by the Laboratory. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results.

(b) All quality control procedures shall be documented by the Laboratory. The range of quality control activities include, but are not limited to:

(1) Use of appropriate quality control samples (QCs).

(i) Appropriate positive and negative QCs shall be included in every analytical run both for the Initial Testing Procedure(s) and B Sample procedure(s), unless otherwise specified by the Agency.

(ii) Appropriate internal standard(s) shall be used for chromatographic methods.

(iii) For Threshold Substances, quality control charts (QC-charts) referring to appropriate control limits depending on the Analytical Testing Procedure employed (*e.g.,* +/−2SD; +/−3SD; +/−MU95%), shall be regularly used to monitor method performance and inter-batch variability (when applicable).

(2) Implementation of an Internal Quality Assurance Scheme (iQAS).

(i) The Laboratory shall establish a functional and robust iQAS program, in accordance with the requirements of ISO/IEC 17025, which challenges the entire scope of the Analytical Testing process (*i.e.,* from Sample accessioning through result reporting). The Laboratory shall implement a procedure that prevents the submission of iQAS results to the Agency.

(ii) The iQAS plan shall include and evaluate as many Laboratory procedures as possible, including the submission of a sufficient number of test samples on a regular basis (*e.g.,* monthly) and shall incorporate as many categories of Prohibited Substances and Prohibited Methods as possible.

(iii) The Laboratory shall have a dedicated SOP for the iQAS program which incorporates a detailed procedure for the planning, preparation (blind or double-blind), introduction of the iQAS samples, and management of the iQAS results (*i.e.,* reviewing and follow-up of nonconformities).

(3) Mandatory participation in the Agency EQAS.

(4) Implementation of internal audits.

(i) Internal audits shall be conducted in accordance with the requirements of ISO/IEC 17025 and shall have a dedicated SOP incorporating a detailed procedure for the planning and performance of the audits, the training and selection of internal auditors, and specification of their auditing activities, as well as for management of the internal audit conclusions (*i.e.,* reviewing and follow-up of nonconformities).

(ii) Internal audit responsibilities may be shared amongst personnel provided that any Laboratory staff member does not audit his or her own area.

(iii) Internal audits shall be carried out by qualified Laboratory staff members. In addition, qualified members of the Laboratory's host organization (*e.g.,* university, institute, company) may also be included in the internal auditing teams.

(5) Implementation of external audits. Laboratories may also consider having their procedures and systems audited by other Laboratory Directors or external auditors. However, this shall not replace the performance of internal audits by the Laboratory.

Rule 6315. Results Management

(a) Review of results. The Laboratory shall conduct a minimum of one independent review of all Initial Testing Procedure raw data and results. The review process shall be recorded.

(b) A minimum of 2 Certifying Scientists shall conduct an independent review of all Adverse Analytical Findings and Atypical Findings before a test result is reported. Evidence of the review and approval of the analytical run/batch shall be recorded.

(c) Second opinion. The Laboratory may request a second opinion from another Laboratory, selected by, and upon approval of, the Agency, before reporting an Adverse Analytical Finding or Atypical Finding. Such requests for second opinions may be required by specific Technical Document(s) or Technical Letter(s), required by the Agency from certain Laboratories for all or for specific Analytical Testing Procedures under certain conditions (*e.g.,* following the recent obtaining of HEAL accreditation or after a period of

suspension or Analytical Testing Restriction), or requested at the discretion of the Laboratory (*e.g.,* for firstly detected Analytes or for difficult to interpret findings). In any case, the request for a second opinion shall be made in writing, and the second opinion received shall be recorded as part of the Sample's documentation. Any transfer of data and information necessary for the second opinion shall be made securely and respecting the confidentiality of the analytical data and any other information. The Laboratory that performed the analysis is responsible for the result and for issuing the final test report.

(d) Laboratory review of Adverse Analytical Findings and Atypical Findings. At a minimum, the review of Adverse Analytical Findings and Atypical Findings shall include:

(1) Documentation linking the Sample (as specified in the Sample collection documentation) to the Laboratory Internal Chain of Custody documentation;

(2) Laboratory Internal Chain of Custody documentation;

(3) Initial Testing Procedure(s) and Confirmation Procedure(s) analytical data and calculations;

(4) Quality control data;

(5) Completeness of technical and analytical documentation supporting the reported findings;

(6) Compliance of test data with the Analytical Testing Procedure's validation results (*e.g.,* MU); and

(7) Assessment of the existence of significant data or information that would cast doubt on or refute the Laboratory findings.

(e) When the Confirmation Procedure result(s) are not determined to be Adverse Analytical Finding(s) or Atypical Finding(s) based on the results review, the reason(s) for the rejection shall be recorded in the laboratory test report.

(f) Traceability of results and documentation. The Laboratory shall have documented procedures to ensure that it maintains a record related to each Sample analyzed. In the case of an Adverse Analytical Finding or Atypical Finding, the record shall include the data necessary to support the conclusions reported.

(1) Each step of Analytical Testing shall be traceable to the staff member who performed that step;

(2) Significant deviation from a written SOP shall be recorded;

(3) Where instrumental analyses are conducted, the operating parameters for each run shall be included as part of the record;

(4) Requests for information by the Agency to a Laboratory shall be made in writing;

(5) Laboratories are not required to produce a Laboratory Documentation Package for a Sample in which no Prohibited Substance or Prohibited Method or their Metabolite(s) or Marker(s) was detected, unless requested by an adjudication body as part of a Results Management process or Laboratory disciplinary proceedings.

(g) Confidentiality of the Analytical Data and Covered Person or Covered Horse's identity.

(1) The Laboratory shall not make any attempt to identify a Covered Person linked to, or the Covered Horse that has provided, a Sample.

(2) Information sent by a facsimile is acceptable, provided that the correct facsimile number is verified prior to transmission and the receipt is verified after the facsimile has been transmitted.

(3) Secure emails or documents shall be used for reporting or discussion of Adverse Analytical Findings or Atypical Findings if the Covered Person or Covered Horse can be identified or if any information regarding the identity of the Covered Person or Covered Horse is included.

Rule 6316. Reporting Test Results

(a) Reporting times (including confirmatory analysis).

The Laboratory should report all A Sample results to the Agency in a form designated by the Agency within 10 business days of receipt by the Laboratory of the Sample. The reporting time may be altered by agreement between the Laboratory and the Agency. The Agency shall be promptly informed of any delay in the reporting of A Sample results.

(b) Reporting requirements.

(1) The Laboratory shall record the test result for each individual Sample to, and in a form designated by, the Agency.

(2) The Laboratory shall report test results to the Agency in a form designated by the Agency. When reporting test results, the Laboratory shall include the following, in addition to the mandatory information required by the Agency, in any relevant Technical Document(s) or Technical Letter(s), and in the ISO/IEC 17025 standard:

(i) The specific gravity of the Sample, if applicable (Initial Testing Procedure and A and B Confirmation Procedures);

(ii) Relevant comments, if necessary, for proper interpretation of the test result or recommendations to the Agency (for example, for Target Testing of the Covered Horse);

(iii) Specific tests performed, in addition to the Laboratory's routine Analytical Testing menu (*e.g.,* EPO, bisphosphonates, hGH); and

(iv) Any irregularities noted on Samples.

(c) The Laboratory is not required to provide any additional test report, either in hard-copy or digital format, other than the submission of test results to, and in a form designated by, the Agency. Upon request by the Agency, the Laboratory shall report a summary of the results of analyses performed in a format specified by the Agency. In addition, the Laboratory shall provide any information requested by the Agency in relation to the Monitoring Program (Protocol).

(d) The Laboratory shall qualify the result(s) of the analysis in the Agency's test report as:

(1) Adverse Analytical Finding;

(2) Atypical Finding;

(3) Negative Finding; or

(4) Not Analyzed.

(e) Any Sample received at the Laboratory and not subject to Analytical Testing for a valid, documented reason (as instructed or agreed to by the Agency), such as Sample irregularities or intermediate Samples of a Sample Collection Session, shall be dealt with in accordance with ISO/IEC 17025.

(f) Test report for Non-Threshold Substances.

(1) A Sample test report.

(i) The Laboratory is not required to report concentrations for Non-Threshold Substances. The Laboratory shall report the actual Prohibited Substance(s) or its Metabolite(s), or Marker(s) of the Use of Prohibited Substance(s) or Prohibited Method(s) present in the Sample and in accordance with any reporting requirements established by the Agency or in any applicable Technical Document.

(ii) However, the Laboratory shall provide estimated concentrations when possible and for information purposes only, upon request by the Agency, if the detected level of the Non-Threshold Substance(s), its Metabolite(s), or Marker(s) may be relevant to the Results Management of an anti-doping case. In such instances, the Laboratory shall indicate the estimated concentration while making it clear to the Agency that the concentration was obtained by an Analytical Testing Procedure that has not been validated for quantitative purposes.

(2) B Sample test report. For Non-Threshold Substances, irrespective of whether they have a Minimum Reporting Level, the Laboratory result for the B Sample shall only establish the presence (*i.e.,* the identity) of the

Prohibited Substance(s) or its Metabolite(s) or Marker(s) in accordance with any reporting requirements established by the Agency or in relevant Technical Document(s). The Laboratory is not required to quantify or estimate the concentration of such Prohibited Substance, or its Metabolite(s) or Marker(s).

(g) Test report for Threshold Substances. For Threshold Substances, the Laboratory test report for the A Sample shall establish that the identified Prohibited Substance(s) or its Metabolite(s) or Marker(s) is present at a concentration, ratio, or score of measured analytical values greater than the Threshold, or that the Prohibited Substance(s) or its Metabolite(s) or Marker(s) is of exogenous origin.

Rule 6317. Control of Nonconformities in Analytical Testing

(a) The Laboratory shall have policies and procedures that shall be implemented when any aspect of its Analytical Testing does not comply with then-current requirements.

(b) Any nonconformities in Analytical Testing shall be recorded and kept as part of the documentation of the Sample(s) involved.

(c) When conducting a corrective action investigation, the Laboratory shall perform and record a thorough Root Cause Analysis of the nonconformity.

Rule 6318. Complaints

Complaints shall be handled in accordance with ISO/IEC 17025.

Rule 6319. Storage of Samples

(a) Storage of urine Samples. All urine Samples retained for storage in the Laboratory shall be stored frozen in a secure location under continuous Chain of Custody. The Laboratory shall keep all Chain of Custody and other records (either as hard-copy or in digital format) pertaining to those Samples unless and until notified in writing by the Agency that such records may be destroyed.

(1) Urine Sample(s) without an Adverse Analytical Finding or Atypical Finding: The Laboratory shall retain the A and B urine Sample(s) without an Adverse Analytical Finding or Atypical Finding for a minimum of 3 months after reporting the final analytical result to the Agency, and they may be discarded after this time, unless the long-term storage of the Sample(s) has been requested, in writing or electronically, by the Agency and unless the Agency requests the Laboratory retain the Sample for a longer period. The Laboratory may charge storage costs to the Agency, as applicable, for the storage of Samples for periods longer than the stated minimum storage times. However, the Laboratory may store Samples beyond the applicable minimum storage times at their own discretion and expense. In such cases, the Laboratory shall inform the Agency in writing. Any Further Analysis on these Samples will require the approval of the Agency. The maximum storage period is 10 years after the Sample collection date.

(2) Urine Samples with irregularities: The Laboratory shall retain the A and B urine Sample(s) with irregularities for a minimum of 3 months after reporting to the Agency, or for a longer period as determined by the Agency.

(3) Urine Sample(s) with an Adverse Analytical Finding or Atypical Finding: The Laboratory shall retain the A and B urine Sample(s) with an Adverse Analytical Finding or Atypical Finding for a minimum of 6 months after reporting the final analytical result for the A or the B Sample, as applicable to, the Agency and shall not dispose of any such Samples without approval by the Agency.

(4) Urine Samples under challenge, dispute or investigation: If the Laboratory has been informed by the Agency (in writing and within the applicable storage period as defined in this Rule 6319) that the analysis of a urine Sample is challenged, disputed or under investigation, the Laboratory shall retain both the A and B Samples until further notice by the Agency, as applicable.

(b) Storage of blood Samples.

(1) Samples for which Analytical Testing has been performed on blood serum/plasma fraction only (not on cellular components):

(i) All serum or plasma Samples retained for storage in the Laboratory shall be stored frozen according to established protocols in a secure location under continuous Chain of Custody. The Laboratory shall keep all Chain of Custody and other records (either as hard-copy or in digital format) pertaining to those Samples.

(ii) Serum/plasma A and B Samples without an Adverse Analytical Finding or Atypical Finding: The Laboratory shall retain the serum/plasma A and B Samples without an Adverse Analytical Finding or Atypical Finding for a minimum of 3 months after reporting the final analytical result to the Agency, unless long-term storage of the Sample(s) has been requested by the Agency or the Agency requests the Laboratory retain the Sample for a longer period.

(iii) Unless otherwise requested by the Agency, serum/plasma Samples analyzed only for TCO2 and without an Adverse Analytical Finding or Atypical Finding, shall be retained unless and until the corresponding Post-Race Sample is analyzed and no Adverse Analytical Finding or Atypical Finding is reported (*i.e.,* if the Post-Race Sample is analyzed and an Adverse Analytical Finding or Atypical Finding is reported, then the Agency may consider or conduct Further Analysis on the TCO2 Sample).

(iv) Serum/plasma Samples with irregularities: The Laboratory shall retain the serum/plasma Samples with irregularities for a minimum of 3 months after reporting the final analytical result to the Agency, or for a longer period if directed by the Agency.

(v) Plasma/serum A and B Sample(s) with an Adverse Analytical Finding or Atypical Finding: The Laboratory shall retain A and B plasma/serum Sample(s) with an Adverse Analytical Finding or Atypical Finding for a minimum of 6 months after reporting the final analytical result (for the A or the B Sample, as applicable) to the Agency and shall not dispose of any such Samples without approval by the Agency. If the B Sample Confirmation Procedure is not performed, the Laboratory may dispose of both the A and B whole blood Samples 3 months after reporting the A Sample analytical result. However, if the B Sample Confirmation Procedure is performed, then the Laboratory shall retain both the A and B whole blood Sample(s) for a minimum of 3 months after reporting the B Sample analytical result.

(vi) Plasma/serum A and B Sample(s) under challenge, dispute or investigation: If the Laboratory has been informed by the Agency (in writing and within the applicable storage period as defined in this Rule 6319) that the analysis of a serum/plasma Sample is challenged, disputed or under investigation, the Laboratory shall retain both the A and B Samples until further notice by the Agency, as applicable.

(2) Samples for which Analytical Testing has been performed on cellular fractions of whole blood.

(i) Whole blood A and B Samples without an Adverse Analytical Finding or Atypical Finding: The Laboratory shall retain the whole blood Samples without an Adverse Analytical Finding or Atypical Finding for a minimum of 1 month after reporting the final analytical result to the Agency, unless long-term storage of the Sample(s) has been requested by the Agency or the Agency requests the Laboratory retain the Sample for a longer period.

(ii) Whole blood Samples with irregularities: The Laboratory shall

retain the whole blood Samples with irregularities for a minimum of 1 month after reporting the final analytical results to the Agency, or for a longer period as requested by the Agency.

(iii) Whole blood A and B Sample(s) with an Adverse Analytical Finding or Atypical Finding: The Laboratory shall retain A and B whole blood Sample(s) with an Adverse Analytical Finding or Atypical Finding for a minimum of 3 months after reporting the final analytical result (for the A or the B Sample, as applicable) to the Agency and shall not dispose of such Samples without approval by the Agency.

(iv) Whole blood A and B Sample(s) under challenge, dispute or investigation: If the Laboratory has been informed by the Agency (in writing and within the applicable storage period as defined in this Rule 6319) that the analysis of a whole blood Sample is challenged, disputed or under investigation, the Laboratory shall retain both the A and B Samples until further notice by the Agency, as applicable, and shall not dispose of such Samples without approval by the Agency.

(c) Storage of hair Samples. All hair Samples retained for storage in the Laboratory shall be stored for as long as requested by the Agency in a secure location under continuous chain of custody.

(d) Storage of other Samples. All other Samples shall be stored for as long as requested by the Agency in optimal conditions based on the available information applicable to the Sample type, and at the direction of the Agency. They shall be stored in a secure location under continuous Chain of Custody.

(e) Long-term storage of Samples.

(1) At the direction of the Agency, any urine, serum/plasma, hair or other Sample may be stored in long-term storage after the Sample collection date for the purpose of Further Analysis, subject to the conditions set out in Rules 6313 and 6319.

(2) Sample(s) may be stored in long-term storage under the custody of either a Laboratory or another Fit-for-Purpose facility under the responsibility of the Agency. The Agency shall retain the Sample collection records pertaining to all stored Samples for the duration of Sample storage.

(3) Laboratories as Sample custodians:

(i) The Laboratory shall ensure that Samples are stored according to established protocols in a secure location in the Laboratory's permanent controlled zone and under continuous Chain of Custody. The written request from the Agency for long-term storage of Samples shall be properly documented.

(ii) Samples may also be transported for long-term storage to a specialized, secure Sample storage facility, which is located outside the Laboratory's permanent controlled zone and is under the responsibility of the Laboratory, or may be transported to another Laboratory. If the external Sample storage facility is not covered by the Laboratory's ISO/IEC 17025 accreditation, then the subcontracted external storage facility shall be Fit-for-Purpose and have its own ISO accreditation or certification (*e.g.,* 17025, 20387, 9001). The transfer of the Samples to the external long-term storage facility or Laboratory shall be recorded.

(iii) If Sample(s) are to be transported for storage at a location outside the secured area of the Laboratory that first analyzed the Sample(s), the Laboratory shall secure the A Sample(s) to be shipped either by re-sealing individual A Sample container(s) with a Tamper Evident sealing system, which has similar capabilities for security and integrity as the original sealing system, or by sealing the box in which the Sample(s) are shipped in a manner that maintains Sample integrity and Chain of Custody. For example, Sample(s) may be resealed with new resealing systems (*e.g.,* new bottlecaps) produced by the manufacturer of an appropriate Sample collection equipment that replicates the security and Tamper Evident functionality of the original seal. The resealing system of shipped A Sample(s) shall be Tamper Evident.

(iv) B Sample(s) to be shipped shall be individually sealed, either in the original, sealed B Sample container(s) or, if previously opened, by re-sealing the individual B Sample container(s) with a Tamper Evident sealing system, which has similar capabilities for security and integrity as the original sealing system.

(v) During transport and long-term storage, Sample(s) shall be stored at a temperature appropriate to maintain the integrity of the Sample(s). In any Anti-Doping Rule Violation case, the issue of the Sample's transportation or storage temperature shall be considered where failure to maintain an appropriate temperature could have caused the Adverse Analytical Finding or other result upon which the Anti-Doping Rule Violation is based.

(vi) The Laboratory shall retain all Laboratory Internal Chain of Custody and technical records (as per ISO/IEC 17025) pertaining to a stored Sample for the duration of Sample storage, either as hard-copy or in digital format. In addition, the Laboratory may retain Sample analytical data which would allow retrospective analysis of such data, for example, for the purpose of identifying signals for novel Metabolite(s) of Prohibited Substance(s) or Marker(s) of Prohibited Substance(s) or Prohibited Method(s) (*e.g.,* full-scan mass spectrometry data), as detailed in Rule 6313.

(vii) If Sample(s) are transported to another Laboratory for long-term storage, the Sample's external Chain of Custody and other non-analytical records (*e.g.,* Sample collection documentation) available to the transferring Laboratory shall also be transferred, immediately or upon later request, to the Laboratory storing the Samples or to the Agency, either as originals or copies.

(4) The Agency as Sample custodians:

(i) Sample(s) may also be transported for long-term storage to a Fit-for-Purpose, secure Sample storage facility, which is under the responsibility of the Agency. In such cases, the external storage facility shall have its own ISO accreditation or certification (*e.g.,* 17025, 20387, 9001) and shall maintain security requirements comparable to those applicable to a Laboratory. The Agency shall ensure that Samples are stored according to established protocols in a secure location under continuous Chain of Custody.

(ii) The written request from the Agency for the transfer of the Sample(s) to long-term storage shall be properly documented. The transfer of the Samples to the external long-term storage facility shall also be recorded. The Laboratory shall secure the Sample(s) for transportation to the long-term storage facility as described above.

(iii) The Laboratory shall retain all Laboratory Internal Chain of Custody and technical records (as per ISO/IEC 17025) pertaining to all Samples transferred for long-term storage for the duration of Sample storage, either as hard-copy or in digital format. In addition, the Laboratory may retain Sample analytical data which would allow retrospective analysis of such data, for example, for the purpose of identifying signals for novel Metabolite(s) of Prohibited Substance(s) or Marker(s) of Prohibited Substance(s) or Prohibited Method(s) (*e.g.,* full-scan mass spectrometry data), as detailed in Rule 6313.

(vii) If Sample(s) are transported to another Laboratory for long-term storage, the Sample's external Chain of Custody and other non-analytical records (*e.g.,* Sample collection documentation) available to the transferring Laboratory shall also be transferred, immediately or upon later request, to the Laboratory storing the Samples or to the Agency, either as originals or copies.

(4) The Agency as Sample custodians:

(i) Sample(s) may also be transported for long-term storage to a Fit-for-Purpose, secure Sample storage facility, which is under the responsibility of the Agency. In such cases, the external storage facility shall have its own ISO accreditation or certification (*e.g.,* 17025, 20387, 9001) and shall maintain security requirements comparable to those applicable to a Laboratory. The Agency shall ensure that Samples are stored according to established protocols in a secure location under continuous Chain of Custody.

(ii) The written request from the Agency for the transfer of the Sample(s) to long-term storage shall be properly documented. The transfer of the Samples to the external long-term storage facility shall also be recorded. The Laboratory shall secure the Sample(s) for transportation to the long-term storage facility as described above.

(iii) The Laboratory shall retain all Laboratory Internal Chain of Custody and technical records (as per ISO/IEC 17025) pertaining to all Samples transferred for long-term storage for the duration of Sample storage, either as hard-copy or in digital format. In addition, the Laboratory may retain Sample analytical data which would allow retrospective analysis of such data, for example, for the purpose of identifying signals for novel Metabolite(s) of Prohibited Substance(s) or Marker(s) of Prohibited Substance(s) or Prohibited Method(s) (*e.g.,* full-scan mass spectrometry data), as detailed in Rule 6313.

(f) For the purposes of this rule, ''storage'' refers to A and B Samples stored in Sample collection containers (urine collection bottles, blood collection tubes) and should not be confused with access to Aliquots, which should be accessible to analysts for the performance of Analytical Testing Procedures. However, minimum and maximum retention times apply to any

Aliquot(s) of a Sample that remains after completion of the Analytical Testing.

Rule 6320. Secondary Use or Disposal of Samples and Aliquots

(a) The Laboratory shall maintain SOP(s) pertaining to the secondary use of Samples or Aliquots for research or quality assurance, as well as for the disposal of Samples and Aliquots.

(b) If the Laboratory has discretion to dispose of a Sample, the Laboratory shall do one of the following with the Sample(s) and Aliquots as soon as practicable:

(1) Disposal of the Sample(s) and Aliquots. Disposal of Samples and Aliquots shall be recorded under the Laboratory Internal Chain of Custody.

(2) Secondary use of Samples and Aliquots for research and quality assurance. Samples and Aliquots shall be anonymized to ensure that any subsequent results cannot be traced back to a particular Covered Person or Covered Horse. Only after anonymization, may a Sample or Aliquot be used for:

(i) Anti-doping research. The Covered Person or their representative's consent is not required for these purposes.

(ii) Quality assurance, quality improvement of existing Test Methods, development or evaluation of Analytical Testing Procedures for Prohibited Substances or Prohibited Methods included in the Prohibited List at the time of Sample collection, or to establish reference population ranges or Thresholds or other statistical purposes. The Covered Person or their representative's consent is not required for these purposes.

(c) The use of Samples and Aliquots for the purposes of this Rule 6320 is subject to the following conditions:

(1) The Laboratory must respect the Protocol and the Code of Ethics requirements related to research, types of permitted research, and respect of ethical standards for research or quality assurance studies involving equine subjects;

(2) The Laboratory must not make any attempt to re-identify a Covered Person or Covered Horse from Samples or Aliquots used for the purposes of this Rule 6320 or data arising from any research or quality assurance analysis;

(3) The Laboratory must consult the applicable State and Federal regulations, guidance, or authorities to determine whether a study shall be considered as falling under Rule 6320(c)(1) or (2) (if the Laboratory is unsure whether a study can proceed without consent after consulting the foregoing sources, the Laboratory shall consult with the Agency to determine whether it can proceed); and

(4) In the event the Laboratory wishes to transfer Sample(s) or Aliquots to be used for the purposes of this Rule 6320 to another Laboratory or a third-party research institution or group, or wishes to partner with another Laboratory or research institution or group for the purpose of a study pursuant to Rule 6320(c)(1), the Laboratory shall subject the receiving party to the conditions described in this Rule 6320 by way of a written agreement and shall prohibit the receiving party from further transferring any Sample(s) or Aliquots or related data to another party.

*6400. Evaluation of Laboratory EQAS*

Rule 6410. Penalties

(a) The Agency shall inform a Laboratory in writing about the imposition of penalties, corrective action, or other follow-up measures.

(b) Technical or methodological error. If the Laboratory is able to remedy the technical or methodological error through the implementation of satisfactory corrective actions in a timely manner, as determined by the Agency, the Laboratory will not face any additional penalty.

(c) Clerical/Administrative error. If the Laboratory is able to remedy the clerical or administrative error through the implementation of satisfactory corrective actions in a timely manner, as determined by the Agency, the Laboratory will not face any additional penalty. For the purposes of Laboratory performance evaluation, clerical/administrative errors are defined as those incidental, non-systematic errors of no technical or methodological origin, which have been committed by the Laboratory during the performance of Analytical Testing (*e.g.,* a typographical error when manually recording an analytical result). The Laboratory shall bear no responsibility for clerical/administrative errors reflected in the Laboratory documentation made by the Agency.

Rule 6420. Corrective Action Reports

(a) A Corrective Action Report may be requested by the Agency. Where requested, it shall be submitted within the timeframe specified by the Agency in written notification about the unsatisfactory result. Failure to submit a satisfactory Corrective Action Report or the late submission of the Corrective Action Report without prior approval by the Agency may result in a penalty.

(b) A Corrective Action Report related, for example, to nonconformities detected during the Agency Laboratory assessments, or to procedural or reporting nonconformities with the Laboratory Standards, Technical Documents or Technical Letters, or unsatisfactory performance in the analysis of EQAS samples (not related to a false Adverse Analytical Finding or false Negative Finding), shall be submitted to the Agency within 30 days of the Agency's notification to the Laboratory.

(c) Unless otherwise agreed with the Agency, the corrective and preventive action(s) reported to and approved by the Agency shall be implemented immediately in the routine operations of the Laboratory.

(d) The Corrective Action Report will be reviewed by the Agency as soon as practicable. If applicable, it will establish the source of the incorrect result as either a technical/methodological error or a clerical/administrative error.

(e) Satisfactory Corrective Action Report. A Corrective Action Report will be considered as satisfactory when it meets the following criteria, as determined by the Agency:

(1) Properly and concisely identifies the root cause(s) of the nonconformity, following an appropriate investigation into all the factors that may have caused the problem (Root Cause Analysis);

(2) Leads to the documented implementation of effective corrective action(s) to solve the problem; and

(3) Leads to the documented implementation of appropriate preventive actions, if applicable, to minimize the risk of recurrence of the problem.

(f) A satisfactory Corrective Action Report shall include only the necessary supporting documentation (*e.g.,* raw analytical data, data review files, evidence of procurement of Reference Materials) which demonstrates the implemented actions described in the Corrective Action Report.

(g) Unsatisfactory Corrective Action Report. If the Laboratory's Corrective Action Report is considered unsatisfactory by the Agency, the Agency should provide feedback to the Laboratory and provide it with the opportunity to resubmit a revised Corrective Action Report within 7 days, or as otherwise agreed by the Agency.

(h) If the Laboratory is unable to submit a satisfactory revised Corrective Action Report in a timely manner, as determined by the Agency, the Agency may impose a penalty.

Rule 6430. Laboratory Self-Reporting

The Laboratory must identify and report all errors in Sample analysis resulting in a false Adverse Analytical

Finding or a false Negative Finding. Self-reporting will be taken into consideration by the Agency in determining whether or not to impose a penalty (or what that penalty will be).

Rule 6440. Evaluation of EQAS Results

(a) Satisfactory EQAS performance in a single EQAS round and over a consecutive 12-month period is necessary for maintaining HEAL accreditation. An EQAS round is a distribution of EQAS sample(s) to the Laboratories and the probationary laboratories for Analytical Testing (as defined by the Agency). The 12-month period is defined as the most recent consecutive 12-month interval starting either from the date that the Laboratory or the probationary laboratory reported the nonconforming result (EQAS or routine Analytical Testing, as applicable) to, and in a form designated by, the Agency, or from the date that the Laboratory or probationary laboratory is informed, in writing, of nonconformity by the Agency, whichever is more favorable to the Laboratory or the probationary laboratory.

(b) Unsatisfactory performance in an educational EQAS for a new or the Agency-specific Analytical Testing Procedure may prevent the Laboratory from seeking an extension of the Laboratory's scope of ISO/IEC 17025 accreditation for the Analytical Testing Procedure and from its application in routine Analytical Testing. In such circumstances, the Laboratory may only apply the new Agency-approved method or procedure for routine Sample analysis when it properly corrects the deficiencies identified in the educational EQAS (as determined by the Agency) and the method is included in the Laboratory's scope of ISO/IEC 17025 accreditation. Some Analytical Testing Procedures are not eligible for a flexible scope of ISO/IEC 17025 accreditation and require specific Agency approval before the Laboratory can apply the procedure to the analysis of Samples. Agency approval will be based on its assessment of the Fitness-for-Purpose of the Analytical Testing Procedure, method validation by the Laboratory, and the successful Laboratory participation in an inter-laboratory collaborative study or the Agency EQAS round. The Agency will communicate which Analytical Testing Procedures fall into this category to the Laboratories and to the Accreditation Bodies.

Rule 6441. EQAS Samples Containing Non-Threshold Substances

(a) When a qualitative determination of a Non-Threshold Substance has been reported, the Laboratory result will be evaluated on the basis of the correct reporting of the finding (*e.g.,* Adverse Analytical Finding, Negative Finding) as intended in the preparation of the EQAS sample.

(b) The results for any Non-Threshold Substance or its Metabolite(s) or Marker(s) at concentrations greater than (>) the MRPL (or exceeding 120% of the Minimum Reporting Level, when applicable) shall be evaluated.

(c) The results for any Non-Threshold Substance or its Metabolite(s) or Marker(s) at concentrations between 50% of the MRPL and the MRPL (or less than 120% of the Minimum Reporting Level, when applicable) may require an internal investigation and Corrective Action Report from the Laboratory.

(d) If the results for any Non-Threshold Substance or its Metabolite(s) or Marker(s) are at concentrations below (<) 50% of the applicable MRPL in an EQAS sample, the Laboratory shall report its finding(s) if the analyses are compliant with its validation data, SOPs, the Laboratory Standards, and any applicable Technical Document. Laboratories unable to report such substance(s) are encouraged, on receipt of the EQAS report, to consider re-assessment of their Analytical Testing Procedure.

Rule 6442. EQAS Samples Containing Threshold Substances

(a) For EQAS samples containing Threshold Substances at levels greater than (>) 50% of the Threshold, the quantitative determination will be statistically evaluated (*e.g.,* z-score, degree of equivalence analysis) to determine the compatibility of the reported result with the assigned value (reference, nominal or consensus value, as applicable).

(b) A Laboratory is to achieve a satisfactory statistical evaluation of quantitative results reported based on the mean of 2 replicate determinations. The overall evaluation of the quantitative performance is based on the criteria indicated in any relevant Technical Document or Technical Letter, or the Laboratory Guidelines.

(c) The main criterion applied for the evaluation of EQAS results for the quantification of Threshold Substances is the compatibility of the reported Laboratory result with the assigned value. Therefore, the incorrect reporting of an EQAS sample as a Negative Finding or as an Adverse Analytical Finding, as applicable, when the assigned value of the Threshold Substance in the EQAS sample is close to the Threshold, is not considered as a false Negative Finding or false Adverse Analytical Finding, respectively, if the absolute z-score (truncated to one decimal place) for the Laboratory's quantitative result is <3.0.

(d) Unsatisfactory quantitative result for Threshold Substances (absolute z-score ≥ 3.0). The Laboratory shall provide the Agency with a Corrective Action Report for an unsatisfactory quantitative result. The z-score is calculated according to the formula $[z=(\bar{y}-\hat{y})/\delta]$, where $\bar{y}$ is the mean value of the Laboratory's replicate determinations; $\hat{y}$ is the assigned value (reference, nominal or consensus value, as applicable); $\delta$ is the target standard deviation (*e.g.,* uc_Max or robust Reproducibility sR of results from all participant Laboratories). The z-score is truncated to one decimal place.

(e) Questionable quantitative result (absolute z-score >2.0 and <3.0). The Laboratory shall perform an internal investigation to determine the root cause(s) of the questionable result and implement appropriate corrective measures to resolve them.

(f) EQAS evaluation of Laboratory performance. Where an EQAS result is reported incorrectly, the Laboratory shall provide the Agency with a Corrective Action Report.

(g) Double-blind, blind EQAS and educational EQAS samples. Failure to report accurately, in accordance with criteria, 3 blind or double-blind EQAS, or educational EQAS results within a continuous twelve 12-month period may result in penalties imposed by the Agency, including, but not limited to, potential suspension or revocation of HEAL accreditation, or Analytical Testing Restrictions.

Rule 6443. False Adverse Analytical Finding or False Negative Finding

(a) If the Laboratory discovers that it reported a false Adverse Analytical Finding or false Negative Finding, the Laboratory shall inform the Agency immediately.

(b) When the false Adverse Analytical Finding or false Negative Finding is identified by the Agency, through the Agency's own Results Management activities or through any other means, the Agency shall inform the Laboratory as soon as practicable.

(c) The Agency, considering the nature of the error that caused the false Adverse Analytical Finding or false Negative Finding, may impose a penalty, including, but not limited to, potential suspension or revocation of HEAL accreditation, or Analytical Testing Restrictions against the Laboratory for a particular Analytical Testing Procedure or for the analysis of a particular class of Prohibited Substances or Prohibited Methods, as

applicable, or other follow-up measures. For example, the Laboratory may be required by the Agency to analyze EQAS samples or to review the relevant analytical results and to re-analyze any relevant and available Samples previously reported as Adverse Analytical Findings during the preceding 12 months (or during a period otherwise determined by the Agency) within 7 days (unless informed otherwise by the Agency). Depending on the nature of the error that caused the false Adverse Analytical Finding or false Negative Finding, this re-analysis may be limited to one Analyte, a class of Prohibited Substances or Prohibited Methods, or may include any Prohibited Substance or Prohibited Method. A statement signed by the Laboratory Director shall record this re-analysis. The retrospective review of the analytical results and re-analysis of previous relevant Samples reported as Adverse Analytical Finding(s) shall be performed with the objective of determining whether any other related (*i.e.,* produced by the same root cause(s)) false Adverse Analytical Finding(s) have been reported by the Laboratory. The discovery of additional false Adverse Analytical Finding(s) shall lead to the implementation of corrective measures and shall be communicated to the Agency.

(1) During the period of suspension, the Laboratory shall follow the instructions provided in Rule 6561 in regard to Samples in the Laboratory's possession at the time of suspension. Alternatively, if an Analytical Testing Restriction has been imposed, the Laboratory shall subcontract the affected analyses as provided in Rules 6560 and 6302.

(2) During the suspension or Analytical Testing Restriction period, the Agency will conduct an assessment (preferably on-site) of the Laboratory, including the analysis of further EQAS samples.

(3) The suspension or Analytical Testing Restriction of the Laboratory shall be lifted only when the aforementioned conditions are satisfactorily completed, and the Laboratory provides sufficient evidence, as determined by the Agency and in the Agency's sole discretion, that appropriate steps have been taken to remedy the issue(s) that resulted in the suspension or Analytical Testing Restriction.

Rule 6450. Further Procedural Evaluations

If the Agency considers that a Corrective Action Report is unsatisfactory, and the Laboratory is not able to provide a satisfactory revised Corrective Action Report within a reasonable time frame after receiving feedback from the Agency, the Laboratory may receive a penalty, at the Agency's discretion. Rule 6450 does not apply to the evaluation of Corrective Action Reports for false Adverse Analytical Findings or false Negative Findings, which are covered in Rule 6443.

Rule 6460. Overall Laboratory Evaluation

(a) The Agency shall evaluate Laboratory EQAS performance for each EQAS round, as well as Laboratory performance for routine Analytical Testing, and assign penalties, including corrective actions or other follow-up measures, in the Agency's sole discretion.

(b) If a Laboratory under suspension as a result of EQAS performance is not capable of correcting the issue(s) before the end of the suspension period, then the Agency may extend the Laboratory's suspension for up to an additional 6 months or until such a time when the Laboratory can satisfactorily correct all the issues identified (at the Agency's discretion). If the Laboratory under suspension fails to satisfy performance criteria during an extended period of suspension (beyond the initial 6 months), then the Agency may Revoke the Laboratory's accreditation.

(c) Laboratories under an Analytical Testing Restriction remain operational (except for any activities under the Analytical Testing Restriction) and, therefore, are evaluated during the Analytical Testing Restriction as any other, fully operational Laboratory.

Rule 6470. Probationary Period and Probationary Laboratory Evaluation

(a) The probationary EQAS is a part of the initial evaluation of a probationary laboratory seeking HEAL accreditation. Successful participation in the Agency probationary EQAS is required before a probationary laboratory is eligible to be considered for full HEAL accreditation. The Agency may decide, based on its evaluation of the overall performance of the probationary laboratory, to extend the probationary period of accreditation.

(b) The Agency will evaluate probationary laboratory EQAS performance.

(c) Serious and repeated issues in the probationary EQAS shall result in the removal of the laboratory's status as a probationary laboratory by the Agency.

(d) Any false Adverse Analytical Finding or false Negative Finding of a technical or methodological nature reported automatically suspends a probationary laboratory from further consideration for HEAL accreditation.

(e) A suspended probationary laboratory wishing to re-enter the probationary EQAS is required to provide documentation of corrective and preventive action(s) no later than 30 days prior to the end of the suspension period (unless otherwise indicated by the Agency). Failure to do so will preclude the laboratory from participating in the probationary EQAS.

(f) Lifting of the suspension occurs only when proper corrective and preventive actions have been implemented and reported to the Agency. The Agency may choose, at its sole discretion, to submit additional EQAS samples to the laboratory or to require that the laboratory be reassessed, at the expense of the laboratory. Laboratories re-entering the probationary EQAS shall be considered candidate laboratories and are required to provide the applicable accreditation fee and documentation to the Agency.

Rule 6480. Removal of Samples by the Agency for Analysis or Further Analysis

(a) Within the context of an investigation or Laboratory performance monitoring activity (for example, during an on-site Agency Laboratory assessment), the Agency, initially at its expense, may remove Sample(s) from a Laboratory to conduct Further Analysis, or analysis of the Sample if the analytical results for that Sample have not yet been reported, for any purpose described in the Protocol. The Agency shall retain the right to request analysis or Further Analysis, at its expense, as permitted by the Protocol.

(b) The Agency may delegate an observer to monitor the removal of the Samples, which shall be implemented in accordance with the Agency's instructions. During the removal of Samples, the Agency shall be responsible for maintaining proper Sample Chain of Custody documentation and the safety and integrity of the Samples until receipt by the other Laboratory(-ies).

(c) The Agency may also require that the Laboratory transfer the Samples to other Laboratories selected by the Agency. In such situations, the Laboratory shall be responsible for maintaining proper Chain of Custody documentation for all transferred Samples and the safety and integrity of the Samples until receipt by the receiving Laboratory(-ies).

(d) Where for any reason (except where Rule 6312 applies), a Laboratory transfers a Sample to another Laboratory, the first Laboratory shall

send the Sample within 5 business days following receipt by the first Laboratory of the request to transfer the Sample.

(e) In connection with its monitoring of Laboratory performance, the Agency may direct Further Analysis of a Sample which has resulted in an Anti-Doping Rule Violation without consent of the Covered Person or approval from an adjudication body, as provided in the Protocol.

Rule 6490. Removal of Samples by the Agency for Laboratory Quality Assessment

The Agency may also direct the re-analysis of anonymized Samples, which have met the conditions described in Rule 6320, for purposes of Laboratory quality assurance and education, including the implementation of a system of transfer of Samples reported as Negative Findings between Laboratories. In this regard, the number of Samples directed by the Agency for re-analysis may vary.

*6500. Withdrawal of Heal Accreditation*

Rule 6510. Withdrawal of HEAL Accreditation

(a) A Laboratory's HEAL accreditation may be suspended, Revoked, or subject to an Analytical Testing Restriction, whenever the Laboratory fails to comply with the Laboratory Standards, Technical Documents, or Technical Letters, or where the suspension, Revocation or Analytical Testing Restriction is otherwise required to protect the integrity of the Samples, the Analytical Testing process or the interests of the anti-doping community.

(b) The imposition of an Analytical Testing Restriction or the suspension of a Laboratory's HEAL accreditation shall not imply the automatic withdrawal of its ISO/IEC 17025 accreditation. The status of the Laboratory's ISO/IEC 17025 accreditation is to be independently assessed by the relevant accreditation body.

(c) The Agency may suspend a Laboratory's HEAL accreditation or impose an Analytical Testing Restriction against a Laboratory if the Agency identifies noncompliance with the Laboratory Standards, Technical Documents, or Technical Letters based on the Laboratory's performance during the EQAS or during routine Analytical Testing.

(d) The Laboratory may not challenge the penalty imposed by the Agency.

Rule 6520. Noncompliance With the Laboratory Standards

(a) Noncompliance with the Laboratory Standards that may lead to an Analytical Testing Restriction, suspension or Revocation of HEAL accreditation, or other follow-up measures include, but are not limited to:

(1) Suspension or withdrawal of ISO/IEC 17025 accreditation;

(2) Failure to establish or maintain administrative and operational independence as described in paragraph (b)(7) of Rule 6110;

(3) Failure to analyze the minimum number of Samples indicated in paragraph (i) of Rule 6130 (except where the Agency fails to send the minimum annual number of Samples to the Laboratory);

(4) Reporting of false Adverse Analytical Findings or false Negative Findings;

(5) Failure to implement a Technical Document or Technical Letter by the effective date without prior approval of the Agency;

(6) Failure to comply with any of the requirements or standards listed in the Laboratory Standards, Technical Documents or Technical Letters;

(7) Noncompliance with results reporting timelines in Rule 6316;

(8) Failure to take appropriate corrective action after an unsatisfactory performance during routine Analytical Testing or in a blind EQAS or double-blind EQAS round;

(9) Failure to take appropriate corrective action for Laboratory Standards, Technical Document(s), or Technical Letter(s) noncompliance(s) identified from the Agency Laboratory assessment(s);

(10) Analysis of Samples from the Agency in violation of a suspension or Analytical Testing Restriction decision;

(11) Failure to cooperate with the Agency in providing documentation or other requested information;

(12) Noncompliance with the Code of Ethics; or

(13) Any other cause that materially affects the ability of the Laboratory to ensure the full reliability and accuracy of Analytical Testing and the accurate reporting of test results.

(b) Laboratory staff or management issues which may lead to an Analytical Testing Restriction, suspension or Revocation of HEAL accreditation, or other follow-up measures include, but are not limited to:

(1) Major changes in senior Laboratory management positions (*e.g.,* Laboratory Director, Quality Manager) without proper and timely notification (usually within 30 days) to the Agency;

(2) Failure to appoint a permanent Laboratory Director or other senior management positions (*e.g.,* Quality Manager) within a reasonable time period;

(3) Failure to guarantee the competence or proper training of scientific staff including, for example, the qualification of analysts as Certifying Scientists and Laboratory Supervisory Personnel;

(4) Significant loss or lack of experienced staff (*e.g.,* Certifying Scientists) that affects, as determined by the Agency, the Laboratory's ability to ensure the full reliability and accuracy of Analytical Testing and reporting of test results;

(5) Conviction of any key personnel for any criminal offence that is determined by the Agency to impact the operations of the Laboratory;

(6) Loss of sufficient Laboratory support and resources that affects, as determined by the Agency, the quality or viability of the Laboratory; or

(7) Failure to cooperate in any Agency inquiry in relation to the activities of the Laboratory.

Rule 6530. Notification of Penalty Decision

The Agency shall provide the Laboratory with written notice of its decision regarding penalties. This notice shall state the following:

(a) That the Laboratory's HEAL accreditation has been maintained (including warnings, if applicable); or

(b) That the Laboratory's HEAL accreditation has been suspended or Revoked or that an Analytical Testing Restriction has been imposed against the Laboratory. Such notice shall include:

(1) the reason(s) for suspension, Revocation, or the imposition of an Analytical Testing Restriction;

(2) the terms of the suspension, Revocation, or Analytical Testing Restriction;

(3) the period of suspension or Analytical Testing Restriction, if applicable; and

(4) Any corrective actions or other follow-up requirements imposed upon the Laboratory by the Agency.

Rule 6540. Effective Date and Appeals

(a) A Revocation, suspension, or Analytical Testing Restriction is effective immediately upon receipt of notification of the Agency's decision.

(b) The Agency's decision is not subject to appeal.

Rule 6550. Public Notice

(a) The Agency shall publicly announce a change in a Laboratory's accreditation status (including, if appropriate, any Analytical Testing Restriction) on its website as soon as practicable after the Laboratory is notified by the Agency of its decision.

(b) The Agency's website shall be updated regarding a Laboratory's accreditation status when:

(1) the Laboratory's HEAL accreditation is reinstated following a suspension;

(2) an Analytical Testing Restriction is removed (if appropriate); or

(3) a Laboratory whose accreditation has previously been Revoked is re-accredited.

Rule 6560. Consequences of an Analytical Testing Restriction

(a) If the Agency determines that the noncompliance(s) are limited to a class of Prohibited Substances or Prohibited Methods or to a specific Analytical Testing Procedure, which are not included in the standard Analytical Testing menu requested by the Agency for Samples received by the Laboratory, the Agency may impose an Analytical Testing Restriction for that class of Prohibited Substance(s) or Prohibited Method(s) or for the specific Analytical Testing Procedure in which the noncompliance(s) occurred.

(b) If the reason for the Analytical Testing Restriction was related to the reporting of false Adverse Analytical Finding(s), all analyses employing the affected Analytical Testing Procedure(s) shall cease immediately.

(c) The Laboratory under an Analytical Testing Restriction shall contact the Agency to arrange for the transfer of the relevant Samples to subcontracted Laboratory(-ies), selected by the Agency, within 30 days of being notified of the Analytical Testing Restriction decision. All associated costs shall be borne by the Laboratory under Analytical Testing Restriction. The Laboratory shall transfer the following Samples (A and B Samples) in the Laboratory's custody, which involve the analysis of the same class of Prohibited Substances or Prohibited Methods, or the application of the affected Analytical Testing Procedure(s) subjected to the Analytical Testing Restriction, to another Laboratory(-ies) for the performance of the A and, if needed, the B Confirmation Procedures, unless otherwise instructed by the Agency:

(1) Samples which had been previously reported as an Adverse Analytical Finding (as requested by the Agency);

(2) Samples which had been opened and were undergoing analysis for the Initial Testing Procedure(s) at the time of the Analytical Testing Restriction decision;

(3) Samples for which, at the time of the Analytical Testing Restriction decision, Initial Testing Procedure(s) had been completed and had produced Presumptive Adverse Analytical Findings requiring Confirmation Procedures, and Samples that are the subject of other Confirmation Procedures;

(4) Samples for which the A or B Confirmation Procedures had been completed, but results of the analysis had not been reported by the Analytical Testing Restriction date, and Samples which were undergoing A or B Confirmation Procedures at the time of the imposition of the Analytical Testing Restriction;

(5) Samples which had been reported as Adverse Analytical Findings based on the A Confirmation Procedure prior to the imposition of the Analytical Testing Restriction. These Samples shall be kept in the Laboratory under proper Laboratory Internal Chain of Custody and appropriate storage conditions. Should a B Confirmation Procedure be requested during the period of the Analytical Testing Restriction, both A and B Samples shall be transferred to another Laboratory(-ies) selected by the Agency for the A Confirmation Procedure to be performed again and for the performance of the B Confirmation Procedure, if applicable; and

(6) If the Analytical Testing Restriction was caused by the reporting of false Negative Finding(s), and further investigation reveals that other Negative Finding(s) had been reported for Samples that are still stored in the Laboratory, the Laboratory shall inform the Agency. In such cases, both the A and B containers of the relevant Samples shall be transferred to another Laboratory(-ies) selected by the Agency for Further Analysis, as determined by the Agency. These re-analyses may be applied to the class of Prohibited Substances or Prohibited Methods or to the Analytical Testing Procedure(s) that were associated with the Negative Finding(s), as determined by the Agency.

Rule 6561. Consequences of Suspension

(a) A Laboratory whose HEAL accreditation has been suspended is ineligible to perform Analytical Testing of Samples.

(b) Suspension for violation of the Code of Ethics. If the reason for the suspension was related to a violation of the Code of Ethics, all Analytical Testing in the suspended Laboratory shall cease immediately and the Laboratory shall transfer all Samples (both the A and B Samples) in the Laboratory's custody to other Laboratory(-ies) selected by the Agency.

(c) Suspension for reporting of false Adverse Analytical Finding(s). If the reason for the suspension was related to the reporting of false Adverse Analytical Finding(s), all Analytical Testing shall cease immediately. In addition, the Laboratory shall transfer the following Samples (A and B Samples) in the Laboratory's custody to another Laboratory(-ies) selected by the Agency for the performance of the A and, if needed, the B Confirmation Procedures, unless otherwise instructed by the Agency:

(1) Samples which had been previously reported as an Adverse Analytical Finding for the same class of Prohibited Substances or Prohibited Methods when applying the same Confirmation Procedure (as requested by the Agency);

(2) Samples for which, at the time of the suspension decision, Initial Testing Procedure(s) had been completed and had produced Presumptive Adverse Analytical Findings requiring Confirmation Procedures, and Samples that are the subject of other Confirmation Procedures;

(3) Samples which had been opened and were undergoing analysis for the Initial Testing Procedure(s) at the time of the suspension;

(4) Samples which had been received at the Laboratory but had not been opened at the time of the suspension. (These Samples shall be kept sealed in the Laboratory under proper Laboratory Internal Chain of Custody and appropriate storage conditions until transfer to another Laboratory(-ies) selected by the Agency);

(5) Samples for which A or B Confirmation Procedures had been completed, but results of the analysis had not been reported by the suspension date, and Samples which were undergoing A or B Confirmation Procedures at the time of the suspension; and

(6) Samples which had been reported as Adverse Analytical Findings based on the A Confirmation Procedure prior to the suspension.

(d) Suspension for other reasons. A Laboratory that has had its HEAL accreditation suspended for reasons other than a violation of the Code of Ethics or the reporting of false Adverse Analytical Findings(s) shall take the following steps with respect to the Samples in the Laboratory's custody, unless otherwise instructed by the Agency:

(1) Samples which had been analyzed and reported as a Negative Finding, and which have either been stored in the Laboratory for a period of less than 3 months or have been placed in long-term storage upon request by the Agency shall be kept in the Laboratory

under proper Laboratory Chain of Custody and appropriate storage conditions. The Laboratory shall inform the Agency of such actions, including the provision of the Sample codes.

(2) If the suspension was caused by the reporting of false Negative Finding(s), and further investigation reveals that other Negative Finding(s) had been reported by the Laboratory, the Laboratory shall inform the Agency. In such cases, both the A and B containers of the relevant Samples shall be transferred to another Laboratory(-ies) selected by the Agency for Further Analysis, as determined by the Agency. These analyses may be applied for all the Prohibited Substances and Prohibited Methods included in the Analytical Testing menu requested by the Agency or be limited to the class of Prohibited Substances or Prohibited Methods or to the Analytical Testing Procedure(s) that were associated with the Negative Finding(s), as determined by the Agency.

(3) Samples for which Initial Testing Procedures had been completed, but results had not been reported at the time of the suspension:

(i) If the Initial Testing Procedure(s) produced Presumptive Adverse Analytical Finding(s) or other Confirmation Procedures were required, both the A and B Samples shall be transferred to another Laboratory(-ies) selected by the Agency for the performance of the A and, if needed, the B Confirmation Procedures.

(ii) In addition, if the suspension was caused by the reporting of false Negative Finding(s) and the Initial Testing Procedure(s) had produced negative results, both the A and B Samples shall also be transferred to another Laboratory(-ies) selected by the Agency for the repetition of the Initial Testing Procedure(s) and, if needed, the performance of Confirmation Procedures. These analyses may be applied for all the Prohibited Substances and Prohibited Methods included in the Analytical Testing menu requested by the Agency or be limited to the class of Prohibited Substances or Prohibited Methods or to the Analytical Testing Procedure(s) that were associated with the Negative Finding, as determined by the Agency.

(iii) If the reason for the suspension was not related to the reporting of false Negative Findings and the Initial Testing Procedures had produced negative results, the Sample(s) shall be reported to the Agency as Negative Finding(s). These Samples shall be kept in the Laboratory under proper Laboratory Internal Chain of Custody and appropriate storage conditions until further notice by the Agency. The Laboratory shall inform the Agency of such actions including the provision of the Sample codes.

(4) Samples which had been opened and were undergoing analysis for the Initial Testing Procedure(s) at the time of the suspension:

(i) If the reason for suspension was not related to the reporting of false Negative Finding(s), the Laboratory shall continue to analyze the relevant Samples until all Initial Testing Procedures are completed. If the Initial Testing Procedures produce Negative Findings, the Laboratory shall report these findings to, and in a form designated by, the Agency, and these Samples shall be kept in the Laboratory under proper Laboratory Chain of Custody and appropriate storage conditions until further notice by the Agency. The Laboratory shall inform the Agency of such actions, including the provision of the Sample codes.

(ii) However, if the Initial Testing Procedure produced a Presumptive Adverse Analytical Finding, both the A and B Samples shall be transferred to another Laboratory(-ies) selected by the Agency for the performance of the A and, if needed, the B Confirmation Procedures.

(iii) If the suspension was caused by the reporting of false Negative Finding(s), then the Laboratory shall cease all Analytical Testing and have the A and B Samples transferred to another Laboratory(-ies) selected by the Agency for the performance of the A and, if needed, the B Confirmation Procedures.

(5) Samples which had been received at the Laboratory but had not been opened yet at the time of the suspension: these Samples shall be kept sealed in the Laboratory under proper Laboratory Chain of Custody and appropriate storage conditions until transfer to another Laboratory(-ies) selected by the Agency for Analytical Testing.

(6) Samples for which A or B Confirmation Procedures had been completed, but results of analysis had not been reported by the suspension date, and Samples which were undergoing A or B Confirmation Procedures at the time of the suspension: both the A and B Samples shall be transferred to another Laboratory(-ies) selected by the Agency for the repetition of the A and, if applicable, the B Confirmation Procedures.

(7) Samples which had been reported as an Adverse Analytical Finding based on the A Confirmation Procedure prior to the suspension:

(i) These Samples shall be kept in the Laboratory under proper Laboratory Internal Chain of Custody and appropriate storage conditions. Should a B Confirmation Procedure be requested during the suspension, both A and B Samples shall be transferred to another Laboratory(-ies) selected by the Agency for the A Confirmation Procedure to be performed again and for the performance of the B Confirmation Procedure, if applicable.

(ii) During a suspension or Analytical Testing Restriction period, the Laboratory shall continue to participate in the Agency EQAS program. The Agency may require the Laboratory to analyze additional blind EQAS samples or perform a Laboratory assessment, at any time and at the expense of the Laboratory, in order to evaluate the Laboratory's status.

Rule 6562. Revocation

(a) A laboratory whose HEAL accreditation has been revoked is ineligible to perform Analytical Testing of Samples. The Laboratory Internal Chain of Custody maintained by a revoked laboratory for stored Samples is valid until such time that arrangements can be made, in consultation with the Agency, for the transfer of relevant Samples to a Laboratory(-ies) selected by the Agency.

(b) A laboratory whose HEAL accreditation has been revoked shall arrange the transfer of Samples in the laboratory's custody to a Laboratory(-ies) selected by the Agency, respectively, within 30 days of being notified of the decision revoking its HEAL accreditation. In such circumstances, the Samples to be transferred shall be selected by the Agency. The laboratory transferring the Samples shall inform the Agency and provide the relevant Sample codes and the selected Laboratory(-ies). In addition, the revoked laboratory shall assist with the transfer of the relevant Sample data and records to the Laboratory(-ies) that have been selected to receive the Samples.

(c) The revoked laboratory shall transfer all Samples in its custody for which the Analytical Testing process has not been completed at the time of the Revocation. The Agency may also choose to transfer additional Samples retained in the laboratory in accordance with paragraphs (a) through (d) of Rule 6319, or other Samples for which it is the owner pursuant to the Testing and Investigations Standards and that had been analyzed and were in long-term storage at the time of the Revocation of the laboratory's HEAL accreditation. In addition, the Agency may identify and

request that Samples be transferred to another Laboratory(-ies) selected by the Agency.

Rule 6563. Reinstatement of Suspended Accreditation or Lifting of Analytical Testing Restriction

The Agency shall lift the suspension of the Laboratory's HEAL accreditation or lift the Analytical Testing Restriction only when the Laboratory provides satisfactory evidence, as determined by the Agency in its sole discretion, that appropriate steps have been taken to remedy the noncompliance(s) that resulted in the suspension of the Laboratory's HEAL accreditation or the imposition of the Analytical Testing Restriction, and that proper measures have been implemented to satisfactorily address the condition(s) specified, if any, for reinstatement of HEAL accreditation.

Rule 6564. Extension of Suspension or Analytical Testing Restriction

(a) If a Laboratory whose HEAL accreditation has been suspended or which has been the subject of an Analytical Testing Restriction has not satisfactorily corrected the Laboratory Standards, Technical Document(s), or Technical Letter(s) noncompliance(s) that resulted in the suspension or Analytical Testing Restriction, or if the Agency identifies any additional Laboratory Standards, Technical Document(s) or Technical Letter(s) noncompliance(s) during an Agency Laboratory assessment conducted during the initial suspension or Analytical Testing Restriction period, either the suspension of the Laboratory's HEAL accreditation or the Analytical Testing Restriction may be further extended, or the Laboratory's accreditation shall be revoked, as determined by the Agency. The suspension or Analytical Testing Restriction period may be extended up to an additional 6 months, if the Laboratory provides valid explanation(s) for the delay, as determined by the Agency, in addressing the conditions to lift the suspension or Analytical Testing Restriction (including the submission of satisfactory corrective actions).

(b) If applicable, a delay in the delivery of the ISO/IEC 17025 accreditation to the Laboratory by the relevant accreditation body may also constitute grounds to extend the suspension of the Laboratory's HEAL accreditation.

(c) The decision to extend the suspension of a Laboratory's HEAL accreditation or the period of the Analytical Testing Restriction shall be made in the Agency's sole discretion.

(d) If, in accordance with the terms of the extension of the suspension of the Laboratory's HEAL accreditation or the terms of the extension of the Analytical Testing Restriction, the Laboratory provides evidence determined to be satisfactory by the Agency that all of the identified Laboratory Standards, Technical Document(s), or Technical Letter(s) noncompliance(s) have been corrected, the Laboratory's accreditation may be re-instated or the Analytical Testing Restriction may be lifted by decision of the Agency in its sole discretion.

(e) If the Laboratory has not provided evidence determined to be satisfactory by the Agency at the end of the extended suspension or extended Analytical Testing Restriction period, the Agency may Revoke the Laboratory's accreditation.

(f) The Agency will notify the Laboratory of its decision to revoke the Laboratory's HEAL accreditation in accordance with Rule 6530.

Rule 6565. Revoked Accreditation

(a) If a laboratory whose HEAL accreditation has been revoked wishes to seek a new HEAL accreditation, it must apply for HEAL accreditation as a new laboratory in accordance with Rule 6110.

(b) When seeking a new HEAL accreditation, the laboratory may request that the Agency expedite the laboratory re-accreditation procedure, which may be approved by the Agency. To do so the laboratory shall provide the Agency, as part of its application for a new accreditation, information that it considers constitutes ''exceptional circumstances'' as justification for modifying the requirements of Rule 6110 to expedite the entry of the laboratory into, or shortening the duration of, the probationary phase of accreditation. At its sole discretion, the Agency may determine whether such modifications are justified, and which steps must be followed prior to granting approval to the laboratory to enter the probationary phase of accreditation.

Rule 6570. Voluntary Cessation of Laboratory Operations

(a) A Laboratory may decide to voluntarily cease its anti-doping Analytical Testing operations on either a temporary or permanent basis, despite not having been found to have committed any analytical failures or other Laboratory Standards noncompliance(s) and not having been subject to an Analytical Testing Restriction or suspension or Revocation of its HEAL accreditation.

(b) In such circumstances, the Laboratory shall inform the Agency and provide, in writing, the reason(s) for the cessation of anti-doping Analytical Testing operations as soon as the decision is made to cease its operations and, in any event, no later than 3 months prior to the date on which its decision shall take effect. The Laboratory shall also take all necessary measures to notify all its clients of the decision to cease its operations and to arrange, in consultation with its clients, to transfer Samples to another Laboratory(-ies) selected by the Agency, in accordance with Rule 6561 (temporary closure) or Rule 6562 (permanent closure).

(c) If a Laboratory voluntarily ceases its anti-doping Analytical Testing operations on a temporary basis, the Laboratory shall maintain satisfactory performance in the analysis of EQAS samples during the period of inactivity. The period of temporary cessation of Analytical Testing activities shall not exceed 6 months, with one possible extension of up to 6 months (as determined by the Agency). If the Laboratory is unable to resume its Analytical Testing operations within a 12-month period, the Agency shall revoke the Laboratory's accreditation, unless otherwise approved by the Agency.

(d) If a Laboratory decides to cease its operations on a permanent basis, the Laboratory shall assist the Agency with the transfer of relevant Sample data and records to the Laboratory(-ies) that have been selected by the Agency to receive the Samples.

*6600. Code of Ethics for Laboratories and Research and Development Activity Requirements*

Rule 6610. Code of Ethics for Laboratories

(a) Compliance. Directors of Laboratories, their delegates and all Laboratory staff shall respect and comply with the Laboratory Standards and the Protocol. Laboratories and all of their staff shall maintain the confidentiality of all of data, items and information received in connection with Doping Control and Medication Control, including, but not limited to, Samples, Testing documentation, and communications with the Agency.

(b) Research in support of Doping Control.

(1) Laboratories shall participate in research programs, provided that the Laboratory Director is satisfied with their bona fide nature and the program(s) have received proper ethical approval, if applicable. The Laboratory

shall not engage in any research activity that undermines or is detrimental to the purposes of the Act.

(2) Laboratories are expected to develop a research and development program to support and expand the scientific foundation of Doping Control. This research may consist of the development of new methods or technologies, the pharmacological characterization of a new doping agent, the characterization of a masking agent or method, and other topics relevant to the field of Doping Control.

(3) Laboratories are expected to conduct research on Equine (and other animal species) subjects.

(4) Laboratories shall follow institutional animal care and use guidelines and requirements regarding the use of animal subjects in research.

(5) Covered Horses who may undergo Doping Control Testing shall not be the subjects of drug administration studies that include Prohibited Substances or Prohibited Methods.

(c) Controlled substances. Laboratories are expected to comply with the relevant and applicable local, State and Federal laws regarding the handling, storage and discarding of controlled or illegal substances.

(d) Analysis. Laboratories shall not engage in any analysis or activity that undermines or is detrimental to the purposes of the Act.

(e) Analytical Testing for other anti-doping organizations. Laboratories shall accept Samples for Analytical Testing only if all the following conditions have been met:

(1) The Sample matrix is of the proper type (*e.g.,* blood, urine, hair or other Samples) for the requested analyses;

(2) The Samples have been collected, sealed and transported to the Laboratory in accordance with procedures equivalent to the Testing and Investigations Standards; and

(3) The collection is a part of a legitimate anti-doping and medication control program, as determined by the Agency, or satisfies any of the conditions for Sample analysis indicated in Rule 6307.

(f) Analytical Testing for Covered Persons or those acting on their behalf. Laboratories shall not accept Samples directly from individual Covered Persons or from individuals or organizations acting on his or her behalf (unless approved in writing and in advance by the Agency and on the condition that Samples will be treated as Samples under the Protocol). Proceedings may be brought against the relevant Covered Person(s) if evidence of an Anti-Doping Rule Violation or a Controlled Medication Rule Violation emerges from such Sample analysis.

(g) Other analytical activities.

(1) Laboratories shall not provide analytical services in a Doping Control adjudication, unless specifically requested by the Agency or an adjudication body as part of a Results Management process.

(2) Laboratories shall not engage in analyzing commercial material or preparations (*e.g.,* dietary or herbal supplements), unless:

(i) Specifically requested by the Agency or an adjudication body as part of a Results Management process;

(ii) If done as part of a legitimate anti-doping research program, as determined by the Agency; or

(iii) If a request is made by a Covered Person or his or her representative, a Laboratory may conduct the analysis if agreed in advance and in writing by the Agency, which may also specify conditions that must be followed prior to or during the analysis (*e.g.,* verification of original sealed packages, product batch number).

(3) Laboratories shall not provide results, documentation or advice that, in any way, could be used as an endorsement of products or services.

(4) Analytical activities performed outside the Act will not fall under Agency-accredited status of the laboratory and shall not negatively affect the Analytical Testing of Samples from the Agency. Laboratory test reports or other documentation or correspondence related to these other analytical activities shall not declare or represent that any such testing is covered under the Laboratory's Agency-accredited status.

(h) Sharing of knowledge.

(1) When information on new doping substance(s), method(s), or practice(s) is known to a Laboratory, such information shall be shared with the Agency within 60 days. When possible, Laboratories shall share information with the Agency regarding the detection of potentially new or rarely detected doping agents as soon as possible. Immediately after having been notified of the Use of a new substance or method as a doping agent, the Agency will inform all Laboratories.

(2) The Laboratory Director or staff shall participate in developing standards for best practice and enhancing uniformity of Analytical Testing in the HEAL-accredited laboratory system.

(i) Duty to preserve the integrity of the Program contemplated in the Act and to avoid any detrimental conduct.

(1) Laboratory employees and consultants shall not engage in conduct or activities that undermine or are detrimental to the anti-doping and medication control program contemplated in the Act. Such conduct includes, but is not limited to, fraud, embezzlement, perjury, or any other conduct that might cast doubt on the integrity of the anti-doping and medication control program.

(2) Laboratory employees and consultants shall maintain the confidentiality of all of data, items and information received in connection with Doping Control and Medication Control, including, but not limited to, Samples, Testing documentation, and communications with the Agency.

(3) No employee or consultant of any Laboratory may (directly or indirectly) provide counsel, advice, or information to Covered Persons or others regarding techniques or methods used to mask or avoid detection of, alter metabolism of, or suppress excretion of a Prohibited Substance or its Metabolite(s), or Marker(s) of a Prohibited Substance or Prohibited Method in order to avoid an Adverse Analytical Finding.

(4) No employee or consultant of any Laboratory may (directly or indirectly) provide information about a Test Method to a Covered Person (or to any individual or organization acting on his or her behalf) that could be used to avoid the detection of doping. Instead, any such Covered Person (or individual or organization) will be referred to the Agency.

(5) No employee or consultant of any Laboratory may (directly or indirectly) assist a Covered Person in avoiding collection of a Sample (*e.g.,* advice on masking strategies or detection windows). However, this paragraph does not prohibit the publication or presentation of scientific research results, general presentations to educate Covered Persons, students, or others concerning anti-doping programs and Prohibited Substances or Prohibited Methods.

(6) If an employee or consultant of a Laboratory is requested to provide evidence in anti-doping proceedings, he or she is expected to provide independent, scientifically valid expert testimony.

(7) Laboratories shall not issue any statements related to their analytical processes or findings, unless otherwise provided in the Protocol or as directed by the Agency or Authority. The responsibility for evaluation of these findings with further action and publication, if considered necessary, shall be the sole responsibility of the Agency.

(j) Breach and enforceability.

(1) A failure to respect any of the provisions of this Code of Ethics may result in a Laboratory being subject to Disciplinary Proceedings instituted by the Agency to either suspend or revoke its HEAL accreditation or its Agency approval, as applicable.

(2) In addition, a failure to respect any of the provisions of this Code of Ethics may result in staff of a Laboratory being subject to disciplinary action by the Laboratory, resulting in consequences beyond those stipulated under the Laboratory Standards, including potential termination of employment or, where applicable, the imposition of criminal charges.

Rule 6620. Research and Development Activity Requirements

(a) Laboratories must receive a minimum score of 10 points annually:

(1) 5 points for each peer-reviewed manuscript;

(2) 5 points for the production of educational materials;

(3) 5 points for each funded research project;

(4) 5 points for hosting hands-on training workshop for all HEAL Laboratories; and

(5) 2 points for each Laboratory (internal) method development.

(b) The validation or implementation of established anti-doping methods with only minor adjustments, or the repetition of research previously published or presented by others, is not sufficient to be considered as a research and development activity.

*7000. Arbitration Procedures*

Rule 7010. Applicability

The Arbitration Procedures set forth in this Rule 7000 Series shall apply to all adjudications arising out of the Rule 3000 Series.

Rule 7020. Delegation of Duties

(a) Subject to Rule 3249, Anti-Doping Rule Violations arising out of the Rule 3000 Series and violations of Rule 3229 (together, ''EAD Violations'') shall be adjudicated by an independent arbitral body (the ''Arbitral Body'') in accordance with the Rule 3000 Series and these Arbitration Procedures. The Arbitral Body may also adjudicate any other matter referred to it under the Protocol, and any other matter that might arise from time to time under the Protocol that the Agency considers should be determined by the Arbitral Body. The Arbitral Body is selected by mutual agreement of the Authority and the Agency. The Arbitral Body will ordinarily assign a sole arbitrator to hear a case concerning an EAD Violation. However, the Arbitral Body may assign 3 arbitrators to hear a case involving an EAD Violation upon request by the Agency, based on the nature or complexity of the case.

(b) Subject to Rule 3349, Controlled Medication Rule Violations arising out of the Rule 3000 Series, violations of Rule 3329, and violations of Rule 3510 (ECM or Other Violations) shall be adjudicated by an adjudication panel (the Internal Adjudication Panel) in accordance with the Rule 3000 Series and these Arbitration Procedures. The Internal Adjudication Panel may also adjudicate any other matter referred to it under the Protocol, and any other matter that might arise from time to time under the Protocol that the Agency considers should be determined by the Internal Adjudication Panel. The Internal Adjudication panel is selected by mutual agreement of the Authority and the Agency. The Internal Adjudication Panel will ordinarily assign a single Internal Adjudication Panel member to adjudicate a case involving an ECM or Other Violation; in exceptional circumstances only, the Internal Adjudication Panel may assign 3 members to adjudicate a case upon request by the Agency.

(c) Final decisions issued by the Arbitral Body or Internal Adjudication Panel are subject to review as specified in section 3058 of the Act.

Rule 7030. Arbitral Body

(a) The Arbitral Body shall have a pool of arbitrators consisting of a minimum of 5 members appointed by mutual agreement of the Authority and the Agency.

(b) Arbitrators shall be appointed for 4-year terms. Candidate arbitrators shall complete an application in a form designated by the Authority.

(c) Candidates shall not be or have been in the previous 2 years an officer, director, trustee, employee, consultant, or official, or be in a policy making position for any Equine Constituencies or the Agency, except that this requirement does not apply to former State Racing Commission officials or employees.

(d) Candidate arbitrators shall be required to submit on request to a background check before appointment and shall commit in writing to accept appointment to all cases to which they are selected except:

(1) when they have been involved in the Provisional Hearing for the matter;

(2) when they have an actual or perceived conflict of interest; or

(3) for personal hardship (candidates shall agree not to decline appointment for personal hardship in more than 2 cases in any 12-month period, except in exceptional circumstances).

(e) If an arbitrator dies, resigns, becomes incapacitated during the arbitrator's term (legal incapacity is not required), or is removed for an ethical breach or deficiency in carrying out his or her duties, a new arbitrator shall be selected and appointed for a full 4-year term, following the procedures set forth in this Rule 7030.

Rule 7040. Internal Adjudication Panel

(a) The Internal Adjudication Panel shall consist of impartial members appointed by mutual agreement of the Authority and the Agency to hear ECM or Other Violations (''IAP members''). The Internal Adjudication Panel shall have a pool of IAP members. The Authority and the Agency may appoint as many IAP members as they consider necessary to the pool of IAP members in accordance with the Arbitration Procedures.

(b) Candidate IAP members shall be required to submit on request to a background check before appointment and shall commit in writing to accept appointment to all cases to which they are selected except:

(1) when they have been involved in the Provisional Hearing for the matter;

(2) when they have an actual or perceived conflict of interest; or

(3) for personal hardship (candidates shall agree to not decline appointment for personal hardship in more than 2 cases in any 12-month period, except in exceptional circumstances).

(c) IAP members are appointed for 4-year terms.

(d) Apart from appointment to the Internal Adjudication Panel, IAP members shall not have any business or economic interest with a party in a case.

(e) If an IAP member dies, resigns, becomes incapacitated during the IAP member's term (legal incapacity is not required), or commits an ethical breach or deficiency, the Authority or the Agency may remove the IAP member from the Internal Adjudication Panel. The Agency will publish a list of members of the Internal Adjudication Panel on its website.

(f) A person is not precluded from serving as an IAP member concomitantly with his or her service as an association or state steward, provided that doing so does not put that him or her in a position of actual or perceived conflict of interest.

Rule 7050. Training of Arbitrators and IAP Members

Arbitrators and IAP members shall receive at least 2 hours of continuing education each year on issues related to

proper and efficient handling of cases. The education must be approved by the Authority. Failure to complete this required continuing education is grounds for immediate dismissal.

Rule 7060. Initiation by the Agency

(a) EAD Violations. Unless Rule 3249 applies, if the Agency charges a Covered Person with an EAD Violation, the Agency shall initiate proceedings with the Arbitral Body. If a Covered Person is charged with both an EAD Violation and an ECM or Other Violation, the procedures for EAD Violations apply. The parties to the proceeding shall be the Agency and the Covered Person(s) charged. The Owner and the Authority shall be invited to join in the proceedings as observers and, if accepted as such, receive copies of the filings in the case. In the context of EAD Violation cases, the Owner may be permitted to intervene and make written or oral submissions.

(b) ECM and Other Violations. Unless Rule 3349 applies, if the Agency charges a Covered Person with an ECM or Other Violation, the Agency shall initiate proceedings with the Internal Adjudication Panel. The Covered Person may request a hearing before the Internal Adjudication Panel. However, the Internal Adjudication Panel may decide in its sole discretion to determine the matter based solely on the written submissions without a hearing, if the Internal Adjudication Panel considers itself sufficiently well-informed to render a decision on the written submissions alone. The parties to the proceeding shall be the Agency and the Covered Person(s) charged. The Owner and the Authority shall be invited to join in the proceedings as observers and, if accepted as such, receive copies of the filings in the case. In the context of ECM and Other Violation cases, the Owner shall not be permitted to intervene or make written or oral submissions.

(c) Only the following persons may attend hearings as the Owner of the Covered Horse, unless otherwise agreed by the hearing panel:

(1) if the Covered Horse is owned by one individual, that individual;

(2) if the Covered Horse is owned by more than one individual or by a partnership, corporation, limited liability company, syndicate, or other association or entity, the Designated Owner or Managing Owner.

Rule 7070. New or Additional Charges

If after charging a Covered Person with a violation, the Agency has cause to bring any new or different charge(s) against the Covered Person, the charge shall be made in writing and filed with the other party or parties and (as applicable) the Internal Adjudication Panel or Arbitral Body. The arbitrator(s) or IAP member(s) appointed to hear the case shall decide whether the charges should be consolidated and heard in the same proceedings or whether the new or additional charge(s) should be heard separately.

Rule 7080. Expedited Procedures

(a) At the request of any party, any time period set forth in the Arbitration Procedures may be shortened by the arbitrator(s) or IAP member(s) if doing so is reasonably necessary to resolve any Covered Person's or Covered Horse's eligibility before a Covered Horserace, while continuing to protect the right of a Covered Person to a fair process.

(b) Pursuant to Rule 3262 or Rule 3362, the Agency may, in its sole discretion, shorten any deadlines within the Arbitration Procedures proportionately to ensure resolution prior to a Covered Horserace.

(c) If the Agency does not agree to the process being expedited, the arbitrator(s) or IAP member(s), as applicable, shall determine whether the adjudication process shall be expedited and the schedule pursuant to which the process shall proceed.

Rule 7090. Jurisdiction

(a) An arbitrator or IAP member shall have the authority to rule on his or her own jurisdiction, including any objections with respect to the existence, scope, or validity of the applicable rules.

(b) A party must object to the jurisdiction of the arbitrator(s) or IAP member(s) or to the arbitrability of a charge by the Agency no later than the filing of the answering statement to the charge that gives rise to the objection. The arbitrator(s) or IAP member(s) may rule on such objections as a preliminary matter or as part of the final decision, in his or her sole discretion.

Rule 7100. Consolidation

Matters involving more than one Covered Person may, in the Agency's discretion, be consolidated into a single matter. If an EAD Violation is alleged by the Agency against any of the Covered Persons who are parties in the consolidated matter, the process for EAD Violations will be followed.

Rule 7110. Location and Means of Conducting Hearings

(a) Hearings regarding EAD Violations shall take place in person, unless the arbitrator(s) order(s) the hearing (or parts thereof) to take place by use of an audio-visual teleconferencing system.

(b) Hearings regarding ECM or Other Violations shall take place by use of an audio-visual teleconferencing system, unless the IAP member(s) order(s) the hearing to take place in person.

(c) In-person hearings shall be held in the United States at a location determined by the arbitrator(s) or IAP member(s).

Rule 7120. Qualifications

Any arbitrator(s) or IAP member(s) appointed pursuant to Rule 7130 shall be subject to disqualification for the reasons specified in Rule 7140.

Rule 7130. Appointment of Hearing Panels to Adjudicate Cases

(a) The arbitrator(s) shall be appointed in the following manner: immediately after the initiation of a proceeding by the Agency as set forth in Rule 7060, the Arbitral Body shall appoint a single arbitrator or three (3) arbitrators from the pool of arbitrator(s) on a rotating basis, after confirming that the arbitrator(s) will not decline the appointment due to personal hardship. The arbitrator(s) adjudicating the Provisional Hearing shall not serve as an arbitrator determining the merits of the charge against the Covered Person. The Arbitral Body shall communicate to the parties the name of the arbitrator(s) appointed to hear the matter within 3 days of initiation by the Agency.

(b) The IAP member(s) shall be appointed in the following manner: Immediately after the initiation of a proceeding by the Agency as set forth in Rule 7060, the Internal Adjudication Panel shall appoint a single IAP member (or in exceptional cases three IAP members) from the pool of IAP members on a rotating basis, after confirming that the IAP member(s) will not decline the appointment due to personal hardship. The IAP member(s) adjudicating the Provisional Hearing shall not serve as the IAP member(s) determining the merits of the charge against the Covered Person. The Internal Adjudication Panel shall communicate to the parties the name of the IAP member(s) appointed to hear the matter within 3 days of initiation by the Agency.

(c) Once appointed, the arbitrator(s) and IAP member(s) shall receive an electronic copy of the charge letter, Arbitration Procedures, Rule 3000 Series and related rule series, and the Billing Standards.

Rule 7140. Disclosure and Challenge Procedure

(a) Each arbitrator and IAP member appointed to hear a particular case shall

disclose to the parties any circumstance likely to affect his or her impartiality, including any bias or any financial or personal interest in the result of the case, or any past or present relationship with the parties or their representatives.

(b) Upon objection of a party to the continued service of an arbitrator or IAP member, the Arbitral Body or Internal Adjudication Panel (as applicable) shall determine whether the arbitrator or IAP member is evidently partial, and (if so) the arbitrator or IAP member shall be disqualified. The Arbitral Body or Internal Adjudication Panel shall inform the parties of its decision, which shall be final and not subject to review or any other challenge.

Rule 7150. Communication

Once appointed, no party and no Person acting on behalf of any party shall communicate unilaterally concerning the case with any arbitrator or IAP member appointed to hear the case. All communications with the Arbitral Body or Internal Adjudication Panel or any arbitrator or IAP member concerning the case shall include the other party or parties.

Rule 7160. Vacancies

If for any reason following assignment to the case an arbitrator or IAP member becomes unable to perform his or her duties in a particular case, the Arbitral Body or Internal Adjudication Panel (as applicable) may fill the vacancy on a rotating basis as described in these rules.

Rule 7170. Procedures for EAD Violations

(a) For matters involving an alleged EAD Violation arising from an Adverse Analytical Finding, each Covered Person's pre-hearing submission must be filed with the Arbitral Body on or before 14 days after submitting a request for a hearing (or after the deadline to make such request expires), and the Agency's pre-hearing submission must be filed with the Arbitral Body on or before 14 days after the last Covered Person's pre-hearing submission. There shall be no reply pre-hearing submission unless ordered otherwise by the arbitrator(s), but each party may present rebuttal evidence at the hearing.

(b) For matters involving an alleged EAD Violation involving a non-analytical violation or a violation of Rule 3229, the Agency's initial pre-hearing submission must be filed with the Arbitral Body on or before 14 days after the last Covered Person requests a hearing (or after the deadline to make such request expires). Each Covered Person's pre-hearing submission must be filed with the Arbitral Body on or before 14 days after the Agency's initial pre-hearing submission, and the Agency's reply pre-hearing submission must be filed with the Arbitral Body seven 7 days after the last Covered Person's pre-hearing submission.

(c) A Covered Person's pre-hearing submission shall include a brief not to exceed 30 double-spaced single-sided pages and shall include all exhibits, schedules, witness statements, expert reports, and all other evidence (except summaries and demonstrative aides) that the Covered Person intends to rely upon at the hearing. The Covered Person's pre-hearing submission shall include a designation of witnesses providing the identity of witnesses, or name of the organization (in the case of an organization representative) expected to be called to testify at the hearing, along with signed statements for each of those witnesses. For expert witnesses, the pre-hearing submission shall include a C.V. and expert report, identifying all opinions to which they will testify and the facts and scientific methods upon which those opinions are based, as well as to identify all scientific treatises, studies, or articles on which the expert relies in rendering their opinion(s), for each expert included in the witness designations.

(d) The Agency's initial pre-hearing submission shall include a brief not to exceed 30 single-sided double-spaced pages for each Covered Person charged in the case and shall include all exhibits, schedules, witness statements, expert reports, and all other evidence (except impeachment evidence, summaries, and demonstrative aides) that the Agency intends to rely upon at the hearing. The Agency's initial pre-hearing submission shall include a designation of witnesses providing the identity of witnesses, or name of the organization (in the case of an organization representative) expected to be called to testify at the hearing, along with signed statements for each of those witnesses. For expert witnesses, the initial pre-hearing submission shall include a C.V. and expert report, identifying all opinions to which the expert will testify, and the facts and scientific methods upon which those opinions are based. The submission shall identify all scientific treatises, studies, or articles on which the expert relies in rendering his or her opinion(s), for each expert included in the witness designations. The Agency's reply pre-hearing submission shall include all additional evidence upon which it intends to rely for rebuttal (except impeachment evidence, summaries, and demonstrative aides) and a reply brief not to exceed 15 single-sided double-spaced pages for each Covered Person charged in the case.

(e) Each party is responsible for updating its disclosures as such information becomes available. If a party should have submitted evidence in the party's pre-hearing submission but did not submit such evidence, the arbitrator(s) shall not admit such evidence absent a showing of good cause.

(f) The hearing should take place no more than 60 days from the date the last Covered Person requested a hearing in a particular case.

(g) At the request of any party, or at the discretion of the arbitrator(s), the arbitrator(s) may schedule, as soon as practicable, a preliminary hearing with the parties or their representatives. The preliminary hearing shall be conducted by telephone or video conference. During the preliminary hearing, the parties and the arbitrator(s) shall discuss any preliminary matters to ensure compliance with the procedures herein.

(h) Upon a showing of exceptional circumstances, the arbitrator(s) may extend any of the deadlines set forth in Rule 7170 for the minimum time necessary to address the circumstance. If all parties agree to an alternative schedule in a particular case, the arbitrator(s) shall alter dates accordingly.

(i) If any of the dates described in Rule 7170 fall on a weekend or a Federal holiday, they shall be moved to the next business day.

Rule 7180. Procedures for ECM and Other Violations

(a) Subject to paragraph (b) below, the IAP member(s) may determine to hold a hearing and require written submissions to be filed prior to the hearing, or to require written submissions and determine the matter based solely on the written submissions without a hearing. The IAP member(s) shall have wide discretion to determine the conduct of the proceedings in order to ensure that they are commensurate to the violations at issue. The IAP member(s) may issue directions to the parties as necessary. The IAP member(s) shall also have discretion to amend any time limits as they see fit in the circumstances, but any extension of deadlines shall be granted only for the minimum time necessary to address the circumstance, as all matters before the IAP member(s) shall proceed expeditiously.

(b) A person charged with a violation may request that the IAP member waive the requirement that written submissions be filed by the parties, and permit the person charged to make an

oral presentation at a hearing. The IAP member may grant the request in the interest of justice, if the conduct of the hearing will not prejudice any of the other parties. The IAP member(s) shall provide the Agency the opportunity to respond to the oral presentation and shall have wide discretion to determine the conduct and scope of the hearing. The person charged may request that he or she be assisted by legal counsel or other representative at the hearing.

(c) If the IAP member(s) order the parties to produce written submissions, and the matter involves an alleged ECM or Other Violation arising from an Adverse Analytical Finding, each Covered Person's submission must be filed with the Internal Adjudication Panel on or before 7 days after submitting a request for a hearing before the Internal Adjudication Panel (or after the deadline to make such request expires), and the Agency's submission must be filed with the Arbitral Body on or before 7 days after the last Covered Person's submission. There shall be no reply submissions unless ordered otherwise by the IAP member(s).

(d) If the IAP member(s) order the parties to produce written submissions, and the matter involves a non-analytical ECM Violation or Other Violation, the Agency's initial submission must be filed with the Internal Adjudication Panel on or before 7 days after the last Covered Person requests a hearing before the Internal Adjudication Panel (or after the deadline to make such request expires). Each Covered Person's submission must be filed with the Arbitral Body on or before 7 days after the Agency's initial submission. There shall be no reply submissions unless ordered otherwise by the IAP member(s).

(e) If the IAP member(s) order the parties to produce written submissions, the submissions of each party shall ordinarily not exceed 15 single-sided double-spaced pages and shall include all supporting documentation on which the party relies. If any party intends to call a witness or expert to testify at the hearing, a signed witness statement and expert report (as applicable) shall be filed with the written submission.

(f) If any of the dates described in Rule 7180 fall on a weekend or a Federal holiday, the date shall be moved to the next business day.

Rule 7190. Exchange of Information

Information shall be exchanged electronically, unless otherwise agreed by the parties. The arbitrator(s) and IAP member(s) are authorized to resolve any disputes concerning the exchange of information between the parties consistent with the expedited nature of the proceedings.

Rule 7200. Participation

The Arbitral Body and Internal Adjudication Panel (and their respective members) shall maintain the confidentiality of the proceedings. The arbitrator(s) or IAP member(s) may proceed without the participation of any party or representative who, after due notice, fails to be present or make a submission. If a party defaults, the arbitrator(s) or IAP member(s) may require the party who is present to submit such evidence and documents as the arbitrator(s) or IAP member(s) may require for the making of a final decision. Hearings are not open to the media or the public. However, the arbitrator(s) or IAP member(s) may permit one or more third parties to attend the hearing.

Rule 7210. Representation

Any party may be represented by legal counsel or other representative. The legal counsel or other representative shall provide a letter of representation notifying the other party and the Arbitral Body or Internal Adjudication Panel (as applicable) of his or her name, phone number, email, and mailing address. A party shall be bound by the statements made and positions taken by its legal counsel or other representative.

Rule 7220. Oaths

All testimony at hearings shall be taken under oath or affirmation.

Rule 7230. Stenographic Record

Any party desiring a stenographic record of all or a portion of the hearing shall notify the other parties of the request at least 7 days in advance of the start of the hearing, unless ordered otherwise by the arbitrator(s) or IAP member(s). The Agency shall identify the court reporter to be used for transcription services, and an electronic copy of the transcript shall be provided to the arbitrator(s) or IAP member(s) (as applicable) and to the parties. Parties are responsible for the costs of any transcript they request.

Rule 7240. Interpreters

All proceedings shall take place in English. Any party wishing to have an interpreter present during proceedings shall make all arrangements directly with the interpreter. Interpreters shall have no prior relationship with a party or have any interest in the proceeding, and the arbitrator(s) or IAP member(s) (as applicable) must approve the interpreter in advance. The costs of the interpreter shall be split between the parties. Any document that is not in English shall be officially translated by a certified translator paid for by the party offering or relying upon the document.

Rule 7250. Conduct of Hearings

(a) The Agency shall present evidence to support its charge. The Covered Person(s) charged shall then present evidence to support the Covered Person(s) defense. The Agency is then entitled to present rebuttal evidence. Witnesses for each party shall also submit to questions from the arbitrator(s) or IAP member(s) and the adverse party. The arbitrator(s) or IAP member(s) may vary this procedure, provided that the parties are treated equally and that each party has the right to be heard and is given a fair opportunity to present its case.

(b) The arbitrator(s) or IAP member(s) shall have the power to require the sequestration of any witness, other than a party or other essential person, during the testimony of any other witness. It shall be within the discretion of the arbitrator(s) or IAP member(s) to determine the propriety of the attendance of any other person other than a party and its representatives and the observers identified in Rule 7060.

(c) The arbitrator(s) or IAP member(s) may direct the order of proof, bifurcate proceedings, and direct the parties to focus their presentations on issues the decision of which could dispose of all or part of the case.

(d) The parties may agree to waive oral hearings.

Rule 7260. Evidence

(a) The parties may offer such evidence as is relevant and material to the dispute and shall produce such evidence as the arbitrator(s) or IAP member(s) may deem necessary to make a determination in a case.

(b) Prior to or during the hearing, a party may also request the arbitrator(s) or IAP member(s) to order production of any document which the party believes to be relevant and material to the dispute. The arbitrator(s) or IAP member(s) shall have discretion to grant or reject such a request as they see fit in the circumstances. However, requests for discovery and wide-ranging or otherwise disproportionate document requests shall not be permitted.

(c) The arbitrator(s) or IAP member(s) may retain an expert or seek independent evidence only if (i) agreed to by all of the parties and (ii) the parties or the Agency agree(s) to pay for the cost of such expert or independent evidence. The parties shall have the right to examine any expert retained by the

arbitrator(s) or IAP member(s) and shall have the right to respond to any independent evidence obtained by the arbitrator(s) or IAP member(s).

(d) The arbitrator(s) or IAP member(s) shall determine the admissibility, relevance, and materiality of the evidence offered, including hearsay evidence, and may exclude evidence deemed cumulative or irrelevant. Conformity to legal rules of evidence shall not be necessary, but the Federal rules of evidence may be used for guidance. Evidentiary and other rules for proving violations of the Protocol are also set out in Rule 3120.

(e) The arbitrator(s) or IAP member(s) shall apply relevant principles of legal privilege, including those involving the confidentiality of communications between an attorney and client and the investigative privilege.

(f) The arbitrator(s) or IAP member(s) may issue subpoenas for witnesses, documents, information, or other evidence upon the request of any party, keeping in mind the expedited nature of the proceedings and the procedures set forth in Rules 7170 and 7180. The arbitrator(s) or IAP member(s) shall not issue a subpoena for a deposition, because depositions (along with formal written discovery in civil litigation) are not in keeping with the expedited nature of the Arbitration Procedures.

Rule 7270. Inspection

If the arbitrator(s) or IAP member(s) consider it necessary to make an inspection in connection with a proceeding, the arbitrator(s) or IAP member(s) shall so advise the parties. The arbitrator(s) or IAP member(s) shall set the date and time that shall not delay the procedures in Rules 7170 and 7180 and shall notify the parties. Any party who so desires may be present at such an inspection. If one or all parties are not present at the inspection, the arbitrator(s) or IAP member(s) shall make an oral or written report to the parties and afford them an opportunity to comment.

Rule 7280. Interim Rulings and Measures

The arbitrator(s) or IAP member(s) may make interim rulings and orders, and may order whatever interim measures they deem necessary to provide any party an immediate protection of rights.

Rule 7290. Provisional Hearings

Hearings to resolve challenges to Provisional Suspensions shall be held in accordance with Rule 3247 or 3347, as applicable. Hearsay evidence shall be admissible in a Provisional Hearing.

Rule 7300. Closing of Hearing

Subject to Rule 7310, the arbitrator(s) or IAP member(s) shall declare the hearing closed after the conclusion of closing arguments. Post-hearing briefs shall not be permitted, except as ordered by the arbitrator(s) or IAP members(s) in complex or otherwise exceptional cases. The time limit to issue the final decision shall commence upon the closing of the hearing.

Rule 7310. Reopening of Hearing

To avoid manifest injustice, the hearing may be reopened on the initiative of the arbitrator(s) or IAP member(s), or upon application of a party, at any time before the final decision is made. At the request of a party, the arbitrator(s) or IAP member(s) will determine if the applicable standard has been met to reopen the hearing.

Rule 7320. Waiver of Rules

Any party who proceeds with the adjudication under these rules after knowledge that any provision or requirement of these rules has not been complied with and who fails to state an objection in writing shall be deemed to have waived the right to object.

Rule 7330. Serving of Notice

(a) Any papers, notices, or process necessary or proper for the initiation or continuation of a proceeding under these rules, and any final decision made under these rules may be served by mail or email addressed to the party or its representative at the last known address or by personal service in or outside the state where the arbitration is to be held.

(b) Unless otherwise instructed by the Arbitral Body or Internal Adjudication Panel, any documents submitted by any party to the Arbitral Body or Internal Adjudication Panel shall simultaneously be provided to the other party or parties to the proceeding.

Rule 7340. Final Decision

A final decision shall be in writing and signed by the arbitrator(s) or IAP member(s). The arbitrator(s) shall issue the final decision on or before 14 days after the close of the hearing. The IAP member(s) shall issue the final decision on or before 14 days after the last written submission contemplated in Rule 7180 or after the close of the hearing (as applicable). The 14-day time limit may be extended if additional time is needed due to the complexity of the case or exceptional circumstances.

Rule 7350. Scope of Final Decision

Arbitrators and IAP members may grant any remedy or relief authorized by the Act or the Rules issued pursuant to the Act.

Rule 7360. Case Resolution During Proceedings

If the parties settle the case during the course of the proceedings in accordance with Rule 3249 or 3349, the Arbitral Body or the Internal Adjudication Panel shall issue an order terminating the proceedings.

Rule 7370. Notification of Final Decision

(a) The final decision shall be served on all parties by first class mail, email, or personal service. Interested Parties shall also be notified of the final decision.

(b) The final decision shall be Publicly Disclosed and shall not be considered confidential, unless provided otherwise in the applicable rules.

Rule 7380. Modification of Final Decision

Within 7 days of the issuance of a final decision, any party, upon notice to the other parties, may request the Arbitral Body or Internal Adjudication Panel to correct any clerical, typographical, or computational errors in the final decision. The other parties shall ordinarily be given 5 days to respond to the request.

Rule 7390. Release of Documents for Judicial Proceedings

The Arbitral Body and Internal Adjudication Panel (as applicable) shall, upon the written request of a party, furnish to the party, at the party's expense, certified copies of any papers in the Arbitral Body's or Internal Adjudication Panel's possession that may be required in judicial proceedings relating to the proceeding. If the matter is subject to review by an administrative law judge in accordance with the Act, the Arbitral Body and Internal Adjudication Panel (as applicable) shall furnish copies of any documents requested by the administrative law judge to such judge in connection with that proceeding.

Rule 7400. Right of Review

The final decision of the Arbitral Body or Internal Adjudication Panel is subject to review in accordance with section 3058 of the Act. Notwithstanding any provision set forth in these Arbitration Procedures, nothing herein shall alter the standards of review set forth in the Act.

Rule 7410. Applications to Court and Exclusion of Liability

(a) Arbitration is intended to be the exclusive remedy in all cases arising under the Rule 3000 Series, subject to appeal as described in the Rule 3000 Series and the Act.

(b) No civil action commenced by a party relating to the subject matter of the proceeding under the Arbitration Procedures shall be deemed a waiver of any party's right to adjudicate that party's case under the Arbitration Procedures.

(c) Neither the Arbitral Body nor the Internal Adjudication Panel (nor any arbitrator or IAP member) in a proceeding under these rules is a necessary party in judicial proceedings relating to that proceeding.

(d) Parties to a proceeding under the Arbitration Procedures shall be deemed to have consented that a final decision may be entered in any Federal or State court having jurisdiction, unless the party seeks review pursuant to section 3058 of the Act.

(e) None of the Authority, Agency, Arbitral Body, Internal Adjudication Panel, arbitrators, or IAP members shall be liable to any party for any act or omission in connection with any proceedings conducted under these Arbitration Procedures.

Rule 7420. Costs

(a) The Arbitral Body shall prescribe filing and other administrative fees and service charges to compensate it for the cost of providing administrative services. The fees in effect when the fee or charge is incurred shall be applicable. The Arbitral Body's filing fee and any other administrative fee or charge shall be split equally amongst the parties, and the Agency's portion shall be paid by the Authority.

(b) The Arbitral Body shall split the costs of the proceeding before an arbitrator (including arbitrator fees and expenses, but excluding attorney, witness, and party expert fees) equally amongst the parties with the Agency's portion being paid by the Authority. The Arbitral Body, in its discretion, may require advanced costs be paid by the parties to ensure payment is made.

(c) A party's failure to pay costs or advanced costs by the deadlines imposed by the Arbitral Body will, if not rectified immediately, result in a waiver of charges or defenses to charges (as applicable) and result in imposition and publication of sanctions requested by the Agency.

(d) The Authority shall be solely responsible for the administrative costs stemming from IAP member-resolved cases as described in the Arbitration Procedures.

Rule 7430. Expenses

The expenses of witnesses for any party shall be paid by the party producing such witnesses. Each party shall bear its own attorneys' fees and other expenses.

Rule 7440. Arbitrator's Compensation

(a) Arbitrators shall be compensated and reimbursed in a manner consistent with the Billing Standards.

(b) If there is disagreement concerning the terms of compensation, the disagreement shall be resolved as described in the Billing Standards.

(c) Any arrangement for the compensation or reimbursement of an arbitrator shall be made through the Arbitral Body and not directly between the parties and the arbitrator.

(d) Arbitrator fees and IAP member fees shall be paid in accordance with Rule 7420.

Rule 7450. Application of Rules

The Rule 1000–9000 Series shall be considered part of the agreement to arbitrate and in all instances the arbitrators and IAP members are required to apply the provisions of that arbitration agreement and conform to its terms.

By direction of the Commission.

**Joel Christie,**

*Acting Secretary.*

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Part III

## Department of Education

34 CFR Parts 600, 668, and 690
Pell Grants for Prison Education Programs; Determining the Amount of Federal Education Assistance Funds Received by Institutions of Higher Education (90/10); Change in Ownership and Change in Control; Final Rule

**DEPARTMENT OF EDUCATION**

**34 CFR Parts 600, 668, and 690**

**[Docket ID ED–2022–OPE–0062]**

**RIN 1840–AD54, 1840–AD55, 1840–AD66, 1840–AD69**

## Pell Grants for Prison Education Programs; Determining the Amount of Federal Education Assistance Funds Received by Institutions of Higher Education (90/10); Change in Ownership and Change in Control

**AGENCY:** Office of Postsecondary Education, Department of Education.

**ACTION:** Final regulations.

**SUMMARY:** The Secretary amends regulations for the Federal Pell Grant program (Pell Grants or Pell), institutional eligibility, and student assistance general provisions. First, we amend the regulations for Federal Pell Grants for prison education programs (PEPs), to implement new statutory requirements to establish Pell Grant eligibility for a confined or incarcerated individual enrolled in a PEP to implement the statutory change in the Consolidated Appropriations Act, 2021. Second, we amend the Title IV Revenue and Non-Federal Education Assistance Funds regulations (referred to as ''90/10'' or the ''90/10 Rule'') to implement the statutory change in the American Rescue Plan Act of 2021 (ARP). We further amend which non-Federal funds can be counted when determining compliance with the 90/10 rule to align allowable non-Federal revenue more closely with statutory intent. Finally, we amend regulations to clarify the process for consideration of changes in ownership and control (CIO), to promote compliance with the Higher Education Act of 1965, as amended (HEA), and related regulations and reduce risk for students and taxpayers, as well as institutions contemplating or undergoing such a change.

**DATES:**

*Effective date:* The regulations are effective July 1, 2023.

*Applicability date:* The 90/10 regulations will apply to institutional fiscal years beginning on or after January 1, 2023, consistent with the effective date of the statutory changes to the 90/10 calculation.

**FOR FURTHER INFORMATION CONTACT:** For PEPs: Aaron Washington. Telephone: (202) 987–0911. Email: *Aaron.Washington@ed.gov.* For 90/10: Ashley Clark. Telephone: (202) 453–7977. Email: *Ashley.Clark@ed.gov.* For Change in Ownership: Brian Schelling. Telephone: (202) 453–5966. Email: *Brian.Schelling@ed.gov.* You may also email your questions to *Sophia.Mcardle@ed.gov.*

**SUPPLEMENTARY INFORMATION:**

### Executive Summary

*Purpose of this Regulatory Action*

These final regulations address three areas: Pell Grants for PEPs, the 90/10 rule, and institutional changes in ownership. The PEP final regulations, on which the Affordability and Student Loans Committee reached consensus, implement statutory changes that extend Pell Grant eligibility to confined or incarcerated individuals who enroll in qualifying PEPs. The 90/10 final regulations, on which the Institutional and Programmatic Eligibility Committee (Committee) reached consensus, implement statutory changes that require proprietary institutions to obtain at least 10 percent of their revenue from sources other than Federal education assistance funds and more closely align allowable non-Federal revenue with statutory intent. Finally, the changes to the current CIO regulations provide a clearer and more defined process for institutions undergoing changes in ownership and control.

*Prison Education Programs*

The PEP regulations provide to the Department and stakeholders, including students, correctional agencies and institutions, postsecondary institutions, accrediting agencies, and related organizations, a detailed and clear framework for how to implement the new section 484(t) of the HEA, which takes effect on July 1, 2023. The Department amended the regulations in §§ 600.2, 600.7, 600.10, 600.21, 668.8, 668.32, 668.43, and 690.62, and added part 668, subpart P. Section 484(t) of the HEA sets forth PEP requirements that include: (1) a prohibition on PEPs offered by proprietary institutions; (2) definitions of a ''confined or incarcerated individual'' and a ''prison education program;'' (3) the program approval process by the Bureau of Prisons, State department of corrections, or other entity that is responsible for overseeing the correctional facility (which we refer to throughout these final regulations as the oversight entity); (4) a credit transfer requirement for PEPs; (5) a prohibition against program offerings by institutions that are subject to adverse actions by the Department, their accrediting agency, or the relevant State authorizing agency; (6) requirements that PEPs offer educational programming that satisfies professional licensure or certification, as applicable; (7) student enrollment restrictions for programs where ultimate licensure or employment would be prohibited; (8) the requirement that confined or incarcerated individuals be enrolled in an eligible PEP in order to access a Pell Grant; and (9) various Department reporting requirements for postsecondary institutions offering PEPs.

The final regulations clarify and implement these statutory requirements by setting clear standards for postsecondary institutions offering PEPs and outlining the requirements to develop and implement such programs to gain and maintain access to Pell Grant funds. The final regulations also ensure that institutions report necessary data to the Department to assist in assessing program outcomes, also consistent with statutory requirements under section 484(t)(5) of the HEA for an annual report by the Secretary regarding the impact of the new requirements. The final rule establishes important guardrails for confined or incarcerated individuals and taxpayers, to protect students from enrolling in programs that will not permit them to benefit by finding employment in the field after graduation and release, and to prevent taxpayer funds from financing such programs. It also outlines title IV program requirements for PEPs related to State authorizing agencies and accrediting agencies.

Section 484(t)(1)(B)(iii) of the HEA requires an oversight entity, defined in the final regulations as a State department of corrections or other entity responsible for overseeing correctional facilities or the Federal Bureau of Prisons, to determine that any PEP it approved is ''operating in the best interest'' of the confined or incarcerated individuals it supervises. Congress outlined indicators of ''best interest''—both inputs and outcomes—which are explained below. Because oversight entities may not have previously assessed some of the ''best interest'' indicators outlined in statute, such as student earnings and job placement post-release, the final regulations clarify how to implement this requirement. To facilitate a thorough and well-informed program assessment, these final regulations require oversight entities to seek input from relevant stakeholders in making the ''best interest'' determination.

*90/10 Rule*

The final 90/10 regulations amend § 668.28 to change how proprietary institutions calculate and report to the Department the percentage of their revenue that comes from Federal sources, in accordance with section

487(a) of the HEA. Section 487(a) establishes the requirement that proprietary institutions derive not less than 10 percent of their revenue from non-Federal sources. Section 487(d) of the HEA: (1) defines how proprietary institutions calculate the percentage of their revenue that is derived from non-Federal sources; (2) outlines sanctions for proprietary institutions that fail to meet the requirement in section 487(a); (3) requires the Secretary to publicly disclose on the College Navigator website proprietary institutions that fail to meet the requirement; and (4) requires that the Secretary submit a report to Congress that contains the Federal and non-Federal revenue amounts and percentages for each proprietary institution.

The ARP amended these sections to require proprietary institutions to include other sources of Federal revenue, in addition to title IV revenue from the Department, in the calculation that proprietary institutions make to determine if they comply with the 90/10 rule. These final regulations codify this statutory change and inform proprietary institutions how to determine which Federal funds they must include in their calculations.

Additionally, the final regulations amend how proprietary institutions calculate 90/10 to address practices that some proprietary institutions have used to alter their revenue calculation or inflate their non-Federal revenue percentage. The final regulations also create a new requirement for when proprietary institutions must request and disburse title IV student aid funds to prevent them from delaying disbursements to the next fiscal year. The final regulations will also more closely align allowable non-Federal revenue with statutory intent by clarifying: (1) allowable non-Federal revenue generated from programs and activities that can count for the purposes of 90/10; (2) how schools must apply Federal funds to student accounts and determine the funds' inclusion in the Federal revenue percentage of 90/10; (3) which revenue generated from institutional aid can count as non-Federal revenue for purposes of 90/10; and (4) funds that institutions must exclude from the 90/10 calculation.

The final regulations also modify the steps that proprietary institutions must take if they fail to derive at least 10 percent of their revenue from allowable non-Federal sources by requiring them to notify students of the failure and of the students' potential loss of title IV aid at that proprietary institution. Additionally, the final regulations establish the process that proprietary institutions must follow if they initially determine that they met the 90/10 requirement for the preceding fiscal year but subsequently determine that they did not. Lastly, the final regulations provide that a proprietary institution will be liable for repaying all title IV funds disbursed for the fiscal year after it becomes ineligible to participate in the title IV program due to failing 90/10.

*Changes in Ownership*

To address the risks that some changes in ownership of postsecondary institutions present to students and taxpayers and to address the growing complexity of those transactions, the Department, under the authority of section 498(i) of the HEA, amends regulations covering changes in ownership in §§ 600.2, 600.4, 600.20, 600.21, and 600.31. These changes modify the definitions of ''additional location,'' ''branch campus,'' ''main campus,'' and ''nonprofit institution,'' as well as the terms ''closely-held corporation,'' ''ownership or ownership interest,'' ''parent,'' ''person,'' and ''other entities'' in the context of changes in ownership that result in a change in control, where the individual or entity with control has the power to direct the management or policies of the institution.

Under the final regulations, we require institutions to provide a minimum 90-day notice to the Department when they are to undergo a change in control. The Department may apply conditions to the new Temporary Provisional Program Participation Agreement (TPPPA) after the change and until we issue a decision on the pending application for approval of the change. The final regulations also increase transparency for changes in ownership that do not constitute a change of control by increasing the reporting requirements to the Department on such transactions at lower percentages of ownership.

*Summary of the Major Provisions of This Regulatory Action*

The final regulations make the following changes.

- Update appropriate cross-references.

Prison Education Programs (PEPs) (§§ 600.2, 600.7, 600.10, 600.21, 668.8, 668.32, 668.43, 668.234 through 668.242, and 690.62).

- Extend access to Pell Grants for confined or incarcerated individuals in qualifying postsecondary education programs and define an eligible PEP based on the statutory requirements.
- Clarify that only public or private nonprofit institutions as defined in § 600.4, or vocational institutions as defined in § 600.6, may offer eligible PEPs and require that PEPs offered at a correctional institution be reported to the Department as an ''additional location.''
- Amend requirements for postsecondary institutions to obtain and maintain a waiver from the Secretary to allow students who are confined or incarcerated to exceed 25 percent of the institution's regular student enrollment.
- For a PEP designed to meet educational requirements for a specific professional license or certification, require disclosures to students of typical State or Federal prohibitions on the licensure or employment of formerly incarcerated individuals.
- Prohibit institutions from enrolling a confined or incarcerated individual in a PEP that is designed to lead to licensure or employment in a specific job or occupation where State or Federal law would prohibit that individual from licensure or employment based on the type of the criminal conviction for which the student has been confined or incarcerated.
- Define the process and the factors that the oversight entity will use to determine if a PEP is operating in the best interest of the confined or incarcerated individuals they supervise, including consulting with interested third parties and conducting periodic re-evaluations.
- Define the requirements for approval from the Secretary and the Institutions of Higher Education's (''IHE's'') accrediting agency for the first PEP at the institution's first two additional locations at prison facilities.
- Require a postsecondary institution to obtain and report to the Department the release or transfer date of all confined or incarcerated individuals who participated in its PEP.
- Outline the process for winding down eligible programs for confined or incarcerated individuals that are not operating at a Federal or State correctional facility and are not approved as eligible PEPs, prior to July 1, 2023.
- Outline the process a postsecondary institution must follow to reduce a Pell Grant award that exceeds the confined or incarcerated individual's cost of attendance. Title IV Revenue and Non-Federal Education Assistance Funds (90/10 Rule) (§ 668.28)
- Amend the revenue calculation methodology in the 90/10 rule by changing references to ''title IV revenue'' to ''Federal revenue'' where appropriate to align with the statutory amendment that changes the 90/10

revenue requirement to include all Federal revenue.

- Outline how the Department will publish, and update as necessary, which Federal funds it requires proprietary institutions to include in their 90/10 calculation.
- Create a new requirement for when proprietary institutions must request and disburse title IV, HEA program funds to prevent them from delaying disbursements to reduce their Federal revenue percentage for a fiscal year in order to meet the 90/10 revenue requirement.
- Clarify the allowable revenue generated from programs and activities that can be counted as non-Federal revenue for purposes of the 90/10 revenue requirement to provide additional consumer protections.
- Revise how proprietary institutions apply funds to student accounts and determine the funds' inclusion in the 90/10 revenue requirement calculation to incorporate statutory changes, clarify how grants from non-Federal public agencies that include Federal funds must be treated, and add additional consumer protection measures.
- Revise the provisions governing which revenue generated from institutional aid can be included in the 90/10 revenue calculation to remove paragraphs that are no longer applicable, codify existing practices in regulation, promote consumer protection measures, and close potential loopholes related to Income Share Agreements (ISAs) or other alternative financing agreements issued by the institution or a related party.
- Revise the provisions governing which funds must be excluded from a proprietary institution's calculation of its revenue percentage to remove regulations that no longer apply and to limit certain types of revenues that some proprietary institutions have employed to alter their revenue calculation.
- Revise the steps that a proprietary institution must take to better protect students and taxpayers if it does not generate 10 percent or more of its revenue from allowable non-Federal sources in a fiscal year. The regulations provide reporting procedures for proprietary institutions that become aware, based on information received after the initial 45-day reporting period, that they failed the revenue requirement for the previous fiscal year.

*Changes in Ownership (CIO) (§§ 600.2, 600.4, 600.20, 600.21, and 600.31)*

- Clarify the definitions of ''additional location,'' ''branch campus,'' ''main campus,'' and ''nonprofit institution;'' and for nonprofit institution, we describe institutional characteristics that do not generally meet the definition of a ''nonprofit institution.''
- Require that institutions provide the Department with 90 days' notice of an impending change in ownership, ensure that accreditation and State licensure are in effect as of the day before the proposed change, and codify practices on submission of financial statements and provision of financial protection.
- Explain the terms by which a TPPPA may be extended to institutions seeking a change in ownership.
- Clarify what constitutes a change in ownership and, more narrowly, a change in control, distinguishing between natural persons and entities in § 600.21 and the conditions under which they constitute a change of control.
- Add ''trust'' to the definition of ''person'' and refine the definitions of the terms ''ownership or ownership interest,'' ''parent,'' and ''other entities,'' as applied to changes in ownership.''
- Add to the list of covered transactions the acquisition of another institution and clarify the application of the regulations in cases of resignation or death of an owner.

*Costs and Benefits:* As further detailed in the *Regulatory Impact Analysis,* the final regulations have significant impacts on students, borrowers, educational institutions, taxpayers, and the Department.

The PEP regulations benefit incarcerated individuals, taxpayers, and communities by creating higher employment and earnings, and lower recidivism rates, for those who enroll in higher education programs in prison, as described in the *Regulatory Impact Analysis.* Institutions that offer programs in correctional facilities and do not currently receive Pell Grants may bear some or all costs of that programming. Institutions that do not currently receive Pell funds for these programs benefit from these changes. Pell Grant transfers to institutions and students are estimated to increase by $1.1 billion from these programs. These transfers are overwhelmingly the result of the statutory changes made by Congress to make incarcerated students eligible for Pell Grants again. There are increased costs for the Department due to various requirements in the final regulations including, but not limited to: data collection and dissemination, approval of PEPs, and required reporting to Congress and the public. There are increased costs to the oversight entity due to the required ''best interest determination'' defined in § 668.241. There are no direct costs to students. Completing the Free Application for Federal Student Aid (FAFSA®) is free (though there is some minimal burden associated with completing the form) and grants under the Pell Grant program do not need to be repaid. To qualify for a Pell Grant, the student must be charged tuition and the charges cannot be covered by another source. Generally, students do not pay anything to participate in these programs. However, there could be occasions where a student only qualifies for a partial Pell Grant and owes a balance to the postsecondary institution.

Under the final 90/10 regulations, military-connected students will benefit as proprietary institutions' incentive to aggressively recruit GI Bill and Department of Defense (DOD) Tuition Assistance recipients is greatly reduced because Federal assistance for those students will be treated the same as title IV funds in the 90/10 revenue calculation. The Department is aware that some proprietary institutions have sought to enroll additional Department of Veterans Affairs (VA) or DOD recipients because their dollars provide a larger cushion in their 90/10 calculation to pursue more title IV, HEA funds, sometimes to the detriment of those veterans and service members. The regulatory changes remove that incentive by counting all Federal education assistance funds on the 90 side of the 90/10 calculation. These changes produce some savings to the taxpayer in the form of reduced expenditures of title IV, HEA aid to institutions that are not able to adapt and lose title IV eligibility. As indicated in the *Regulatory Impact Analysis,* we estimate transfers are reduced by -$292 million from the changes to the 90/10 provisions. These reduced transfers are mostly a result of the statutory changes made by Congress to amend the 90/10 provision. In as much as only repayment of principal on institutional loans and ISAs may be counted as revenue, the regulatory changes may further decrease proprietary institutions' incentive to rely on such potentially costly student financing options to meet 90/10 requirements. Costs to institutions include the need to ensure compliance with the regulations. For example, institutions unable to generate sufficient non-Federal revenues through their eligible programs may create programs that are not title IV eligible to generate revenue to meet 90/10 requirements.

The changes to the CIO regulations benefit institutions and the Department by clarifying requirements as well as providing timely feedback for institutions undergoing CIO

transactions. Students and borrowers benefit from the 90-day CIO notice requirement that provides students with timely information that impacts their education and enables them to make future decisions based on that knowledge. Costs to institutions include compliance and the paperwork burden associated with the increased reporting and disclosure requirements.

On July 28, 2022, the Secretary published a notice of proposed rulemaking (NPRM) for these parts in the *Federal Register* (87 FR 45432). These final regulations contain changes from the NPRM, which we explain in the *Analysis of Comments and Changes* section of this document.

*Public Comment:* In response to our invitation in the NPRM, 142 parties submitted comments on the proposed regulations.

We discuss substantive issues under the sections of the proposed regulations to which they pertain. Generally, we do not address technical or other minor changes or recommendations that are out of the scope of this regulatory action or that would require statutory changes.

*Analysis of Public Comment and Changes:* Analysis of the comments and of any changes in the regulations since publication of the NPRM follows.

*General Comments Regarding the Negotiated Rulemaking Process*

*Selection of Negotiators and Negotiated Rulemaking Process Comments:* A few commenters wrote that there should have been other negotiators to represent other interests or sectors, including ISAs, proprietary institutions, and veterans. A few commenters stated that the Committee members were not sufficiently familiar with the issues involved in 90/10. One commenter questioned why the Department selected a Committee member whose employer was under investigation by the Department of Veterans Affairs (VA) Office of Inspector General. One commenter claimed that the Department did not provide adequate time for Committee negotiators to consider the Department's proposed language. Finally, one commenter stated that because 90/10 negotiations happened in caucus that the consensus language does not meet the statutory requirement that negotiations provide for a comprehensive discussion and exchange of information.

*Discussion:* Section 492 of the HEA provides that the Secretary ''select individuals with demonstrated expertise or experience in the relevant subjects under negotiation, reflecting the diversity in the industry, presenting both large and small participants, as well as individuals servicing local areas and national markets.'' The Department identified the relevant subjects to be negotiated and invited the public to nominate negotiators and advisors. The Department reviewed the qualifications of nominees and made selections for Committee members. Further, during the first negotiation session, negotiators had the opportunity to suggest additional Committee members by consensus. The Committee added one additional Committee member representing civil rights organizations through this process. We have used this process for many years and believe it meets the statutory requirements for selecting negotiators. Further, none of the commenters identified nominated individuals who should have been selected but were not.

On October 4, 2021, the Department published a *Federal Register* document announcing public hearings on 90/10 (86 FR 54666). We held those hearings October 26–27, 2021. The Department also accepted written public comments from October 4, 2021, through November 2, 2021. We then held three weeks of virtual negotiated rulemaking sessions on January 18–21, 2022, February 14–18, 2022, and March 14–18, 2022, that we livestreamed.

The Committee adopted by consensus a set of protocols that allowed any Committee member, including the Federal negotiator, to call for a caucus with other Committee members. The protocols also stated that the Department would provide its proposed language prior to the start of the week's negotiation sessions, which the Department did with its initial proposed 90/10 language. During the last week of negotiations, the Federal negotiator and the negotiator representing proprietary institutions called for caucuses to discuss possible 90/10 regulatory language with a small group of negotiators during the final session. The Federal negotiator presented this language to the full Committee for discussion and review before taking the consensus check. This process met the statutory requirements and provided ample time for discussion of the regulations.

*Changes:* None.

*Public Comment Period*

*Comments:* A few commenters asked the Department to extend the public comment period an additional 30 days. These commenters pointed out that there were several large regulatory packages that impact the higher education sector out for public comments at once, and the commenters also observed that Executive Orders 12866 and 13563 cite 60 days as the recommended length for public comment. One commenter asked the Department why the Department's proposed regulations related to Title IX received more time for public comment than these regulations.

*Discussion:* As discussed previously, the Department's negotiated rulemaking process provides ample time for public comment and engagement before the public comment period. Additionally, the proposed regulations for 90/10 were the same as the regulations agreed to by consensus in March 2021, providing the public with additional time to review the Department's proposed regulations. Further, the regulations related to Title IX are not subject to the negotiated rulemaking process, and therefore the public did not have the same opportunity to weigh in on the regulations before they were published for public comment. The Executive orders provide a recommendation for an appropriate time for public comment, but that timeline is not a requirement, nor does it take into account the Department's individual process for regulating under the HEA. The Department declines to extend the comment period for an additional 30 days.

*Changes:* None.

**Prison Education Program (PEP) (§§ 600.2, 600.7, 600.10, 600.21, 668.43, 668.234 through 668.242, and 690.62)**

*General Support*

*Comments:* Several commenters submitted general letters of support by noting that the regulations will benefit both taxpayers and incarcerated individuals and may ultimately lead to lower recidivism rates, which could lead to a smaller prison population.

*Discussion:* We thank the commenters for their support.

*Changes:* None.

*General Opposition*

*Comments:* Many commenters stated that the regulations will be bureaucratic, burdensome, and costly and that the additional proposed regulatory requirements go beyond the statutory framework.

*Discussion:* The Department disagrees with these comments and believes the regulations strike an appropriate balance between imposing requirements that will increase access to incarcerated individuals, improving the quality of PEPs, and limit administrative burden to schools, correctional agencies, and other stakeholders.

We also disagree that the regulations exceed the scope of the statutory

authority for PEPs. The Department has the authority to expand on and clarify statutory text, and we believe that the requirements in the final regulations are a logical outgrowth of the HEA. For example, the main concern from commenters was the prescriptive nature of the best interest determination and the accompanying requirement to assess PEP outcomes under § 668.241. While the HEA requires the oversight entity to determine if a PEP is operating in the best interest of the confined or incarcerated individual, it does not prescribe how often and when that process should be undertaken. The regulations supply that necessary clarification.

The statute also requires the oversight entity to approve PEPs, but we heard from non-Federal negotiators and from commenters that the oversight entities may not be equipped to make these determinations because they are not education experts. By identifying what factors to consider, who to consult, and how often to revisit the determinations, we created a formal process with clear measurements that will be consistent across all oversight entities.

We also believe that the oversight entity should continue to reassess PEPs operating in a correctional facility because a PEP will not always be operating in the best interest of its population. For example, changes over time in program offerings, instructors, academic counseling, transfer of credits, or labor market trends might impact a PEP, such that it no longer operates in the best interest of the confined or incarcerated individuals. We believe that mandatory periodic assessment will ensure that PEPs serve the programmatic and financial purposes for which they were authorized. We have set reasonable standards, with extensive public input, to ensure that the process is not overly burdensome to the oversight entity.

Commenters also raised concerns about the initial two-year approval period, accreditation requirements, and reporting requirements. We respond to those comments and other commenter concerns in the individual sections devoted to those topics below.

*Changes:* See the discussion under Best Interest Determination (§ 668.241) for changes the Department has made in the final regulations.

*General Comments*

*Comments:* One commenter requested that the Department require standardization of access to technology for confined or incarcerated individuals across the United States and within States.

*Discussion:* The Department does not have the authority to require postsecondary institutions or correctional facilities to standardize technology across all spaces. Further, technology requirements will vary between PEPs, and a one-size-fits-all approach could inhibit the flexibility of institutions to offer appropriate forms of technology in their PEPs.

*Changes:* None.

*Comments:* One commenter stated that the Department should extend Pell Grant eligibility to individuals who have been released from a correctional facility. That commenter also recommended that the Department increase the amount of the Pell Grant.

*Discussion:* Under existing law, individuals released from a correctional facility will qualify for Pell Grant funds if they otherwise continue to meet all applicable eligibility requirements and enroll in eligible postsecondary programs.

The Department does not have the authority to adjust the maximum Pell Grant award because that amount is established annually through Congressional appropriations.

*Changes:* None.

*Comments:* One commenter stated that all Pell Grant funding received by a confined or incarcerated individual must go directly to support the individual's education and should not be used to support the postsecondary institution's main campus or other non-PEP locations.

*Discussion:* The Department lacks the authority to adopt the commenter's suggestion. The Department maintains authority over the use of Pell Grant funds only to the extent that the grants are appropriately calculated, awarded, and disbursed to students. As long as the institution follows all applicable laws and Department regulations, once Pell Grant funds have been correctly disbursed, the Department does not control institutional budgets or how institutions use funds that have been correctly applied to institutional charges.

*Changes:* None.

*Comments:* One commenter noted that the subcommittee that discussed these regulations during negotiated rulemaking should have included greater representation from oversight entities (which are defined in § 668.235). The commenter requested that in the future any issue that does not fit well with the regulatory agenda should have its own negotiated rulemaking instead of discussing the topic in a subcommittee.

*Discussion:* We believe the subcommittee had appropriate representation from oversight entities. The eight-member subcommittee included representatives from both State departments of corrections and State correctional education directors, and the representative from State departments of corrections was added during negotiated rulemaking specifically to ensure additional representation in that area.

Moreover, the Department has successfully used subcommittees during several prior rulemakings to gain additional critical feedback from specialists with experience related to the issues to be discussed. Use of a subcommittee during the Affordability and Student Loans Committee Meetings was appropriate and valuable because the eight subcommittee members provided substantial background on the topic of postsecondary education in carceral settings to the main committee, offered numerous recommendations that were adopted by the main committee, and ultimately expressed their support for the draft regulations to the main committee at the conclusion of the negotiations, all of which enabled the main committee to reach consensus on the proposed regulatory language. Three members of the subcommittee also had a seat on the main committee, including representatives for independent students, private nonprofit institutions, and State departments of corrections. An additional member of the subcommittee presented information to the main committee and was available during the November and December sessions to answer questions.

*Changes:* None.

*Comments:* Many commenters requested that the Department provide guidance to ensure smooth implementation of the regulations, including guidance or additional actions the Department should take on the following topics:

- The Second Chance Pell experiment under the Experimental Sites Initiative.
- How to apply for PEP, step-by-step.
- Overcoming barriers to completing the FAFSA® and verification of application information.
- Supporting students with delinquent or defaulted Federal student loans.
- Automatically enrolling confined or incarcerated individuals with Federal loan debt into income-driven repayment plans.
- Cancelling Federal student loans if the borrower is incarcerated for a minimum of five years.
- Supporting individuals post-release in collaboration with the Office of Career, Technical, and Adult Education.
- The grievance or complaint process for confined or incarcerated individuals.

• Protecting confined or incarcerated individuals who do not meet Satisfactory Academic Progress (SAP) standards for confined or incarcerated individuals.
• Monitoring issues related to lack of access to technology and accessing coursework online.
• Dependency overrides for confined or incarcerated individuals.
• Return of Title IV funds (R2T4) calculations for confined or incarcerated individuals.
• The conditions for Pell restoration in the event of closure of an institution.
• Releasing and making public an annual listing of PEPs by correctional facility and State.
• Developing an interagency communications process between the oversight entity, accrediting or State approval agency, and the Department.
• Establishing that correctional facilities that are additional locations need not be included in Clery Act campus reporting.
• The roles and responsibilities of accrediting and State approval agencies, especially regarding accreditation requirements in § 668.237.
• The timelines for reporting requirements under § 668.239.
• The best interest determination under § 668.241(a), including data sources or infrastructure that are available to stakeholders.
• The role of the advisory committee.
• The role of community-based organizations.

*Discussion:* The Department appreciates the recommendations for additional guidance and actions the Department should take to support confined or incarcerated individuals and address other implementation issues that may arise. The Department plans to publish guidance addressing many of the topics identified by commenters. The Department is also currently developing a dedicated landing page for PEP resources about prison education programs, and we have also created a central mailbox, *pep@ed.gov,* for ongoing PEP questions from stakeholders.

*Changes:* None.

**Definitions (§ 600.2)**

*General Comments*

*Comments:* One commenter requested definitions and clarification of several phrases in the preamble to the NPRM, including ''greater oversight'' and ''high program standards.'' The commenter also asked what metrics we will use to ascertain whether a PEP is providing confined or incarcerated individuals with education that meets high program standards, and how frequently and through what mechanism we will evaluate and report on such high program standards.

*Discussion:* The Department elects not to provide definitions of these terms or to outline these operational processes in regulation. Instead, the Department will consider providing guidance to postsecondary institutions, accrediting and State approval agencies, and oversight entities, as appropriate.

*Changes:* None.

Additional Location

*Comments:* Several commenters requested that the Department remove juvenile justice facilities and jails from the definition of ''additional location'' and exempt programs offered at such facilities from statutory and regulatory PEP requirements. They argued that the ''scale'' and cost associated with the regulations will harm small programs.

*Discussion:* The Department declines to remove juvenile justice facilities and local jails from the ''additional location'' definition. The statute does not provide an exemption or waiver for such programs. To qualify for Pell Grant funds, the statute requires that all confined or incarcerated individuals be enrolled in an eligible PEP that adheres to statutory requirements. These regulations reinforce statutory protections for the benefit of all confined or incarcerated individuals by ensuring that PEPs also comply with requirements of the Department, the State authorizing agency, the accrediting agency or the State approval agency, and oversight entities.

Including juvenile justice facilities and jails as additional locations also allows the Department to track and monitor PEPs offered at these facilities and include them in data collection, trending, and reporting. This will help us better understand if certain PEPs need more oversight or supports, or both.

Finally, as noted in the NPRM, if an institution ceases all operations at a correctional facility (the additional location of the postsecondary institution) the confined or incarcerated individual may be eligible for Pell Grant restoration. 87 FR 45441. Without the inclusion of these facilities in the definition of an additional location, confined or incarcerated individuals may not be eligible for restoration of their Pell Grant if all PEPs at the correctional facility close.

*Changes:* None.

*Comments:* One commenter noted that some of their institution's programs operating in a prison setting are extensions of their existing academic programs and are not distinct programs operating at a correctional facility. The commenter asked if these types of programs would need to be reported as additional locations.

*Discussion:* Even if the program the postsecondary institution plans to offer at the correctional facility is an extension of a program offered either at the main campus or at another additional location, the program still must meet the definition of and be approved as a PEP. In addition, the correctional facility where that program is offered must be reported as an additional location.

*Changes:* None.

*Comments:* One commenter requested that correctional facilities only offering correspondence courses be removed from the definition of ''additional location,'' because the postsecondary institution would be unable to consistently review the facility or gain access to locations where the confined or incarcerated individuals complete their coursework.

*Discussion:* The Department declines to adopt the commenter's request. We seek to hold all programs accountable to the standards outlined in these final regulations, regardless of the method of delivery. With the monitoring and oversight required under these regulations, the Department will be able to track and monitor PEPs offered at these facilities and include them in data collection, trending, and reporting. This will help us to better understand if certain PEPs need more oversight and supports.

The Department also noted in the NPRM that if an institution ceases all operations at a correctional facility (the additional location of the postsecondary institution), enrolled students may be eligible for Pell Grant restoration. 87 FR 45441. Without the inclusion of facilities where only correspondence courses are offered, confined or incarcerated individuals may not be eligible for restoration of their Pell Grant in the event all PEPs at the correctional facility close.

*Changes:* None.

Confined or Incarcerated Individual

*Comments:* The same commenters that requested removal of juvenile justice facilities and jails from the definition of ''additional location'' also requested removal of these facilities from the definition of ''confined or incarcerated individual.'' They argued that the ''scale'' of the regulations and cost associated with the regulations would harm small programs.

*Discussion:* The Department declines to make this change, for the reasons

described in the ''additional location'' discussion above.

*Changes:* None.

*Comments:* Several commenters suggested additions to the types of individuals who are not considered to be confined or incarcerated, including individuals in pretrial detention, individuals under correctional custody in temporary release programs, or individuals living in a halfway house.

*Discussion:* To be eligible for a Pell Grant, those meeting the definition of a ''confined or incarcerated individual'' must enroll in a PEP. Section 484(t)(1)(a)(i) of the HEA defines a ''confined or incarcerated individual'' as ''an individual who is serving a criminal sentence[.]'' An individual who is not serving a criminal sentence thus is not considered to be confined or incarcerated for the purposes of the PEP provision and would not be required to enroll in a PEP to establish eligibility for Pell Grant funds. The Department also notes that, under section 484 of the HEA, individuals living in a halfway house are not considered to be incarcerated and therefore would qualify for Pell Grant eligibility through enrollment in any eligible program, whether or not it is a PEP. While the Department did not amend the definition of ''confined or incarcerated individual,'' we plan to release guidance as necessary to assist postsecondary institutions with questions that may arise regarding student eligibility.

*Changes:* None.

**Conditions of Institutional Eligibility (§ 600.7)**

*Comments:* One commenter asserted that the waiver of the enrollment cap for incarcerated individuals under § 600.7(c) is overly narrow because the commenter believed it would only apply to a subset of PEPs that had already received an initial waiver. The commenter also believed that some of the considerations listed in § 600.7 may not be appropriate when determining whether to grant a waiver.

*Discussion:* The commenter appears to have misunderstood the application of § 600.7, which applies to any institution seeking a waiver to exceed the 25 percent enrollment cap on incarcerated individuals. As provided in the regulations, an institution that does not already have a waiver must wait at least two years from the date of its first approved PEP before applying for a waiver. We thank the commenter for making the Department aware of implementation considerations and note that we accepted a proposed revision from a different commenter below that will make the waiver language clearer.

While we do not anticipate a large number of applications that will exceed the 25 percent cap on enrollment of confined or incarcerated individuals, the Department intends to provide guidance for institutions that wish to exceed the 25 percent cap, as necessary. We also do not anticipate a large number of applications will exceed the 25 percent cap. The Department plans to provide direct one-on-one assistance to postsecondary institutions that wish to apply for the waiver to assist with regulatory compliance.

*Changes:* None.

*Comments:* One commenter asked whether non-profit institutions that exclusively provide educational services to students who are incarcerated will be required to apply for a waiver.

*Discussion:* The only automatic exemption in § 600.7(c) is for public institutions chartered for the explicit purpose of educating confined or incarcerated individuals. The Department declines to include private non-profit institutions in this automatic exemption. Public institutions are likely to be backed by the full faith of a State government, and there are stronger centralized administrative processes and support systems in place. We believe that these State processes will ensure that a postsecondary institution that is chartered for the purpose of exclusively providing educational services to confined or incarcerated individuals will receive a thorough review by an entity within the State government and be found capable of fulfilling the needs of confined or incarcerated individuals. Private non-profit institutions would thus have to apply for the waiver.

*Changes:* None.

*Comments:* One commenter noted that the draft language in § 600.7(c) refers to two 5-year waiver periods allowing expansion first to 50 percent and then to 75 percent incarcerated student enrollment, but that it is unclear what happens after the second five-year period has elapsed, specifically whether the Department would automatically extend the waiver if there was no reason to limit or terminate it.

*Discussion:* The Department will not automatically extend the waiver. At the end of the five-year period following the Department's initial approval of the waiver, if the Department has not otherwise informed the institution that it is revoking the institution's waiver, up to 75 percent of the institution's regular enrolled students may be confined or incarcerated individuals. However, at each recertification, defined under § 668.13, the Department will review whether the postsecondary institution is eligible to maintain its waiver. We believe that monitoring an institution's administrative capability and financial health at recertification is important because the administrative capability and financial responsibility of an institution can fluctuate. Failures in either of those areas could call into question whether the institution is best situated to maintain its waiver or have it revoked. Additionally, the Department's recertification evaluation provides an opportunity to evaluate whether the oversight entity has determined whether the program continues to be offered in the best interest of students and whether the program continues to meet all of the Department's requirements for PEPs. We have the authority to review for compliance as a normal part of operational considerations and decline to include additional regulatory language to this effect.

The Department agrees, however, that certain language in proposed § 600.7(c)(4)(i)(B) is unclear regarding the extent of available waivers. That provision allows up to 75 percent of an institution's students to be confined or incarcerated ''for the five years'' following the period described in § 600(c)(4)(i)(A) (which allows enrollment up to 50 percent). Because the regulations are intended to cap institutions at 75 percent enrollment of confined or incarcerated individuals, the cited five-year clause is unnecessary.

*Changes:* To clarify that enrollment of incarcerated individuals at postsecondary institutions will be capped at 75 percent enrollment, the Department amends § 600.7(c)(4)(i)(B) to clarify that, following the period described in paragraph (c)(4)(i)(A), no more than 75 percent of the institution's regular enrolled students may be confined or incarcerated.

*Comments:* One commenter questioned the rationale for the 75 percent enrollment cap given that the Department has the authority to limit or terminate the waiver at any point if it determines the institution does not meet the waiver requirements.

*Discussion:* Section 102 of the HEA says that an institution of higher education is not an eligible institution for the purposes of the title IV aid if the institution has a student enrollment in which more than 25 percent of the students are incarcerated, except that the Secretary may waive the limitation for a public or nonprofit institution that provides a two- or four-year program of instruction (or both) for which the institution awards a bachelor's degree, or an associate's degree or a

postsecondary diploma, respectively. Because it is optional for the Secretary to waive the limitation, the Department has authority to set reasonable upward limits through regulation. A subcommittee member recommended the 75 percent limit on enrollment of confined or incarcerated individuals, and the Department formally adopted the recommendation, which was agreed to by the committee. The Department believes that the upper limit strikes an appropriate balance between increasing options to serve this population and the heightened demands and responsibilities of operating successful PEPs. Public postsecondary institutions that are specifically chartered for educating confined or incarcerated individuals are exempt from the 75 percent cap on enrollment.

Some postsecondary institutions currently have a waiver to exceed 25 percent enrollment of confined or incarcerated individuals. Institutions that received a waiver prior to the implementation date of these regulations are currently permitted to enroll up to 100 percent of confined or incarcerated individuals and are automatically granted a waiver. However, we will limit the growth of incarcerated enrollment at those institutions to ensure consistent program quality and adequate oversight. Beginning on the implementation date of July 1, 2023, enrollment of incarcerated individuals in any such institution will be limited to 50 percent in the first five years after the regulations take effect, and the cap will be raised to 75 percent if the institution is granted an additional waiver after the initial five-year period.

*Changes:* None.

*Comments:* One commenter asked whether the entire postsecondary institution becomes ineligible for the title IV, HEA programs, or if only the PEP would lose eligibility if the Secretary limits or terminates an institution's waiver of the limitation on the percentage of regular students who may be confined or incarcerated.

*Discussion:* Under § 600.7(c)(6), the entire postsecondary institution becomes ineligible at the end of the award period that begins after the Secretary's action, unless the institution comes back into compliance or reduces its enrollment of confined or incarcerated individuals to no more than 25 percent of its regular enrolled students.

*Changes:* None.

*Comments:* One commenter asked the Department to restructure § 600.7(c) to separate the waiver from the waiver denial.

*Discussion:* The Department agrees with the recommended edit and believes the change will improve the clarity of the regulations.

*Changes:* Paragraph (c)(1) will now be split into paragraphs separately addressing waiver grant and waiver denial.

*Commenter:* One commenter asked the Department to define ''demonstrated program success'' and explain what is meant by ''expand the number of incarcerated students.''

*Discussion:* The Department intends to provide details of the waiver application process, such as information about program success and expanding the number of an institution's confined or incarcerated students, in subregulatory guidance.

*Changes:* None.

*Comments:* One commenter asked how the Secretary will utilize the required reviews, assessments and reporting by the accrediting agencies and the oversight entity to approve, deny, or delay the waiver request and increase.

*Discussion:* The accrediting agency and oversight entity must provide approval at various points the throughout the process. We note here and under the preamble discussion for § 668.237 that the PEP is not eligible if either the oversight entity or the accrediting or State approval agency denies approval. The PEP must meet all regulatory requirements to be an eligible PEP. The Department plans to release more subregulatory guidance to postsecondary institutions wishing to apply for a waiver and to institutions that already have the waiver.

*Changes:* None.

*Comments:* One commenter asked for clarification concerning the Secretary's revocation and reduction of the waiver under paragraph (c)(6)(i).

*Discussion:* If the institution demonstrates to the Secretary that it met all the requirements under paragraph (c)(1) prior to the end of the award year that begins after the Secretary's action to limit or terminate the waiver, then the institution may keep the waiver and need not reapply or reduce its confined or incarcerated student enrollment.

*Changes:* None.

**Date, Extent, Duration, and Consequence of Eligibility (§ 600.10)**

*Comments:* One commenter noted that there should be an ''and'' at the end of § 600.10(c)(1)(iii).

*Discussion:* The commenter is correct.

*Changes:* We have added an ''and'' to the end of § 600.10(c)(1)(iii).

*Comments:* One commenter stated that the Department should remove § 600.10(c)(1)(iv), which requires Department approval for the first eligible PEP offered at an institution's first two additional locations, because it is too burdensome given other requirements.

*Discussion:* The Department disagrees that the requirements under § 600.10(c)(1)(iv) are excessively burdensome to institution. We also believe that the requirements outlined in the final rule, including securing all necessary program approvals, will benefit confined or incarcerated individuals, by ensuring that PEPs serve their best interests and avoiding needless exhaustion of their Pell Grant eligibility. The requirements will benefit postsecondary institutions and oversight entities by providing a clear regulatory framework. Finally, the rules will benefit the taxpayer by ensuring that Pell Grant funds are directed to postsecondary institutions that are compliant.

*Changes:* None.

**Student Eligibility General (§ 668.32)**

*Comment:* Multiple commenters stated that the Department must consider in these regulations ways to prevent postsecondary institutions and oversight entities from applying additional eligibility restrictions that are unrelated to academic qualifications. Commenters suggested the regulations should stipulate that PEPs cannot bar people based on nature or length of their sentence, for example. Alternatively, the commenters suggested that, at a minimum, the Department must require postsecondary institutions and oversight entities to disclose to accreditors, the Department, and confined or incarcerated individuals any additional eligibility restrictions they intend to put in place, including but not limited to restrictions based on sentence, release date, convictions, and facility-based disciplinary infractions.

*Discussion:* The Department declines to add additional disclosures as requested for a few reasons. First, we do not have the authority to regulate an institution's admissions requirements. Additionally, the Department also does not have the authority to mandate how the oversight entity manages its internal operations, including restrictions on enrollment in postsecondary programs. If a confined or incarcerated individual is eligible for Pell Grant, meaning the individual has met all student eligibility requirements under the HEA and the regulations, and the individual has been accepted into a PEP, that individual cannot be denied the Pell Grant for which they are eligible. Furthermore, there is no statutory or regulatory

provision that would prohibit a postsecondary institution from enrolling or admitting a confined or incarcerated individual into a PEP due to nature or length or the individual's sentence. For example, an institution could choose to admit a student that is likely to be released within a year even if the student's program is two years in length.

*Changes:* None.

*Comments:* One commenter asked the Department to clarify that confined or incarcerated individuals enrolled in PEPs through correspondence are eligible for a Pell Grant.

*Discussion:* A confined or incarcerated individual who is enrolled in a correspondence course as defined in § 600.2 is eligible for a Pell Grant, as long as the standards for student, program, and institutional eligibility are met. It is important to note, however, that if an institution offers correspondence courses to a student that is confined or incarcerated at a correctional facility and the student can complete at least 50 percent of the program through such correspondence courses, the institution must add that facility as an additional location.

*Changes:* None.

**Institutional Information (§ 668.43)**

*Comments:* One commenter disagreed that postsecondary institutions should be responsible for providing information regarding whether an occupation typically involves State or Federal prohibitions on the licensure or employment of formerly confined or incarcerated individuals. The commenter asserted that responsibility for making and reporting this determination lies with the State correctional agency. The commenter stated that providing such information would be costly and time consuming because of the diversity of convictions and changes in State law.

*Discussion:* The Department disagrees with the commenter. The postsecondary institution is the entity offering the educational programming and, as such, needs to be aware of licensing and employment conditions in the field. Therefore, it is best situated to ascertain State or Federal prohibitions on licensure or employment. Moreover, if a postsecondary institution chooses to offer a PEP in a State, it already must comply with § 668.236(a)(7) and (8), which require the program to satisfy certain educational requirements for professional licensure or certification, and thus the additional requirements in § 668.43 are not significant.

The Department notes that postsecondary institutions are not required to be aware of State or Federal prohibitions on licensure or employment in States where they do not offer a PEP, unless the postsecondary institution offers it in a Federal correctional facility. For a Federal correctional facility, the institution is only required to be aware of any prohibitions in the State where most confined or incarcerated individuals will reside post release. See discussion of § 668.236.

*Changes:* None.

*Comments:* A few commenters requested that the Department require postsecondary institutions to disclose the use of any third-party vendors involved in the development, management, maintenance, and provision of programs, as well as involvement in marketing, recruitment, and enrollment management of programs, regardless of the way in which the vendor classifies or identifies its services to clients or the public.

*Discussion:* Postsecondary institutions are subject to all applicable requirements under § 668.25, which pertain to contracts between an institution and a third-party servicer. Also, the Department plans to establish procedures for eligible PEP applications. Therefore, we decline to add specific regulations for PEPs. If the Department needs more information about third-party vendors, we have authority under § 668.239(a) to require the submission of reports.

*Changes:* None.

*Comments:* One commenter requested clarification on the word ''other'' in § 668.43(a)(5)(vi). The commenter stated that neither paragraph (a)(5)(vi) nor the preceding paragraph (a)(5)(v) refers to a specific State or group of States that would be distinguished from the ''other'' States referred to in paragraph (a)(5)(vi).

*Discussion:* The ''other'' States referenced toward the end of § 668.43(a)(5)(vi) are those not already identified earlier in the sentence through § 668.236(a)(7) and (8). Section 668.236(a)(7) and (8), respectively, require a PEP to meet any applicable educational requirements for professional licensure or certification, and not offer education that is designed to lead to licensure or employment for a specific occupation if there are prohibitions on licensure or employment, ''in the State where the correctional facility is located, or, in the case of a Federal correctional facility, in the State where most of the individuals confined or incarcerated in such a facility will reside upon release[.]'' The ''other'' State reference in § 668.43(a)(5)(vi) refers to any other State that falls outside those states identified in § 668.236(a)(7) and (8).

*Changes:* None.

*Comments:* A few commenters stated that the Department should provide institutions with a central location where they can access information about licensure restrictions in a particular State or disclose information about licensure restrictions and update that information annually.

*Discussion:* State licensure restrictions will likely continue to change and there is no language in the HEA or regulations that requires institutions or other organizations to report licensure restrictions to the Department. Therefore, at this time we decline to create a central location to access such information. The Department endeavors to provide up-to-date resources and technical assistance to postsecondary institutions, but it is incumbent upon postsecondary institutions, prior to and while offering a PEP, to remain current with State and Federal licensure restrictions and ensure they are correctly implementing the requirements in § 668.236(a)(7) and (8).

Additionally, institutions can avail themselves of resources provided by other organizations. For example, the National Reentry Resource Center maintains a National Inventory of Collateral Consequences of Conviction at *https://niccc.nationalreentryresourcecenter.org* that may be useful to institutions and students.

*Changes:* None.

*Comments:* One commenter indicated that the Department should expand its requirement that postsecondary institutions provide information about PEPs that typically involve State or Federal prohibitions on the licensure or employment of formerly incarcerated individuals, to require similar information from all educational programs designed or advertised as leading to a required license for employment in a State. The commenter acknowledged that the request may not be a logical outgrowth of the PEP regulations.

*Discussion:* The Department agrees that this requirement would not be a logical outgrowth of regulations focused on PEPs and, therefore, declines to make the requested change.

*Changes:* None.

**Definitions (§ 668.235)**

*Comments:* One commenter requested that the Department eliminate the definitions of ''feedback process'' and the ''advisory committee'' due to the complexity and cost.

*Discussion:* Because the definitions of ''feedback process'' and ''advisory committee'' are tied to many concepts throughout subpart P, including the best interest determination in § 668.241, we decline to remove these definitions.

*Changes:* None.

*Comments:* A few commenters suggested that the Department define PEP and proposed this definition: ''an education or training program that meets the definitions in § 668.236. The [PEP] is created exclusively for incarcerated individuals as defined in § 600.2 who are eligible for and will be awarded a Federal Pell Grant to pay for the program's cost of attendance, as defined in 20 U.S. Code § 1087.''

*Discussion:* We decline to make this change because § 668.236 defines a PEP and believe that adding an additional definition would be redundant. We agree with the commenter, however, that a PEP is distinct from an institution's other eligible programs, and that the definition of ''confined or incarcerated individual'' under § 600.2 only allows a PEP to be offered at locations that are classified as Federal, State, or local penitentiaries, prisons, jails, reformatories, work farms, juvenile justice facilities, or other similar correctional institutions.

*Changes:* None.

*Relevant Stakeholder*

*Comments:* Several commenters requested that the Department add various stakeholders to the definition, including community colleges, boards, commissions, associations, and departments at the State level that oversee, coordinate, or otherwise represent community colleges, employers, workforce development boards, industry associations and community-based organizations; community-based organizations that provide reentry services; employers who have demonstrated a commitment to hiring justice-involved individuals; and current and former confined or incarcerated individuals.

*Discussion:* We do not believe it is necessary to add additional members to the relevant stakeholder definition. We are not convinced that an oversight entity could feasibly gather information from all of the new groups that commenters proposed in a reasonable timeframe. This could create administrative burden that could limit the implementation of PEPs. We note that the Department's definition permits the oversight entity to include additional stakeholders as appropriate.

*Changes:* None.

*Oversight Entity*

*Comments:* Several commenters suggested removing the Bureau of Prisons and State departments of corrections from the definition of ''oversight entity'' or expanding the definition to include other members.

*Discussion:* Section 484(t)(1)(B)(ii) of the HEA confers authority on ''the appropriate State department of corrections or other entity that is responsible for overseeing correctional facilities, or by the Bureau of Prisons'' to approve PEPs at any correctional facility it oversees. The Department proposed using the term ''oversight entity'' as a short-hand reference for that statutory list. The Department does not have the authority to amend the list. While the statute allows for some flexibility by including ''or other entity that is responsible'' for oversight, it will be within the purview of the Bureau of Prisons, State departments of corrections, and the correctional facilities themselves to determine if a different entity also has the requisite level of control.

*Changes:* None.

*Feedback Process*

*Comments:* One commenter stated that the advisory committee mentioned in the definition of feedback process should be mandatory.

*Discussion:* The Department believes that relevant stakeholder input through the feedback process is sufficient. Requiring an advisory committee could also be too burdensome for some oversight entity systems. Additionally, the Federal Bureau of Prisons would likely need to follow the Federal Advisory Committee Act if it convened an advisory committee, which would significantly limit the development of PEPs.

*Changes:* None.

*Comments:* One commenter asked the Department to include examples of input that the relevant stakeholders can provide to the oversight entity to assist with PEP operation, including information on reentry services, services offered by a community-based organization that are available to confined or incarcerated individuals, and information on in-demand industries or occupations with career opportunities available to formerly incarcerated individuals.

*Discussion:* The Department believes that these are all excellent examples of input that the relevant stakeholders can provide to the oversight entity. We decline to prescribe these in regulation, however.

*Changes:* None.

**Eligible Prison Education Program (§ 668.236)**

*Comments:* One commenter suggested that the Department require all PEPs to partner with a community-based organization offering reentry services and counseling.

*Discussion:* As a part of the application process for the first PEP at the first two additional locations, the Department requests information about reentry services, see § 668.238(b)(5), and the Department strongly encourages institutions to offer reentry services to students enrolled in PEPs. However, the Department declines to require reentry services as a part of every PEP. Because the statute does not require reentry services and we are prohibited from regulating on educational program offerings, we believe that requiring each program to maintain such services is beyond our authority.

We also note that oversight entities are required to consider whether a PEP's academic services, including in advance of reentry, are comparable to similar services that the institution offers to its on-campus students. We believe that this consideration will provide institutions with an incentive to create strong reentry services for students enrolled in their PEPs.

*Changes:* None.

*Comments:* One commenter was opposed to excluding proprietary institutions from offering PEPs under § 668.236(a)(1).

*Discussion:* The HEA specifically excludes proprietary institutions from offering PEPs. See HEA, section 484(t)(1)(B)(i) (limiting PEP offerings to institutions of higher education as defined in sections 101 or 102(a)(1)(B) of the HEA, which do not include proprietary institutions).

*Changes:* None.

*Comments:* Several commenters questioned whether every PEP would get a two-year initial approval, who gives the two-year initial approval, what the accrediting or State approval agencies must do for the initial approval process, on what basis the oversight entity should make the two-year initial approval, and finally, how the term ''initial'' is defined in different contexts in the regulations.

*Discussion:* Every PEP must be approved by the oversight entity, which will permit initial operation of the program for up to two years. Every PEP is eligible to be considered for initial approval by the oversight entity for two years. The oversight entity has sole authority to provide the two-year initial approval. Initial approval may be granted without making a best interest

determination. Specifically, to allow flexibility and time to build the PEP, there are no specific requirements for the initial approval, and the oversight entity can use whatever information it has available. After two years, the oversight entity must assess all PEPs using the requirements in § 668.241(a). The accrediting or State approval agency must follow the requirements under § 668.237. The Department intends to provide guidance to further explain the regulatory text, as necessary.

*Changes:* None.

*Comments:* One commenter asked what happens if a PEP is not approved after the initial two-year period.

*Discussion:* If a PEP is not determined to be operating in the best interest of confined or incarcerated individuals, the PEP would lose eligibility. The Department will provide additional information on the process for the loss of eligibility in future guidance, as necessary.

*Changes:* None.

*Comments:* One commenter suggested that the Department reduce the two-year initial approval period to one year because, in the commenter's opinion, two years is too long to remove a failing program.

*Discussion:* The Department declines to make this change, because we believe that one year is not sufficient time to make reasonable determinations about whether a program is operating in the best interests of students. If an oversight entity has concerns about the quality of a program in the initial two-year period, it has the authority at any time to revoke approval of a PEP to operate in a facility that it oversees, even after the oversight entity has approved the program. Additionally, the Department has the authority under part 668, subpart G, to terminate the eligibility of a program that it has determined does not meet our PEP regulatory requirements.

*Changes:* None.

*Comments:* Multiple commenters offered that the initial two-year approval period under § 668.236(a)(3) is too short. The commenters claimed that such a short period will disincentivize institutions from offering slow-growing or small programs and that the initial two-year period is not based in evidence or research.

*Discussion:* The Department noted in the proposed rule that the two-year timeframe would ensure confined or incarcerated individuals receive the protections of the best interest framework in a timely manner, while recognizing the need for some time to gather the necessary information to meet the statutory requirement for a data-informed decision by the oversight entity. Two years is sufficiently long enough to assess outcomes for shorter programs and will ensure accountability for poorly performing programs.

During negotiations, in response to similar concerns, the Department amended its proposed language in § 668.241 to make the assessment of certain ''best interest'' indicators—namely program outcomes—permissive instead of mandatory. This change will relieve institutions of conducting outcome assessments at the two-year point where no data may yet be available, while retaining an assessment of program inputs to ensure the foundation for the program remains strong.

Finally, we note that a two-year assessment timeframe is used elsewhere in the title IV, HEA regulations to establish continuity of operations and experience at new institutions. In § 600.6(a)(5), for example, to establish institutional eligibility, a postsecondary vocational institution must be in existence for at least two years.

*Changes:* None.

*Comments:* Multiple commenters requested that the Department add language to § 668.236(a)(4) either requiring or encouraging transferability of credits to more than one institution in the State in which the correctional facility is located.

*Discussion:* The Department declines to make this change, because section 484(t)(1)(B)(iv) of the HEA states that credits from a PEP must transfer to ''at least 1 institution of higher education[.]'' A postsecondary institution, the oversight entity, or the accrediting or State approval agency could set higher standards. The Department strongly encourages institutions to ensure that credits earned by students in PEPs are transferable to more than one other eligible institution, thus providing students enrolled in such programs with as many options as possible for continuing their education following release from incarceration.

*Changes:* None.

*Comments:* One commenter stated that Pell Grant eligibility through a PEP should be expanded to include enrollment in liberal arts subjects.

*Discussion:* Neither the HEA nor the applicable PEP regulations prohibit enrollment in liberal arts subjects offered through a PEP.

*Changes:* None.

*Comments:* In regard to § 668.236(a)(6) and (b), one commenter wrote that the text itself specifies that an institution already offering one or more PEPs that are subject to an initiated adverse action may maintain eligibility for those existing PEPs, provided that they submit a teach-out plan. However, when read together, these provisions state that ''An eligible PEP means an education or training program that . . . [i]s offered by an institution that is not subject to a current initiated adverse action,'' which, according to the commenter, would seem to create a blanket policy of ineligibility for programs offered by institutions subject to an adverse action.

*Discussion:* We believe the paragraph is clear both in the general description of the program and in defining the limited situation in which a program loses approval to enroll new students while teaching out those who are currently enrolled.

*Changes:* The Department made non-substantive technical edits to restructure the paragraphs to improve the flow and clarity of the text.

*Comments:* One commenter suggested that the Department further regulate on the teach-out plan required under § 668.236(b)(2), to require that the plan include options for confined or incarcerated individuals beyond transferring to a postsecondary institution once they are no longer incarcerated.

*Discussion:* The definition of ''teach-out plan'' is in § 600.2 and the requirements related to teach-out plans and agreements for accrediting agencies are in § 602.24(c). The Department declines to establish additional requirements for teach-out plans. The Department has not generally regulated on the contents of a teach-out plan because they are not one size fits all. The postsecondary institution's accrediting or State approval agency could also set standards for the teach-out plan.

*Changes:* None.

*Comments:* One commenter asked what would happen when a fully informed student is aware of licensure restrictions in advance but, nevertheless, desires to earn that credential and attempt to overturn an unjust licensure restriction. The commenter also recommended providing resources to approved PEPs, State Higher Education Executive Offices (SHEEOs), community-based partners, and prospective employers to help them advocate for the removal of unjust licensure restrictions that prevent people with felony convictions from attaining their educational and career goals.

*Discussion:* There is no exception in the regulations to waive the requirements under § 668.236(a)(8). While the Department acknowledges the commenter's concern, § 668.236(a)(8) was adopted to protect confined or

incarcerated individuals from unnecessary exhaustion of their Pell Grant benefits, and to ensure PEP enrollees receive the full benefit of their education. These goals are undermined if time and money are spent pursuing training in an employment field barred to the student. If a State or Federal law prohibits licensure or employment of the formerly incarcerated individual in the State the correctional facility is located, or, for a Federal correctional facility, the State the most individuals will reside upon release, then that individual cannot enroll in the PEP. In general, the Department cannot lobby, recommend lobbying, or provide resources to aid in lobbying a State legislature for the purpose of removal or modification of laws.

*Changes:* None.

*Comments:* One commenter asked the Department to require oversight entities and postsecondary institutions to annually review collateral consequences relevant to education and workforce training pathways and add new pathways that align with confined or incarcerated individual's interests and labor market demands in the State and region under § 668.236(a)(8).

*Discussion:* The Department does not have the authority to mandate that a postsecondary institution offer a PEP or add new pathways that better align with students' interests and labor market demands in the State or region. It is the postsecondary institution's choice whether to offer a PEP.

For institutions that choose to offer a PEP, while we can prohibit them from enrolling students in programs for fields where they know their students will be barred, we cannot dictate how they otherwise structure the academic component of the PEP. The Department's authority in postsecondary education matters is limited to issues relating to Federal student aid, the use of Federal funds, and the specific programs administered by the Department. The Department is prohibited from exercising any direction, supervision, or control over curriculum or a certain type of PEP.

*Changes:* None.

*Comments:* One commenter suggested that we consider advising postsecondary institutions that, where they offer a vocational program affiliated with employment bans for a confined or incarcerated individual with certain convictions, the provider should offer another non-degree or degree program that does not lead to such licensure or employment prohibitions.

*Discussion:* The Department does not have the authority to require that postsecondary institutions offer a confined or incarcerated individual specific prison education programming. We also do not have any regulations prohibiting a postsecondary institution from providing non-degree programs.

*Changes:* None.

*Comments:* One commenter stated that the requirement to meet ''any applicable education requirements'' in § 668.236(a)(7) and (c)(1) and (2) is too broad in scope and would not allow for the materiality of education requirements to be considered. The commenter stated that postsecondary institutions may not have the resources to make these decisions annually.

*Discussion:* The requirements in § 668.236(a)(7) and (8) (and corresponding requirements in § 668.236(c)(1) and (2)) are based in statute and further clarified through the regulation. The Department has the authority to set reasonable parameters in regulation. PEPs may not be widely accessible within a correctional facility and confined or incarcerated individuals may have to rely on the postsecondary institution's determinations regarding educational requirements for and prohibitions on licensure or employment to a greater extent than would individuals who are not incarcerated. A postsecondary institution is not required to offer a PEP in a State where it is unsure about educational or licensure requirements or where it does not wish to remain up to date regarding these requirements. The Department believes many postsecondary institutions will recognize the benefits of the regulatory framework for confined or incarcerated individuals.

*Changes:* None.

**Accreditation Requirements (§ 668.237)**

*Comments:* One commenter asked whether the regulations define the actions an accrediting agency should take to determine the academic quality of a program for an established PEP through the Second Chance Pell program, or whether an accrediting agency would be allowed to fully use their process and professional assessment standards in determining the academic quality of a program.

*Discussion:* The accrediting agency must evaluate the first PEP at the first two additional locations. Additionally, the accrediting agency must conduct a site visit at those locations to evaluate the first additional PEP offered by a new method of delivery. They must also approve the methodology for how the institution made the best interest determination under § 668.241. We fully specify the accreditation requirements for PEPs in these final regulations.

*Changes:* None.

*Comments:* One commenter called for the elimination of § 668.237 because accrediting and State approval agencies already have standards by which they evaluate educational programs, regardless of location. The commenter stated that prescribing additional program evaluations is unnecessary and burdensome and will discourage participation in PEPs.

*Discussion:* The Department disagrees with the commenter. First, we wish to make clear that the policies and standards of accrediting and State approval agencies differ, and the Department's regulations for agency recognition do not require the evaluation of every new program or location. Furthermore, PEPs are unique in that participants may only have one educational option at their correctional facility. The Department has chosen to mandate additional safeguards so that the PEP is beneficial to the confined or incarcerated individual. We also believe that requiring that the accrediting or State approval agency take a more proactive role in ensuring quality in PEPs is a logical outgrowth of the statutory requirements. Section 484(t)(1)(B)(v) of the HEA specifically provides, for example, that an institution offering a PEP cannot be subject to an adverse action in the last five years ''by the institution's accrediting agency or association.''

Finally, the Department has similar rules for other programs, such as direct assessment programs under § 668.10(a)(5), that require evaluation by the accrediting or State approval agency to establish eligibility for title IV purposes.

*Comments:* One commenter believed that programs offered via correspondence courses should be exempt from the Department's requirements for accreditation review because postsecondary institutions are already required to be approved for that method of delivery by their accrediting or State approval agency. The commenter stated that the accreditation requirements would add unnecessary burden to correctional facilities and postsecondary institutions.

*Discussion:* The Department disagrees with the commenter, as we seek to hold all programs regardless of the method of delivery to the standards outlined in these final regulations. The Department believes that offering educational programming through any method of delivery in a correctional facility for the first time may present various challenges that require creative thinking and collaboration amongst several stakeholders. A new method of delivery

in a correctional facility may also involve unique obstacles that institutions are unaccustomed to, which in turn could result in risks to confined or incarcerated individuals that may not have been addressed when the accrediting agency or State approval agency last approved the institution's use of distance education or correspondence courses. The accrediting and State approval agencies are uniquely authorized to confirm educational quality and we believe they must do so for all methods of delivery.

*Changes:* None.

*Comments:* One commenter asked the Department to require that any postsecondary institution offering a PEP at an additional location for a program that also exists on the postsecondary institution's main campus be included in any programmatic accreditation that may be held by the institution for that same program.

*Discussion:* The Department declines this recommendation because it can only require a postsecondary institution to hold accreditation by a nationally recognized accrediting agency for title IV purposes. We do not have the authority to require an institution to obtain programmatic accreditation for its PEPs.

*Changes:* None.

*Comments:* One commenter requested that, under § 668.237(b)(1), we require the accrediting or State approval agency, in addition to the oversight entity, to review and approve all PEPs.

*Discussion:* The Department disagrees with this commenter and believes that such a requirement would be overly burdensome to postsecondary institutions and accrediting and State approval agencies. If the PEP is a ''significant departure from existing offerings or educational programs, or method of delivery,'' § 602.22(a)(1)(i) and (a)(1)(ii)(C) already require review and approval by an accrediting agency prior to implementation.

Further, by requiring the Secretary's approval of the first PEP at the first two additional locations the regulations mirror the requirements of the accrediting and State approval agencies. We believe that a postsecondary institution that can sufficiently demonstrate satisfactory standards need not seek direct approval from the accrediting or State approval agency for every PEP. The regulations do not preclude an accrediting or State approval agency itself from requiring every PEP to be approved, however.

*Changes:* None.

*Comments:* Several commenters stated that the Department should approve the PEP prior to the accrediting or State approval agency approval required under § 668.237(b)(1).

*Discussion:* The Department disagrees with commenters because we must have a completed application to decide whether the PEP meets all regulatory requirements, particularly for the first PEP at the first two additional locations.

*Changes:* None.

*Comments:* One commenter asked for clarification on § 668.237(b)(1), specifically about the process for a postsecondary institution that has recently completed the accreditation process for the first or second additional location at a correctional facility and is in compliance.

*Discussion:* Rather than regulating on operational process, the Department intends to provide this information through guidance.

*Changes:* None.

*Comments:* Several commenters suggested that the Department remove the requirement under § 668.237(b)(3) for site visits, because postsecondary institutions have no control over correctional facilities. Instead, the commenters suggested that the Department require program evaluation, review of contact, and Learning Management System delivery.

*Discussion:* The Department disagrees with the commenters' suggestion. While the postsecondary institution does not have control over the correctional facility, it is important for the accrediting or State approval agency to ensure educational quality is still being achieved in unfamiliar or atypical settings. We believe that it is very important to have in-person on-site visits so that the accrediting or State approval agency can review how confined or incarcerated individuals are learning regardless of the method of delivery of the instruction.

*Changes:* None.

*Comments:* One commenter asked whether they could assume that the next site visit to a correctional facility would occur during the next accreditation cycle rather than no later than one year after initiating the PEPs in the first two additional locations, if an existing Second Chance Pell school's accrediting agency completed their site visit within 5 years of the July 1, 2023, regulations and found the institution to be compliant.

*Discussion:* Under the regulations, a site visit must occur no later than one year after initiating the PEP at the first two additional locations. The Department wants to ensure that the PEP complies with all applicable accreditation requirements in these final regulations. We also want to ensure that sites are visited shortly after a PEP begins, to confirm that there are adequate faculty, facilities, student support systems, and other resources. The next accreditation cycle for an institution could potentially be years into the future and would be too long for an accrediting or State approval agency to wait to confirm that the PEP met their standards. It would also be too long for a PEP that was not providing quality education and could mean significant numbers of students exhaust sizable portions of their Pell eligibility in furtherance of a worthless credential from a low-quality program.

*Changes:* None.

*Comments:* Several commenters asked for clarification about how the accreditation requirements in § 668.237(b)(4) relate to the best interest determination in § 668.241(a)(1) and whether that requirement is an additional evaluation. The commenters also asked whether the accrediting agency has the authority to invalidate the oversight entity's best interest determination if the agency does not find the oversight entity's methodology sufficiently rigorous.

*Discussion:* These are two separate and unique approvals in the regulations. The Bureau of Prisons or the State department of corrections (oversight entity) conducts the best interest determination under § 668.241. The other is the review and approval by the accrediting or State approval agency of methodology used the oversight entity in making the determination that the PEP is in the best interest of the confined or incarcerated individuals under § 668.237(b)(4).

Under § 668.237(b)(4) the accrediting or State approval agency has reviewed and approved the methodology for how the institution, in collaboration with the oversight entity, determined that the PEP meets the same standards as substantially similar programs that are not PEPs at the institution for the elements listed under § 668.241(a)(1)(i) through (iv).

Finally, the PEP is not eligible if either the oversight entity or the accrediting or State approval agency denies approval. The PEP must meet all regulatory requirements to be an eligible PEP.

*Changes:* None.

**Application Requirements (§ 668.238)**

*Comments:* One commenter recommended the removal of § 668.238.

*Discussion:* The Department believes an application process is necessary to ensure that the PEP is able to comply with all applicable standards. We require a similar process for direct assessment programs under § 600.10(c).

The Department is not proposing to approve all PEPs, but only the first PEP at the first two additional locations. We believe this is a reasonable requirement.

*Changes:* None.

*Comments:* One commenter stated there need to be explicit timeframes for each step of PEP approval.

*Discussion:* The Department will work expeditiously to review and approve or deny applications, but we choose not to provide timeframes for those approvals.

*Changes:* None.

*Comments:* One commenter requested that any eligible programs that participated in the Second Chance Pell experiment under the Experimental Sites Initiative should be automatically approved to avoid a bottleneck of applications.

*Discussion:* The Department will not exempt any postsecondary institutions or programs from the application process. Approving the first PEP at the first two additional locations will ensure that the PEP is able to comply with all applicable regulations. The Department continues to consider options for institutions currently participating in the Second Chance Pell experiment to transition to the new statutory and regulatory requirements and will announce its transition plans for the experiment at a later date.

*Changes:* None.

*Comments:* One commenter noted that the way § 668.238(a) is written implies that after one postsecondary institution gets approval to offer a PEP at a particular correctional facility, another postsecondary institution would not need approval to operate a PEP at that correctional facility. The commenter suggested the paragraph be updated to read: ''Following the Secretary's initial approval of an institution's prison education program, additional prison education programs offered by the same institution at the same location may be determined eligible without further approval from the Secretary . . .''

*Discussion:* The Department agrees that this will clarify the regulation. Every postsecondary institution, without exception, must have the first PEP at the first two additional locations where the postsecondary institution offers that PEP approved by the Department.

*Changes:* We have revised § 668.238(a) to provide that following the Secretary's initial approval of an institution's prison education program, additional prison education programs offered by the same institution at the same location may be determined eligible without further approval from the Secretary except as required by § 600.7, § 600.10, § 600.20(c)(1), or § 600.21(a), as applicable, if such programs are consistent with the institution's accreditation or its State approval agency.

*Comments:* One commenter suggested that the Department require a memorandum of understanding between the PEP and oversight entity that requires library services and resources.

*Discussion:* The Department does not have the authority to regulate library services or resources.

*Changes:* None.

*Comments:* One commenter stated that that people are leaving prison having earned a significant number of credits but have no pathway to an actual degree and have exhausted their Pell Grant eligibility. The commenter stated that postsecondary institutions should be required to submit to the Department and oversight entity a curricular plan that details how the program's course offerings will lead to a degree. The commenter requested that the Department amend § 668.238(b)(1) to add a clause at the end as follows: ''A description of the educational program, including the educational credential offered (degree level or certificate), the field of study, and curricular plan or pathway for degree completion.''

*Discussion:* The Department's authority in postsecondary education matters is limited to issues relating to Federal student aid, the use of Federal funds, and the specific programs administered by the Department. We are prohibited for exercising any direction, supervision, or control over curriculum. We cannot evaluate the PEP curriculum but would expect a review of curricula by accrediting agencies and State approval agencies.

*Changes:* None.

*Comments:* A few commenters stated that the oversight entity should be required to prove that it properly gathered input from all the relevant stakeholders. The commenters said the Department should add a rule that requires the oversight entity to disclose all the feedback it received from stakeholders to the postsecondary institution, accrediting agency or State approval agency, and the Department. The commenters also said the Department should require postsecondary institutions to include this documentation in their application to the Department.

*Discussion:* The Department declines to make this change, because we have language in § 668.241(f) that requires a postsecondary institution to maintain records related to the eligibility of a PEP, which includes ensuring that the oversight entity responsible for determining that the PEP is being offered in students' best interest appropriately conducted outreach to stakeholders as part of its evaluation of the program.

*Changes:* None.

*Comments:* One commenter requested that the Department insert language into § 668.238(b)(4) encouraging PEPs to align their data collection methodology and metrics with those required by the Integrated Postsecondary Education Data System, to ensure comparability of data across programs and ease the burden of submission.

*Discussion:* The Department does not want to hinder flexibility and innovation by requiring the standardization of methods.

*Changes:* None.

*Comments:* One commenter stated that requiring the postsecondary institution to explain the oversight entity's methodology for approving the PEP in § 668.238(b)(4) is significant, overly broad, and not well defined.

*Discussion:* Upon further review, the Department acknowledges that the oversight entity will not have to make the best interest determination for the first two years of the prison education program and therefore the postsecondary institution could not detail the methodology the oversight entity used in making the best interest determination under § 668.241(a). The information that the Department will now request is simply any information from the postsecondary institution that the oversight entity used to approve the prison education program. The Department will not prescribe this information in regulation to allow the oversight entity and postsecondary institution flexibility to be innovative in the application.

*Changes:* The Department will amend § 668.238(b)(4) to provide that an institution's PEP application must provide information satisfactory to the Secretary that includes documentation detailing the methodology including thresholds, benchmarks, standards, metrics, data, or other information the oversight entity used in approving the PEP and how all the information was collected.

*Comments:* One commenter stated that the Department needs to be more specific about information on reentry services requested in the application under § 668.238(b)(5). The commenter proposed breaking the paragraph into academic counseling which refers to the educational and career support students receive to help guide their enrollment in the prison education program and beyond; academic reentry counseling which refers to the support students

receive to plan and prepare for continuing their education post-release from incarceration; and reentry counseling which refers to preparing students for all facets of reentry, including securing housing, parole preparation, merit release, etc.

*Discussion:* While we decline to make this change in regulation, any postsecondary institution seeking approval of a PEP is welcome to provide this type of information to the Department. Reentry services are not required in the definition of a PEP in § 668.236, but if they are offered, the Department would appreciate that information.

*Changes:* None.

*Comments:* One commenter requested that the Department make clear that postsecondary institutions can partner with community-based organizations that have expertise in the field of prison education to help provide orientation, tutoring, and academic counseling.

*Discussion:* In § 668.238(b)(5), the Department notes that it is aware that postsecondary institutions partner with community-based organizations to provide certain types of services. This is allowable as long as the postsecondary institution is following applicable rules regarding title IV aid, including those relating to written arrangements under § 668.5.

*Changes:* None.

*Comments:* One commenter stated that § 668.238(b)(9), which allows the Department to request ''[s]uch other information as the Secretary deems necessary,'' is too open-ended. The commenter stated that postsecondary institutions may not be able to comply with the Department's request if the information and supported data are not collected through current information technology data systems.

*Discussion:* The Department needs to be able to ask applicants for more information if any area of an application is lacking. The Department does not intend to request information from postsecondary institutions that they cannot obtain, and if the Department does so, the postsecondary institution will have the opportunity to note that it cannot obtain the information and why.

*Changes:* None.

*Comments:* Several commenters asked that the Department create specific application requirements relating to correspondence PEPs, because the regulations would be burdensome, not feasible and cost prohibitive for those programs.

*Discussion:* As noted throughout the discussion section, the Department will hold PEPs offered through all methods of delivery to the same standards. The Department therefore declines to adopt the commenter's suggestion.

*Changes:* None.

*Comments:* One commenter asked whether a postsecondary institution may offer PEPs in States other than where its main campus is located.

*Discussion:* A postsecondary institution may offer PEPs in States other than where its main campus is located. Note that every correctional facility where a postsecondary institution offers a PEP and enrolls a confined or incarcerated individual must be reported as an additional location of the postsecondary institution, even if the prison education program is offered through distance education or correspondence courses.

*Changes:* None.

**Reporting Requirements (§ 668.239)**

*Comments:* One commenter asked the Department to mandate additional PEP reporting requirements including which PEP courses are equivalent to courses offered on the main campus and are eligible for credit transfer; the share of confined or incarcerated individuals accessing Pell grants who complete the course; and the share of confined or incarcerated individuals accessing Pell grants who fail to complete the course, indicating the reasons, including transfer or release.

*Discussion:* The Department will have information on completion and withdrawal rates in our internal systems or databases. While we decline to incorporate other information collection into the regulation, we will consider these suggestions when developing an information collection under § 668.239(a).

*Changes:* None.

*Comments:* A few commenters believe that the Department should not require postsecondary institutions to report information about transfer and release through an agreement with the oversight entity under § 668.239(c). One of those commenters suggested that the Department modify the National Student Loan Data System to allow the oversight entity to directly provide this information.

*Discussion:* While we appreciate the commenter's input and emphasis on the most efficient method to collect this important data, the Department declines to remove the requirements for institutions to obtain this information. The HEA requires that the Department provide annual publicly available reports to Congress about PEPs. Some of that information is about outcomes, including earnings outcomes or individuals who continue their education post-release. The Department needs information about transfer or release dates to fulfill the statutory mandate, and it is unclear whether the Department can collect such information from the large number of separate agencies and facilities that would otherwise be required.

The Department will also provide data through various systems to the oversight entity and postsecondary institutions to assist in completing the best interest determination.

We commit to continue to analyze the feasibility of information collection directly from oversight entities or correctional facilities, and the regulatory language allows for that option. If the Department ultimately decides to collect such information from oversight entities or correctional facilities, we will not require institutions to obtain the information separately. We also intend to provide guidance regarding how and where transfer and release date information must be reported.

*Changes:* None.

*Comments:* One commenter expressed concern regarding the potential reporting under § 668.239(a). This section allows the Department to publish a notice in the **Federal Register** requesting data from participating institutions. The commenter is concerned that the Department will require postsecondary institutions to report data beyond the specific data items prescribed in the HEA. The commenter was concerned that we will request additional data from the oversight entities and institutions that they may not typically collect. The commenter noted that postsecondary institutions may not have effective information technology systems that are capable to collecting some of the data that the Department may request.

*Discussion:* Because the Department is required to submit an annual report to Congress, we must be able to collect applicable data items. We cannot publish in regulation all of the data elements that we will need from participating institutions, because we may need to update data items. The Department must have the flexibility to amend, change, rescind, or further develop collection items. We have used similar processes in other contexts. For example, we publish an annual notice regarding the application verification of FAFSA® information. The Department has not always added verification criteria; in fact, in response to data analysis and feedback received, we removed several verification items over the years and endeavored to streamline requirements annually. We hope to do the same with any notice regarding PEPs.

*Changes:* None.

**Limitation or Termination of Approval (§ 668.240)**

*Comments:* One commenter stated that the scope of the Department's authority to limit or terminate a PEP for violating any terms of proposed subpart P is unreasonable, too restrictive, does not consider the materiality of violation observed, and does not provide a process to appeal and time to cure the violation. The commenter suggested we clarify term violation and related materiality and establish a process for an institution to appeal and a time to cure the violation.

*Discussion:* The Secretary's action to remove a PEP would be the same as an action to remove any other eligible program, meaning that the action would be taken under part 668, subpart G; through a revocation action under § 668.13(d) for a provisionally certified institution; or addressed during an institution's application for recertification.

The decision to terminate, revoke, or end the approval during recertification of a PEP will be based upon the Department's evaluation of the violation and in consideration of the institution's ability to administer the program. While the Department declines to create a separate process in regulation for removing PEPs, we acknowledge the commenter's concerns about materiality. We have changed the language to clarify these decisions will be made on a case-by-case basis. The Department will work with postsecondary institutions to resolve reasonable issues or minor violations throughout of the PEP requirements.

*Changes:* We have revised § 668.240(a) to state that the Secretary may limit or terminate or otherwise end the approval of an institution to provide an eligible prison education program if the Secretary determines that the institution violated any terms of the subpart or that the institution submitted materially inaccurate information to the Secretary, accrediting agency, State agency, or oversight entity.

**Best Interest Determination (§ 668.241)**

*Comments:* Many commenters submitted concerns regarding the required assessment of the PEP by the oversight entity. Commenters generally stated that the Department was proposing to regulate beyond congressional intent and the Department's statutory authority. The commenters noted that postsecondary institutions and oversight entities may choose not to offer PEPs due to the regulatory burden and cost. Commenters argued that there was little research to support the requirement to assess items proposed in regulation.

Many commenters also noted that the oversight entity may not have the expertise, data, training, or resources in the postsecondary education to set thresholds and benchmarks for the indicators related to outcomes, such as earnings and job placement rates of formerly confined or incarcerated individuals who have been released. Several commenters stated that the regulations do not consider labor market biases or post-release employment barriers to formerly incarcerated students.

The following are recommendations made by commenters to improve the best interest determination:

· Make all best interest indicator assessments permissive instead of mandatory, by changing ''must'' to ''may'' assess.

· Remove the exception for exceptional circumstances from the assessment of transferability of credits to any location of the institution that offers a comparable program.

· Make all the indicators optional except transferability of credits and academic and career advising for at least four years due to lack of data.

· Replace the indicators with faculty contact hours, meaningful engagement with peers, and ability to engage in research.

· Replace the indicators with civic engagement, family reunification, and increased self-efficacy.

· Assess other dimensions including physical, mental, and emotional issues.

· Add as optional metrics information about reentry services, whether credentials gained align with current labor market needs for in-demand industry sectors, and credentials that confined or incarcerated individuals gain through their participation that led to in-demand careers.

· Add an optional metric of how much regular and meaningful involvement programs have between students, faculty, and program administrators at the correctional facility.

· Replace metrics with access to support services and academic resources, tutoring, library resources and services, and technology.

· Add additional indicators that include whether the mode of course instruction for the prison education program is substantially similar to the primary instructional format at the home institution, preferably weighting in-person over virtual instruction, whether the demographics of the confined or incarcerated individual match the wider prison population, regardless of the main campus population of the home institution, and whether the prison education program staff and faculty represent or have experience or background working with or pertaining to underrepresented populations and groups, including individuals directly impacted by systemic racism, generational cycles of poverty and exclusion, or incarceration.

· Remove threshold requirements for the indicators related to outcomes.

· Modify the indicator related to earnings post release to include a succeeding sentence to outline if earnings data for individuals who graduated from the prison education program has been recorded, that data should carry more weight than a comparison to graduates of programs offered by the institution writ large.

· Clarify and rearrange indicators related to transfer.

· Specify how the earnings indicator is calculated.

· Revert to the statutory language for the assessment of earnings.

· Replace the oversight entity with the accrediting or State approval agency as the entity that determines best interest.

· Remove the oversight entity from the best interest determination.

· Replace the oversight entity with the relevant stakeholders for the best interest determination.

*Discussion:* The Department disagrees with commenters that we are regulating beyond congressional intent and the Department's statutory authority. We have the general authority to regulate on the HEA unless otherwise directly prohibited from doing so in statute. We thank the community for its feedback on the best interest determination section. However, we acknowledge the wide-ranging comments and suggestions about the proposed best interest indicators, in particular those indicators focused on student outcomes. Based on persuasive commentary, we have decided to make all outcomes indicators optional but maintain the requirement that the current input indicators must be assessed by the oversight entity. We believe the input indicators are foundational requirements. It is important that the oversight entity assess whether confined or incarcerated individuals are receiving these necessary supports as a part of the PEP.

The Department believes that assessment of inputs and outcomes is paramount in establishing a standardized framework for the oversight entity. We reiterate that the oversight entity is not required to deny a PEP if it fails to satisfy one of the

indicators. The oversight entity can take the totality of circumstances into account, which we have purposefully left undefined for flexibility in making decisions that are unique to each correctional facility and each PEP.

While assessment of outcomes indicators is optional, we encourage the oversight entity to assess as many of them as possible. As we stated in the NPRM, we intend to provide the oversight entity with data to assist in making outcomes assessments, and we will do so even if the oversight entity chooses not to assess one or more of the outcomes metrics. The Department also will assess outcomes, because the HEA requires the Department to provide a publicly available annual report to Congress that includes numerous outcomes measures.

The Department may:

- Publicly report on the rates of confined or incarcerated individuals continuing their education post-release. As the Department obtains transfer and release dates from postsecondary institutions, we could calculate rates of reenrollment using our internal data systems.
- Publicly report of job placement rates. The Department may be able to calculate and report on job placement rates through employment information that may be available via the College Scorecard using Internal Revenue Service (IRS) data or using the employment information of high school graduates from the U.S. Census Bureau.
- Publicly report on earnings of formerly confined or incarcerated individuals through program-level earnings via the College Scorecard using IRS data.
- Publicly report on rates of recidivism of PEP graduates through data obtained through reporting to the Department from States required by the Workforce Innovation and Opportunity Act. There may be additional data on recidivism from the Bureau of Justice Statistics and the U.S. Sentencing Commission that the Department may also be able to incorporate into a published analysis.
- Publicly report about rates of program completion of confined or incarcerated individuals. Postsecondary institutions currently report graduation rates to the Integrated Postsecondary Education Data System (IPEDS) and the Department produces completion rates of title IV recipients through the College Scorecard.

Finally, there may be other items that the Department reports on as required by statute or if the Department requests information from the postsecondary institutions through a **Federal Register** notice as required in § 668.239(a).

With respect to the indicator related to transfers in § 668.241, the Department accepts the suggestion to remove the exception for exceptional circumstances surrounding the student's conviction. It is not our intention to encourage postsecondary institutions to deny admission to formerly incarcerated students that were once enrolled in PEPs, and we are persuaded by the commenter that such language could form the basis for an institution's decision for such a denial.

With respect to the earnings indicator related to earnings, we have amended the language to no longer suggest a comparison to the earnings of a typical high school graduate. Although the Department continues to believe that post-graduation earnings are an important indicator of quality in postsecondary programs, we are persuaded by commenters that due to the ongoing barriers to employment for formerly incarcerated individuals and the resulting discrepancies in earnings between typical high school graduates and such individuals, it is not appropriate to compare the earnings of confined or incarcerated students who complete programs and are released from incarceration and the earnings of high school graduates.

The Department declines to add additional indicators or to further edit the remaining indicators to the regulation, but the oversight entity in collaboration with the relevant stakeholders through the feedback process has the flexibility to add other pertinent indicators relevant to PEP success.

The Department also declines to replace the oversight entity with the accrediting agency or relevant stakeholders. Section 484(t) of the HEA is clear that the oversight entity has sole authority to approve a PEP and make the best interest determination.

With these changes, the Department is confident that there are sufficient existing guardrails in the final regulations to protect confined or incarcerated individuals from subpar prison education programs, support postsecondary institutions and oversight entities, and safeguard the taxpayer investment.

*Changes:* We have revised § 668.241(a) to make the three outcome indicators—postsecondary enrollment following release, job placement rates, and earnings for graduates—optional factors that an oversight entity may consider in its determination of whether a program is operating in students' best interest.

*Comment:* One commenter suggested requiring that PEPs transcript credits in the same way that they would transcript courses offered to students who are not confined or incarcerated individuals.

*Discussion:* The Department does not have the authority to regulate an institution's transcripts.

*Changes:* None.

*Comments:* One commenter suggested that the Department require the oversight entity to identify how it determines the appropriate stakeholders, including any applicable conflict of interest standards.

*Discussion:* Under the statute, the oversight entity has the authority the approve a PEP and determine that it is in the best interest of confined or incarcerated individuals. Relevant stakeholders provide nonbinding feedback to the oversight entity. The list of relevant stakeholders is reported to the Department under § 668.241(f). We decline to add additional requirements, but we do believe that these final regulations will create a more informed, holistic process.

*Comments:* One commenter suggested that the feedback process under § 668.242(b)(1) be open to the public.

*Discussion:* The feedback process allows relevant stakeholders to provide nonbinding input to the oversight entities. The Department does not intend to regulate further on the parameters of the feedback process, to allow the oversight entity flexibility to set up that process.

*Changes:* None.

*Comments:* One commenter suggested that the Department provide guidance on how many indicators a PEP is permitted to not meet under § 668.241(b)(2) but still be deemed as operating in the best interest of confined or incarcerated individuals.

*Discussion:* The statute allows the oversight entity to not only approve a PEP's operation in a correctional facility but also to determine that it is operating in the best interest of the enrolled confined or incarcerated individuals. Apart from identifying the factors that the oversight entity may and must consider in making its determination, the Department will provide flexibility to the oversight entity and not regulate further in this area.

*Changes:* None.

*Comments:* Several commenters suggested that the Department further articulate an appeal process under § 668.241(c) if the oversight entity declines to permit a PEP from operating at a correctional facility. The commenters suggested that the appeal process include an explanation for the rejection, timeframes for an appeal,

incorporating a vote from the relevant stakeholders and a mediation process with the Department.

*Discussion:* The Department agrees that an appeal process is a best practice and supports the use of an appeal process by oversight entities wherever possible. However, the oversight entities include the Federal Bureau of Prisons and the State departments of corrections, and the Department does not have the authority to directly regulate the process of another Federal or State agency.

*Changes:* None.

*Comments:* One commenter suggested that the Department note in regulation that it will review the standards utilized by the oversight entity at recertification or in program reviews to ensure consistency and compliance across the oversight entities.

*Discussion:* The Department will ensure that postsecondary institutions are complying with the regulations during program reviews and at recertification. As stated under § 668.241(f), the postsecondary institution must maintain documentation about the PEP, which can be used by the Department for program reviews or recertification reviews.

*Changes:* None.

*Comments:* One commenter suggested that the Department include language that permits an approved PEP to continue in approved status if the institution provides all required materials to the oversight entity for approval 240 days in advance of the expiration of the program participation agreement. Section 668.241(e)(1) requires an institution to obtain final evaluations of each PEP not less than 120 days before the expiration of the institution's Program Participation Agreement (PPA), but there is no provision for delays by the oversight entity. The commenter requested the addition of regulatory language that permits approved programs to continue to be approved if the institution provides all required materials to the oversight entity for approval 240 days in advance of the expiration of the PPA. This, according to the commenter, would put the onus on the oversight entity to act in a timely fashion.

*Discussion:* The Department will consider the totality of circumstances on a case-by-case basis during the recertification process. The Department will consider whether the postsecondary institution is actively working with the oversight entity and the oversight entity indicates that it is actively reviewing the PEP. The Department declines to regulate on a formal process for case-by-case considerations.

*Changes:* None.

*Comments:* One commenter stated that the term ''subsequent final evaluations'' under § 668.241(e)(1) is not clear.

*Discussion:* ''Subsequent final evaluations'' refers to the requirement that the oversight entity make a best interest determination at least 120 days prior to expiration of the postsecondary institution's program participation agreement, in perpetuity, as long as the institution seeks to maintain the eligibility of the PEP.

*Changes:* We have removed the word ''final'' from § 668.241(e)(1).

*Comments:* One commenter inquired whether the cross-reference to paragraph (c) in § 668.241(e)(1) was correct.

*Discussion:* The cross-reference was incorrect. We updated the paragraph for clarity.

*Changes:* The paragraph will now state that after its initial determination that a program is operating in the best interest of students under paragraph (a), the institution must obtain subsequent evaluations of each eligible prison education program from the responsible oversight entity not less than 120 calendar days prior to the expiration of each of the institution's Program Participation Agreements, except that the oversight entity may make a determination between subsequent evaluations based on the oversight entity's regular monitoring and evaluation of program outcomes.

*Comments:* Under § 668.241(e)(2)(i), the regulation requires the postsecondary institution to submit data on ''all'' students for the oversight entity to determine continued approval. One commenter requested that the Department delete the word ''all,'' because in limited circumstances, data may not be available to the postsecondary institution.

*Discussion:* The Department agrees in part with the recommendation. It is not our intent for an oversight entity to deny a PEP for reasons beyond an institution's control, because the institution may lack data that is unavailable, for example, or that was not part of the oversight entity's determination of whether the program was being operated in students' best interest. We do not agree, however, with the commenters who suggested that the regulation should not apply to all students. Instead, we believe that the regulation should require the institution to provide all applicable data for students who were enrolled in the PEP, which would exclude data that the oversight entity did not require to make its determination and any data that are unavailable and cannot be obtained by the institution.

*Changes:* Section 668.241(e)(2)(i) will be updated to reflect application of ''applicable'' factors, providing that each subsequent evaluation must include the entire period following the prior determination and be based on the applicable factors described under paragraph (a) for all students enrolled in the program since the prior determination.

*Comment:* One commenter suggested to remove the word ''for'' before ''public disclosure'' in § 668.241(f)(1).

*Discussion:* The Department views this as a style preference and declines to make the change.

*Changes:* None.

*Comments:* One commenter suggested that all documentation related to records mandated under § 668.241(f) be made public.

*Discussion:* The Department believes that requiring the oversight entity or postsecondary institution to publish all documentation related to the decision-making process would discourage participation. There are also confined or incarcerated individual privacy considerations that would be particularly problematic given the small size of many of these programs. The oversight entity or postsecondary institution would not be able to publish data that would indirectly identify an individual from the information provided.

The HEA requires the Department to release an annual data report that is available to the public, and we believe that will provide valuable information to both institutions and other policymakers sufficient to evaluate prison education programs.

*Changes:* None.

*Comments:* One commenter stated that State departments of corrections will require financial assistance to offset material and human resources needed to implement the regulations in § 668.241.

*Discussion:* The HEA does not provide for an administrative cost allowance for oversight entities, and the Department does not have the authority to establish such an allowance.

*Changes:* None.

*Comments:* One commenter asked the Department to define several terms, including ''unique constraints,'' ''career advising,'' ''substantially similar,'' and ''overarching requirement.'' In addition, the commenter asked many technical questions regarding how the process of the best interest determination will work.

*Discussion:* The regulations establish a framework to implement the statutory provisions. While we believe this framework is sufficiently clear without providing additional defined terms and decline to provide technical guidance in this document, the Department intends to provide guidance to oversight entities and postsecondary institutions regarding the best interest determination, as required by section 484(t)(2) of the HEA.

*Changes:* None.

**Transition to a Prison Education Program (§ 668.242)**

*Comment:* One commenter requested that the Department specify the date on which a confined or incarcerated individual needs to be enrolled in a formerly eligible program in order to qualify for transitional eligibility. The commenter stated that it is not clear whether this provision applies to a confined or incarcerated individual who was enrolled in an eligible program outside a correctional facility prior to becoming incarcerated. The commenter also stated that it is unclear whether this provision restricts the ability of title IV-eligible institutions to offer non-Pell-eligible programs in correctional facilities.

*Discussion:* Section 668.242(b) provides that an institution is not permitted to enroll a confined or incarcerated individual on or after July 1, 2023, who was not enrolled in an eligible program prior to July 1, 2023, unless the institution first converts the eligible program into an eligible prison education program as defined in § 668.236.

This provision applies to any individual who is confined or incarcerated and who is enrolled in any program at a correctional facility in which the individual is receiving any title IV aid. For example, if an individual was enrolled in a distance education program prior to July 1, 2023, and subsequently becomes incarcerated after July 1, 2023, that individual can continue receiving a Pell Grant only until they have reached the time or eligibility limits under § 668.242(a), unless that distance education program becomes a PEP, which would include reporting the individual's correctional facility as an additional location.

Finally, the Department does not have the authority to restrict the ability of an eligible institution to offer programs that are not eligible for title IV aid, including Pell Grants, at correctional facilities.

*Changes:* None.

**Calculation of a Federal Pell Grant (§ 690.62)**

*Comment:* One commenter stated that the Department should insert language requiring PEPs to include the cost of obtaining required professional credentials for confined or incarcerated individuals in PEPs in their cost of attendance calculations.

*Discussion:* The Department will not regulate on cost of attendance with these final regulations. The Consolidated Appropriations Act of 2021 made changes to allowable costs that may be considered in a confined or incarcerated individual's cost of attendance, which are ''only tuition, fees, books, course materials, supplies, equipment, and the cost of obtaining a license, certification, or a first professional credential[.]'' Therefore, a postsecondary institution may include the cost of obtaining the first professional credential in the individual's cost of attendance. The Department will provide additional guidance on the changes to cost of attendance components established by the Consolidated Appropriations Act of 2021 in the near future.

*Changes:* None.

**90/10 Rule (§ 668.28)**

*General Support*

*Comments:* Many commenters supported the 90/10 regulations and the consensus reached on the regulatory changes. Commenters overwhelmingly supported including financial aid administered by the VA as Federal revenue in the 90/10 calculation. Additionally, many commenters supported the changes to allowable non-Federal revenue and encouraged the Department to enforce the regulations with the full intent of the law.

*Discussion:* The Department thanks commenters for their support. We intend to fully enforce the regulations.

*Changes:* None.

*General Opposition*

*Comments:* Several commenters opposed the proposed regulations on the basis that the regulations unfairly burden one sector of higher education and restrict academic choices of students. Several other commenters opposed the changes to the regulations because they stated that proprietary institutions will be disincentivized to enroll veterans because of the regulations and the significant cost of running a separate and distinct compliance program to remain eligible for VA funds. These commenters further stated that this will lead to decreased opportunities for veterans returning to civilian life after their service. Other commenters opposed the 90/10 rule generally because they claimed that the rule will cause proprietary institutions to increase tuition, incentivize proprietary institutions to recruit students who can pay for tuition without Federal funds, and reduce learning opportunities for low-income students and American students by encouraging proprietary institutions to recruit international students. One commenter suggested that the Department exempt certain institutions, such as those that offer terminal degree programs, post-baccalaureate programs, or medical programs from 90/10 because these institutions are already held to a high standard by other oversight mechanisms and provide unique value by helping the country fill its need for medical providers.

*Discussion:* The ARP modified section 487(a) and (d) of the HEA to require proprietary institutions to count all Federal funds in the numerator of their 90/10 calculation. The Department's regulations for which funds must be counted in the numerator and the formula for how these institutions must calculate the percentage of their revenue derived from Federal funds are consistent with statutory requirements. Further, the statute does not provide a basis to exempt certain proprietary institutions from this requirement.

*Changes:* None.

*Comments:* Several commenters generally opposed the proposed changes to allowable non-Federal revenue. A few of these commenters requested additional facts, evidence, data, or other sources the Department employed as a basis for our assertion that proprietary institutions have maneuvered to game the system and that there is a need to modify allowable non-Federal revenue or other components of the 90/10 calculation, including creating a disbursement rule and disallowing the proceeds from the sale of accounts receivable, in response to these behaviors.

*Discussion:* As stated in the NPRM, the Department based its regulations on observations of 90/10 calculations, audit workpapers, program reviews, and other oversight activities.[1] Based on the Department's observations and its experience enforcing 90/10 (and previous enforcement of 85/15), the Department believes that the changes to allowable non-Federal revenue are necessary to uphold the statutory intent of the 90/10 calculation.[2]

[1] See 87 FR 45454 and 87 FR 45459.

[2] As an example, Kofoed (2020) demonstrates that proprietary institutions account for a

*Changes:* None.

**Calculating the Revenue Percentage (§ 668.28(a)(1))**

*Statutory Authority and Congressional Intent*

*Comments:* Several commenters stated that the 90/10 regulations exceed statutory authority and Congressional intent. Some of these commenters stated that the proposed regulations do not provide a definition for ''Federal revenue,'' and the lack of a definition gives the Department an amount of discretion that Congress did not intend. A few commenters suggested that the Department restart the negotiation process to define ''Federal funds.''

These commenters further stated that it is clear that Congress intended for the Department to include VA and DOD education funds used to attend such proprietary institution as ''Federal education assistance funds,'' and clarified that they are not disputing that portion of the regulations. These commenters further stated that Federal agencies are required to point to clear grants of congressional authority in order to enact the regulations that are contemplated. Commenters requested clarification on the congressional authority that the Department believes allows it to include other types of Federal education assistance funds as Federal funds beyond DOD and VA funding.

*Discussion:* The ARP amended the HEA to state that proprietary institutions should include ''all Federal education assistance funds'' in the numerator of their 90/10 calculation. It is apparent that Congress intended for institutions to include all other Federal funds, in addition to title IV funds, used to pay for tuition, fees, and other institutional charges in the numerator of their 90/10 calculation based on this language, not just DOD and VA funds. Further, Federal appropriations for education assistance programs and disbursements to institutions may change from year to year. We do not want to inadvertently create an incentive for proprietary institutions to identify a large source of Federal funds not on the list and then target students that receive this funding.

The Department defines Federal funds in § 668.28(a)(1)(i) as title IV, HEA program funds and any other education assistance funds provided by a Federal agency directly to an institution or student including the Federal portion of any grant funds provided by or administered by a non-Federal agency, except for non-title IV Federal funds provided directly to a student to cover expenses other than tuition, fees, and other institutional charges. The ARP language is broad, and a broad regulatory definition aligns with statutory intent. We do not believe it is necessary to renegotiate the definition of Federal funds because the current definition implements the statutory change in the ARP.

*Changes:* None.

*Comments:* A few comments stated that in *W. Virginia* v. *EPA,* 142 S. Ct. 2587, 2608 (2022), the Court held that Congress did not grant a Federal agency the authority necessary to create a regulatory scheme that the agency had attempted to enact, and under a body of law, known as the ''major questions doctrine,'' the Court found that, given both the separation of powers principles and a practical understanding of legislative intent, an agency must point to ''clear congressional authorization'' for the authority it claims. These commenters questioned whether Congress provided clear authorization for the Department to make any changes to allowable non-Federal revenue in the proposed 90/10 regulations given that the ARP only modified what funds must be counted in the numerator. In addition, these commenters stated the proposed regulations violate the Administrative Procedure Act (APA) as the regulations are arbitrary and capricious.

*Discussion:* The ARP modified the statutory provisions in section 487 of the HEA governing which funds institutions must include in the numerator of their 90/10 calculation. The statute did not prohibit the Department from amending other portions of the 90/10 regulatory calculation related to allowable non-Federal funds. Further, it included a section directing the Department to amend the 90/10 regulations through the negotiated rulemaking process, without any new limitation on our authority to revise other parts of the 90/10 regulations, as has been done in prior years. The Department has the statutory authority granted by section 437 of the General Education Provisions Act to promulgate regulations that are consistent with statutory requirements and necessary for us to effectively administer the program using the negotiated rulemaking process required in section 492 of the HEA. Additionally, our rulemaking to determine how to calculate the 90/10 statutory requirement is not of such political and economic consequence that involves a major question under *W. Virginia* v. *EPA.* Finally, we have provided our reasoned basis for these regulations in the proposed and final rules.

*Changes:* None.

*Comments:* A few commenters requested clarification on the authority upon which the Department relied for its proposal that it has the authority to publish, on a semi-regular basis, ''updates'' as to what Federal funds should be counted in the 90/10 calculation without any notice and comment rulemaking or negotiated rulemaking process given that the ARP requires that its amendments to section 487 of the HEA be subject to negotiated rulemaking. These commenters stated that we should provide the public with an opportunity to comment on the definition of Federal funds.

Several commenters stated the Department has no authority to enforce the proposed rule prior to the effective date of the regulations, and that the HEA states that a regulation related to title IV programs cannot take effect during the current award year. These commenters further stated the Department lacks the authority under the HEA to force proprietary institutions to early implement the regulation, and that the ARP stated that its statutory changes should follow master calendar. Several commenters questioned the statutory authority on which we relied to justify enforcing a title IV regulation prior to the effective date of the final rule. They requested further clarification on how we will reconcile its application of the proposed regulations to proprietary institutions with a fiscal year beginning on January 1, 2023, with the clear statutory authority set forth in 20 U.S.C. 1089(c). These commenters recommended that revenues subject to the regulation should only be counted after July 1, 2023, regardless of the institution's fiscal year calendar. In addition, these commenters stated that the Department cannot retroactively apply these regulations. Some of these commenters requested that, if the Department contends that the regulations are not retroactively applied, the Department provide legal support for the assertion.

Finally, a few commenters requested that we clarify on which HEA provisions we relied in determining that certain proprietary institutions, but not all, would be required to comply with the changes to the 90/10 regulations on January 1, 2023.

disproportionate share of GI Bill spending while graduating relatively few veterans, which he attributes to the exclusion of GI Benefits from the 90/10 calculation. See Kofoed, Michael (2020). ''Where have all the GI Bill dollars gone? Veteran usage and expenditure of the Post-9/11 GI Bill.'' *Brookings Institute* report available at *https://www.brookings.edu/research/where-have-all-the-gi-bill-dollars-gone/.*

*Discussion:* Section 668.28(a)(1) defines Federal funds. The updates published in the **Federal Register** would simply notify institutions about which types of specific educational assistance funds are covered by the regulatory language. This is similar to how the Department publishes annually in the **Federal Register** which components of the FAFSA® institutions must verify, and this type of guidance does not require notice and comment.[3] Therefore, the Department's rulemaking activity has met the ARP's statutory requirements that the revisions to section 487 of the HEA be subject to public involvement and the negotiated rulemaking process.

Section 2013 of the ARP has two provisions related to the timing of this change. First, it requires that these changes be subject to master calendar requirements. It also states that the amendments to section 487 of the HEA, which describe funds that must be included in the numerator of the 90/10 calculation, apply to institutional fiscal years beginning on or after January 1, 2023. This is why the Department chose to implement the regulations when an institution's fiscal year begins rather than requiring all institutions to implement the changes on January 1, 2023. The regulations meet both requirements because the regulations will apply to institutional fiscal years beginning on or after January 1, 2023, and institutions will determine their compliance with the regulations and file their related audited financial statements after July 1, 2023. The Department would enforce any consequences of failing 90/10 after July 1, 2023, and the regulations are, therefore, not retroactive in their application. It is not correct to characterize this process as ''early implementation'' of the regulations because the audit submissions and compliance requirements go into effect July 1, 2023. Proprietary institutions that fail the 90/10 requirements for the 2023 fiscal year will not be impacted until early in 2024, and an institution must determine if it fails 90/10 within 45 days after the end of its fiscal year.

*Changes:* None.

*Definition of Federal Funds*

*Comments:* A few commenters supported our definition of Federal funds as only those used to pay for tuition, fees, and other institutional charges. These commenters also supported not including in the definition of Federal funds those that are expressly used for other purposes, such as housing or books when those are not included in institutional charges.

*Discussion:* The Department thanks commenters for their support. Our definition most accurately reflects statutory intent.

*Changes:* None.

*Comments:* Several commenters urged the Department to publish the list of Federal funds as soon as possible so that proprietary institutions can begin developing systems and procedures to track these funds. These commenters emphasized that institutions also need adequate notice so that they can effectively manage any changes they might need to make regarding admissions and enrollment. A few commenters asserted that this lack of clarity on which Federal funds must be included in an institution's 90/10 calculation at this point of implementation deprives institutions of fair notice of laws they are supposed to follow. Many of these commenters urged the Department to delay implementation of the new 90/10 regulations for a year or publish an abbreviated list in the first year if we cannot publish the list in a timely manner.

*Discussion:* The Department recognizes the need to publish the list so that proprietary institutions know which funds they must include, and we plan to publish on a timeline that will provide adequate time to account for the full list of Federal funds in the first fiscal year that begins on or after January 1, 2023.

*Changes:* None.

*Comments:* One commenter asked if Chapter 31 of the Veteran Readiness and Employment program would be counted as Federal funds in the 90/10 calculation. A few commenters recommended the Department exclude scholarship aid awarded through the Health Professions Scholarship Program (HPSP), the National Health Service Corps (NHSC) Scholarship Program, and the Indian Health Service Scholarship (IHSS) Program from the definition of Federal funds that institutions must include in the numerator of their 90/10 calculation. These commenters further recommended that we recognize the unique nature of these competitively awarded programs and not consider this aid as Federal funds under these regulations.

*Discussion:* The Department will publish in the **Federal Register** the full list of Federal funds that proprietary institutions must include. We will publish on a timeline that provides institutions with adequate time to account for the full list of identified funds. The statute defines Federal education assistance funds that institutions must count as Federal funds as funds disbursed or delivered to or on behalf of a student to be used to attend the institution. Therefore, the list will include all identified Federal education assistance funds that meet the definition in statute.

*Changes:* None.

*Comments:* Several commenters supported including Federal funds awarded directly to students as Federal funds in the 90/10 calculation. A few other commenters opposed including Federal funds paid directly to students in the numerator of the 90/10 calculation. A few of these commenters expressed concern with how proprietary institutions should account for funds disbursed directly to students if the agency does not provide this information to the institution, and they recommended that the Department should limit this to only funds that the institution receives notice of. One commenter recommended that the Department accept a proprietary institution's use of a certification from an agency or student that contains the details of Federal funds received as sufficient basis for the Federal funds it includes in its 90/10 calculation.

*Discussion:* The Department appreciates commenters' support for including Federal funds disbursed directly to students in the numerator of the 90/10 calculation. The ARP amended section 487(a) of the HEA to require proprietary institutions to include ''Federal funds that are disbursed or delivered to or on behalf of a student,'' and, thus, it is a statutory requirement to include all Federal funds disbursed to a student in the numerator of the 90/10 calculation.

For purposes of 90/10, we understand that proprietary institutions need a basis to calculate the Federal funds disbursed directly to its students. The Department considers a certification from an agency describing the Federal funds that a student received as a sufficient basis for this calculation. In cases where an agency does not provide this information to an institution, we will evaluate on a case-by-case basis whether the institution made a good-faith effort to obtain this information, including if a student certifies that they received Federal funds and the amount of funds received.

*Changes:* None.

*Comments:* A few commenters requested clarification on whether proprietary institutions would only need to include revenues from new Federal sources when those funds paid for institutional costs for the fiscal year

[3] 34 CFR 668.56.

starting after the Federal program has been identified on the published list. These commenters requested further clarification on how proprietary institutions should manage the termination of students based on projections that the students' enrollment and reliance on Federal funds may cause the institution to violate the 90/10 rule. Additionally, one commenter suggested that the Department allow proprietary institutions to exclude in their 90/10 calculation newly identified Federal funds that are added to the **Federal Register** notice that a currently enrolled student receives. A few commenters asked that we publish any updates to the list of Federal funds by November 1 of the preceding year for an institution to be required to include those Federal funds in its fiscal year beginning on or after July 1 of the following year, following the master calendar outlined in section 482 of the HEA. One commenter suggested revising the regulatory language to state that proprietary institutions will only be required to include newly added Federal funds that are added to the **Federal Register** notice at least six months before the start of an institution's fiscal year.

*Discussion:* As we stated in the preamble to the NPRM, in instances where the Department updates the initial **Federal Register** notice midway through an institution's fiscal year, the proprietary institution will be responsible for including those funds paid for institutional costs the fiscal year starting after the Federal program has been identified on the published list.[4] This lead time is also adequate for institutions to begin accounting for Federal funds from currently enrolled students, and therefore it is not necessary to allow institutions to exempt counting newly identified Federal funds that these students receive. Likewise, it is unnecessary to publish updates by November 1 or at least six months before the start of an institution's fiscal year for institutions to include those funds in a fiscal year beginning on or after July 1 of the following year. Proprietary institutions are responsible for generating at least 10 percent of their revenue from allowable non-Federal sources. How to meet this requirement is up to the institutions, provided that they follow regulatory and statutory requirements. The regulations neither contemplate, nor require, institutions to terminate the enrollment of students if they would otherwise fail the 90/10 rule. The Department hopes that institutions make enrollment decisions that are best for students and clearly communicate about potential issues in a clear and timely manner.

*Changes:* None.

*Comments:* A few commenters requested clarification upon what basis, elements, factors, and evidence will the Department evaluate whether an institution has made a ''good faith'' effort to identify all Federal funds. They further requested clarification of what process and procedures the Department will employ to make this determination and what appeal process proprietary institutions will be provided. A few commenters also requested clarification on how the Department will observe institutional due process protections during the determination and appeal procedures.

*Discussion:* We will evaluate the facts of a situation on a case-by-case basis to determine if an institution made a good faith effort to identify all Federal funds. This evaluation may include what information was readily available to an institution and the materiality of funds from that Federal source to an institution's 90/10 measure. Institutions have opportunities to resolve disputes with Department staff regarding the 90/10 measure (for example, providing additional information and/or documentation), or through an administrative process if a resolution is not reached.

*Changes:* None.

*Appendix C*

*Comments:* Several commenters recommended the Department clarify and streamline appendix C in the final rule, including by combining certain refund and adjustment categories and by combining title IV and Federal funds into one section. A few of these commenters suggested that the Department work with external certified public accountants to revise appendix C. Many of these commenters also requested that we include additional examples of adjustment and revenue categories in appendix C to allow institutions to reflect revenues more accurately in their 90/10 calculation. One commenter stated that it is confusing for appendix C to include an institutional matching payment as a subtraction from cash payments as usually it is treated as a non-cash write off. In addition to asking that we publish the list of Federal funds in the **Federal Register** at least six months prior the start of an institution's fiscal year, a few commenters asked the Department to publish any updates to appendix C at least six months before the start of an institution's fiscal year.

Many commenters recommended that as these 90/10 changes are implemented, we should be vigilant in monitoring the cash flows of institutions, through the calculations derived from the modified appendix C, to better understand how the new regulations changes institutional financial behavior and to ensure the regulations are strongly enforced to protect students and taxpayers.

*Discussion:* The Department intends to evaluate the impact of the new 90/10 regulations on institutional financial behavior, as supported in the comments. Thus, the Department declines to combine Federal funds and title IV, HEA funds in appendix C so that the Department can more easily observe how the inclusion of other Federal funds impacts 90/10 rates. Likewise, we decline to collapse and combine the title IV and Federal funds category to only require institutions to report a topline dollar amount for Federal funds received because that would make it difficult for us to ascertain the impact of our new regulations. The Department expects institutions to apply title IV funds before applying other Federal funds to student accounts for 90/10 purposes because these regulations relate to title IV eligibility, and the Department intends to evaluate how the inclusion of Federal funds effects institutions' ability to comply with 90/10 requirements.

We understand that appendix C does not include every type of adjustment an institution may need to make when calculating 90/10. Appendix C is intended to generally outline how institutions must calculate 90/10 by providing an example that cannot reflect every situation. Institutions may need to add other refund or adjustment categories that are not included in our example to calculate their own 90/10 compliance. We have shown a variety of common line items in an institution's 90/10 calculation, and therefore we decline to add additional line items in appendix C. We also clarify that institutions should include a general adjustment category that reflects one adjustment amount for Federal funds rather than calculating and attributing adjustments to specific sources of Federal funds. However, to comply with title IV administration requirements, institutions must track adjustments and refunds by category of title IV funds, and the Department expects that institutions to include this level of detail in their 90/10 calculation for title IV funds.

We also clarify why we included an example of an institutional matching payment as a subtraction from cash

[4] See 87 FR 54453.

payments rather than a non-cash write-off. There are instances where institutional matches to programs are cash payments rather than non-cash write-offs, such as when institutions use state grant funds for matching payments. How an institution reflects institutional matches in its 90/10 calculation is dependent upon the source of the match.

As with publishing new Federal funds, institutions would only be required to comply with changes to appendix C the fiscal year after the changes are made to appendix C, which provides sufficient time for institutions to comply. Additionally, appendix C is an example of how institutions should calculate their 90/10 compliance, and generally we only change appendix C if there are statutory or regulatory changes to the 90/10 calculation, which do not happen often.

*Changes:* None.

**Disbursement Rule (§ 668.28(a)(2))**

*Creation of a Disbursement Rule*

*Comments:* Several commenters expressed support for the creation of the disbursement rule. A few other commenters stated that they do not believe such a rule is necessary, and few of these commenters stated that it is unnecessary because the funds will be included in the 90/10 calculation in the following fiscal year. These commenters also claimed that the disbursement rule conflicts with cash management regulations and forces proprietary institutions to make what they described as a false 90/10 calculation. A few commenters also recommended that the Department add a good faith phrase to the regulations to better ensure that unintentional and unavoidable delays, resulting from various extenuating circumstances, will not become the basis for administrative capability findings or other adverse findings or actions against an institution.

*Discussion:* We appreciates the commenters' support. The Department disagrees with comments that the rule is unnecessary. We have observed through our review of 90/10 calculations and audit workpapers that some proprietary institutions delay disbursements to students to the next fiscal year in order to avoid two consecutive 90/10 failures. The Department also disagrees with commenters that these regulations conflict with cash management regulations. Proprietary institutions can still establish disbursement timelines that are consistent with regulatory requirements (see § 668.14), and we will evaluate whether an institution made timely disbursements, deviated from its standing policy, or created policies for the purpose of impacting its 90/10 revenue calculation. In this evaluation, the Department would also consider if there were factors outside of the institution's control that impacted its disbursement timelines, and therefore does not agree with commenters that there is a need to add this to the regulations.

*Changes:* None.

**Revenue Generated From Programs and Activities (§ 668.28(a)(3))**

*Activities Necessary for the Education and Training of Its Students*

*Comments:* A few commenters opposed the new requirement that allowable non-Federal revenue from activities conducted by the proprietary institution that are necessary for the education and training of its students be related directly to services performed by students. These commenters objected to the preamble of the NPRM citing sales of hair care products as an example of disallowed revenue because commenters claimed that developing sales skills is important for students' careers.

*Discussion:* We disagree with these commenters. Requiring that allowable revenue from these activities be related directly to services performed by students more closely aligns with the statutory intent of 90/10.

*Changes:* None.

*Ineligible Education and Training Programs*

*Comments:* Several commenters generally supported the changes to allowable non-Federal revenue generated from ineligible programs. These commenters encouraged the Department to monitor the percentage of non-Federal revenue that proprietary institutions derive from ineligible programs and publish this information.

*Discussion:* The Department thanks the commenters for their support. We intend to monitor non-Federal revenues that institutions include in their 90/10 calculations through appendix C submissions.

*Changes:* None.

*Comments:* Several commenters opposed the changes that ineligible programs must meet for proprietary institutions to be allowed to count revenue generated from these programs in their 90/10 calculation. These commenters observed that ineligible programs have quality oversight measures, including approval by relevant State agencies or accreditation by another entity, and the commenters encouraged the Department to recognize the quality of these programs. These commenters further stated that other guardrails in the HEA, the existing 90/10 regulations, and the educational marketplace ensure that the ineligible educational programs are subject to consumer protection standards and that the programs prepare students for gainful employment.

A few commenters stated that the Department's proposed regulations concerning the curriculum and content of ineligible programs exceed our statutory authority. One commenter also asserted that our rationale for the proposed changes to allowable revenue from ineligible programs is conjecture and does not meet APA standards.

In response to the Department's request for feedback about how to provide flexibility to proprietary institutions to offer ineligible programs that provide value to students while ensuring appropriate guardrails, many commenters supported ensuring that proprietary institutions offer ineligible programs that provide value to students. These commenters stated current regulations have allowed proprietary institutions to provide student opportunities that not only support their academic pursuits but complement their skills development and there has been a push toward badging and micro-credentialing as a mechanism to affirm student skills. These commenters further stated that the current language in § 668.28(a)(3)(iii)(A) through (D) more adequately provides the flexibility for proprietary institutions to offer ineligible programs that provide value to students. Some of these commenters suggested that, if the Department wants to enact consumer protection measures, we may consider amending § 668.28(a)(3)(iii)(E) or using the *Guide For Audits of Proprietary Schools and For Compliance Attestation Engagements of Third-Party Servicers Administering Title IV Programs* to provide specific direction regarding the standards for industry-recognized credential or certification rather than the proposed changes to § 668.28(a)(3)(iii) introductory text and (a)(3)(iii)(A) through (D).[5] These commenters stated that auditors could require that proprietary institutions provide evidence that a credential is, in fact, industry recognized by documenting job announcements requiring or preferring such qualifications. They cautioned us against a narrow definition that will

[5] This guide and accompanying guidance documents can be found on the Department of Education's Office of Inspector General web page under Reports and Resources: *https://www2.ed.gov/about/offices/list/oig/nonfed/proprietary.html.*

limit student opportunities and maintain the current regulatory language. A few commenters did not support the idea that the programs need to be related to the proprietary institution's eligible programs, stated that this requirement is not stated anywhere in statute or regulations, and stated that the idea that ineligible programs cannot offer courses that are also offered in title IV-eligible programs contracts the idea that they must be related.

*Discussion:* We recognize that some ineligible programs have consumer protection and oversight measures, but others may not since ineligible programs may not be required to be approved by any entity. This is unlike title IV-eligible programs, which are all required to meet the standards of accrediting agencies, State authorizing agencies, and the Department in order to be eligible to participate in the title IV program. Previously, when the 90/10 calculation (and previously 85/15) has been changed, proprietary institutions have made changes to their programs and related activities to meet the new revenue requirements. Some changes likely strengthened the programs and provided better outcomes for students, while other changes were likely made to exploit ambiguities in the regulations and that provided questionable or no value for students. We expect that proprietary institutions will adapt to the statutory change that requires all Federal funds to be included in the numerator of the 90/10 calculation to remain compliant with 90/10 requirements. In response to this change, institutions may seek other ways to bring in non-Federal revenue. The Department wishes to ensure that those revenues are in line with the statutory intent of the 90/10 calculation, which is that an institution provides enough value in its programs to account for at least 10 percent of its revenues. Thus, the Department is implementing appropriate guardrails that provide value to students without limiting the ways that institutions may offer innovative and flexible programs. These guardrails for ineligible programs were developed through negotiations with Committee members and reflect consensus of the Committee.

We appreciate feedback from commenters regarding consumer protection measures. With the guardrails that the regulations enact, it is not necessary to modify or curtail ineligible programs that meet the requirements in § 668.28(a)(3)(iii)(E). The Department may further consider how we can help auditors and proprietary institutions define industry-recognized credential in a meaningful yet appropriately broad manner.

These regulations neither prescribe nor limit the curriculum or content of ineligible programs. In addition, the regulations only apply to revenue generated from ineligible programs that the institution wishes to include in its 90/10 calculation.

The Department agrees with commenters that stated that ineligible programs are not required to be related to the proprietary institution's title IV programs in order to be counted in the 90/10 revenue calculation under the proposed regulation and that these programs may differ. We clarify that we do not expect that ineligible programs must be related to an institution's title IV programs, but we do expect it to meet the outlined requirements in § 668.28(a)(3)(iii).

Finally, these guardrails only apply to revenue included in the 90/10 calculation. Proprietary institutions can continue to offer ineligible programs that do not meet the criteria outlined in § 668.28(a)(3)(iii), but they cannot include revenue generated from these programs in their 90/10 calculation.

*Changes:* None.

*Comments:* Several commenters opposed modifying § 668.28(a)(3)(iii) to exclude revenue from ineligible programs that include courses also offered in eligible programs. These commenters opposed the change because they stated that many ineligible programs include general education courses or other content-specific courses that are also included in title IV-eligible programs, and it is more efficient for institutions to be able to offer the same course in both programs. One commenter stated that it is illogical to exclude these courses because revenue generated from the same courses would count in the 90/10 calculation if included in an eligible program. Commenters also asserted that it is unrealistic to expect proprietary institutions to not have any overlapping courses. Additionally, some of these commenters opined that title IV-eligible courses have demonstrated quality, and therefore the Department's regulations that do not allow students in ineligible programs to enroll in these courses do a disservice to these students. These commenters requested the Department explain the intention of modifying the non-title IV revenue requirements to prohibit programs that include courses offered in an eligible program.

A few commenters stated that they understood why the Department proposed to exclude revenue from ineligible programs that include courses also offered in title IV-eligible programs, but they believed it would be more appropriate to limit the number of courses an ineligible program could incorporate from eligible programs rather than outright prohibiting these courses. A few commenters asked how the Department would define ''course'' for the purposes of § 668.28(a)(3)(iii).

*Discussion:* We recognize that some proprietary institutions will need to adapt to meet the new requirement that proprietary institutions must count all Federal revenue in the numerator of the 90/10 calculation. The Department is concerned this change may incentivize proprietary institutions to push students to enroll in ineligible programs that generate 90/10 revenues rather than programs that are eligible for title IV aid, perhaps even ineligible programs that are similar to, or piecemeal duplicates of, eligible programs if institutions are allowed to include revenue from ineligible programs that offer even a limited number of courses offered in eligible programs. As some commenters noted, there may be eligible programs that include general education courses, as well as more specialized content, and institutions might recruit students to take the specialized content courses that would not be eligible for title IV funds on a standalone basis. Revenues from students who only enroll in courses from an eligible program without enrolling in the eligible program will not be counted in the institution's 90/10 revenues to avoid instances where students eligible for title IV funds might be persuaded to pay for some courses out-of-pocket to alter revenues an institution would report in the 90/10 calculation. The Department is not preventing institutions from offering any ineligible programs and these requirements only apply when an institution wants to include revenue from the ineligible program in its 90/10 calculation.

Regarding the definition of course in the context of ineligible programs, the Department would determine on a case-by-case basis if an institution should not count in its 90/10 calculation revenue from an ineligible program because the ineligible program included content from an eligible program for purposes of § 668.28(a)(3)(iii).

*Changes:* None.

*Comments:* Several commenters requested clarification on proposed § 668.28(a)(3)(iii)(B) and language included in the preamble of the NPRM which stated that a non-eligible course would need to be taught by one of its instructors of an eligible program. These commenters believed that statement differs from the proposed regulatory language, which requires that the course

be taught by one of the institution's instructors. These commenters stated the proposed rule does not conform to the consensus language and that our interpretations as expressed in the NPRM preamble will reduce educational opportunities for students seeking to enter essential professions. These commenters further stated that the NPRM preamble describing the proposed changes to § 668.28(a)(3)(iii) arbitrarily incorporates new language that changes the requirement to one that requires the non-title IV eligible educational program's courses be taught by instructors of a title IV eligible program in order for the associated revenues to be included in the 90/10 calculation.

*Discussion:* We agree with commenters that the regulatory language means that the instructor must be employed by the proprietary institution, not that the instructor must be an instructor in a title IV-eligible program. The Department clarifies that courses in an ineligible program must be taught by one of the institution's instructors, and that instructor may or may not teach in a title IV-eligible program. We interpret this language to mean an instructor employed by the institution, not an instructor under independent contractor status.

*Changes:* None.

*Comments:* One commenter supported the proposed regulations that would allow institutions to include revenue from ineligible programs offered at an employer facility. Several commenters opposed the Department's proposed regulations which would disallow revenue from ineligible programs not offered at the institution's main campus, an approved additional location, another school facility approved by the appropriate State agency or accrediting agency, or an employer facility. One of these commenters observed that institutions can offer up to half of title IV-eligible programs at an unapproved location. A few of these commenters asserted that distance education is a beneficial mode of education and should be allowed when employers accept training offered through this modality or when the program is taught at a main campus approved by the appropriate State licensing or accrediting agency.

*Discussion:* The Department appreciates the commenter's support for allowing institutions to include revenue from an ineligible program offered at an employer facility. We disagree with commenters that we should allow proprietary institutions to count funds generated from programs offered at other unapproved locations or through distance education as non-Federal revenue in their 90/10 calculations. The Department worked with the Committee to develop the language regarding the location of ineligible programs and believes that the regulations strike a balance between providing necessary consumer protections guardrails for purposes of 90/10, while allowing proprietary institutions to incorporate revenue from non-title IV programs of value to students at other approved locations that provide Title IV programs and from their main campus. The guardrails negotiated by the Committee require proprietary institutions to exclude revenue generated from ineligible programs offered through distance education. Restricting program revenues for 90/10 to sources from approved locations will better provide a nexus for those ineligible programs to be offered by the institution's instructors. This will also ensure that the programs are offered from locations that have authorization from an institution's accrediting agency and from the states in which they are located. Limiting these ineligible programs from distance education or from unapproved locations will also permit greater oversight of the reported revenues by the Department. After weighing the potential benefits and risks, the Department has determined that the risk of abuse outweighs the potential benefits. We decline to allow institutions to include revenue generated from these ineligible programs in their 90/10 calculations. We further note that these regulations only govern revenue generated from ineligible programs that an institution counts in its 90/10 calculation and does not exclude a proprietary institution's ability to offer these programs.

*Changes:* None.

*Comments:* A few commenters requested clarification that the appropriate State agency that can approve an ineligible program may be the agency responsible for the profession and not the State educational agency. Commenters stated educational programs not eligible for title IV funding frequently provide specialized training education in specific trades, including entry-level healthcare programs, electrical and plumbing programs, and commercial truck driving. The commenters further stated that in these cases, State agencies outside of the States' Department of Education are often charged with approving trade-specific education programs, such as Boards of Contractors, State Licensing Authorities, Departments of State, Departments of Transportation, or the State may contract out the certification process to a third-party acting under the authority of the applicable State agency.

*Discussion:* The Department interprets the appropriate State agency to mean the agency responsible for approving or licensing the program, which may not be the State education agency.

*Changes:* None.

*Comments:* A few commenters expressed concern that the term ''self-study'' is ambiguous, and depending on the structure of certain courses, the term ''self-study'' might mean a course that does not follow a prescribed lecture format, a course that has little or no direct student or instructor interaction, a course of independent study, or an asynchronous distance education course. These commenters requested clarification from the Department for what constitutes ''self-study.'' One commenter claimed the term is impermissibly vague.

*Discussion:* The Department disagrees with commenters that the term self-study is vague and believes the definition of self-study course is self-evident. Section 487(d) of the HEA states that institutions can count funds paid by a student or on behalf of a student for an ineligible program in their 90/10 calculation if the revenue is generated from an ineligible education or training program if it meets certain requirements related to industry credentialing or external approvals from a state or accrediting agency. Self-taught or similar types of self-directed programs often do not represent anything other than an off-the-shelf product to which the institution adds no value or enrichment for its students. Even in instances where they do not represent an off-the-shelf product, they still represent little value-added by the institution because they are self-taught or directed. One of the purposes of the 90/10 calculation is to show that what the institution offers is of sufficient value that students or others are willing to invest non-Federal money to attend that institution. Charging for an off-the-shelf product and counting that as non-Federal revenue does not reflect any value from the institution any more than revenues from unrelated products an institution might sell.

*Changes:* None.

*Comments:* A few commenters stated that the regulations should allow institutions to count in their 90/10 calculation revenue from programs that prepare students for initial licensure in a field because the proposed regulations allow them to count revenue generated by programs that help students maintain or supplement licensure.

*Discussion:* Ineligible programs that prepare students for licensure would

generally be considered programs that provide an industry-recognized credential or certification. Therefore, the Department would consider revenue generated from these programs as permissible non-Federal revenue for purposes of 90/10, as long as these programs meet the other criteria outlined in § 668.28(a)(3)(iii).

*Changes:* None.

*Comments:* A few commenters noted that the current 90/10 regulations permit institutions to include revenues from programs that prepare students to take an examination for an industry-recognized credential or certification issued by an independent third party to count as non-title IV revenue in their 90/10 calculation, and the proposed regulations remove this provision. These commenters recommended that the Department continue to allow this practice. A few commenters also disagreed with the Department's assertion that quality programs generally prepare students to sit for an exam without an additional test preparation program. A few commenters also stated that students may struggle with taking an exam for an industry-recognized credential and noted that these test preparation courses help those students.

A couple of comments also asked for clarification on the proposed language. They questioned if institutions could include revenue from ineligible programs that train students for an industry-recognized credential that is issued by a third party, not the institution, as non-Federal revenue in their 90/10 calculation. A few of these commenters provided examples of programs that they believe the Department should recognize as allowable revenue.

*Discussion:* Test preparation programs do not constitute education or training as required by section 487(d) of the HEA. These courses represent review material, rather than the substantive training provided to a student that is supposed to underpin the test preparation classes. Additionally, the Department does not want to inadvertently incentivize institutions to offer lower-quality education or training programs that would have to be supplemented by taking a test preparation course to pass the exam for an industry-recognized credential in order to generate institutional revenue from the test preparation class, or add additional requirements such as test preparation courses that might unnecessarily raise costs for students.[6] Institutions may provide test preparation classes so long as the revenues are not included in the 90/10 revenue calculation.

The Department clarifies that the institution itself is not required to provide the industry-recognized credential for the program to be included in the 90/10 calculation. We consider revenue generated from ineligible programs that provide education or training needed for an industry-recognized credential that is issued by a third-party, such as commercial truck driving or allied health professions, as allowable non-Federal revenue for purposes of 90/10.

*Changes:* None.

**Application of Funds (§ 668.28(a)(4))**

*Presumption That Federal Funds Are Used To Pay Tuition, Fees, or Other Institutional Charges*

*Comments:* One commenter recommended that the Department modify the presumption that Federal funds disbursed directly to a student are used to pay tuition, fees, and other institutional charges. The commenter recommended that we clarify that this presumption only applies if the student makes a payment to the institution and that institutions should limit the amount that they include as Federal revenue as the smaller amount of the Federal funds the student received or the payment that the student made to the institution.

*Discussion:* The regulations already clarify that proprietary institutions only make this presumption if a student makes a payment to the institution. In terms of limiting the payment to the lesser amount of the Federal funds received or the funds the student paid the institution, section 487(d) of the HEA states that the institution should presume that ''any Federal education assistance funds that are disbursed or delivered to or on behalf of a student will be used to pay the student's tuition, fees, or other institutional charges.'' Therefore, it would be inconsistent with the statute to limit the presumption to be either the lesser of the payment or the Federal funds received.

*Changes:* None.

*Grant Funds Provided by Non-Federal Agencies That Are Comprised of Federal and State Funds*

*Comments:* Several commenters recommended that the Department not require proprietary institutions to obtain the breakdown of Federal and State portions of grant funds from non-Federal agencies because this would be a *de minimis* amount and would be unduly burdensome for the institution. A few other commenters recommended that the dollar amounts would be so small that the Department should allow institutions to count the full grant from the non-Federal agency as funds that can satisfy a student's tuition, fees, or other institutional charges, even if those grant funds have some Federal dollars. A few commenters suggested that the Department reduce the burden on institutions by publishing the Federal and State percentages of grant funds from non-Federal agencies for institutions to reference. One commenter suggested that we allow institutions to exclude students from their 90/10 calculations if those students received grant funds from a non-Federal agency and the proprietary institution is unable to determine the breakdown of Federal and State funds for the grant. Finally, one commenter asked to what lengths an institution should go to obtain this breakdown of grant funds.

*Discussion:* The Department disagrees with assertions that it will be unduly burdensome for institutions to obtain the Federal portion of grant funds. Non-Federal agencies are required to follow strict accounting procedures for Federal funds, and proprietary institutions should be able to work with the relevant agencies to obtain this breakdown.[7] Institutions, not the Department, are the best situated entities to be familiar with grants from non-Federal agencies and to work with those agencies to obtain additional information as necessary. The statute clearly intends for all Federal funds to be captured in the numerator of the 90/10 calculation, and it would be inconsistent with the statute to allow institutions to count certain Federal funds as reducing other Federal funds or to not count a student's other Federal revenue in limited situations where the institution cannot obtain the breakdown of Federal and non-Federal funds. The regulations clarify that in instances where the institution cannot determine the amount of Federal funds, the institution must exclude the entirety of the funds from the calculation.

Although institutions must exclude funds for which they cannot determine the breakdown, we expect institutions to attempt to determine the Federal and non-Federal breakdown of grant funds. The Department would evaluate whether the institution sufficiently attempted to determine the Federal and non-Federal components of grant funds on a case-by-case basis in when the

[6] 87 FR 45456.

[7] OMB Circular A–87, revised May 10, 2004: *www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A87/a87_2004.pdf.*

institution is unable to obtain this breakdown.

*Changes:* None.

*Funds Allocated Under Workforce Innovation and Opportunity Act (WIOA)*

*Comments:* A few commenters stated the classification of WIOA-type funds as Federal education assistance funds would violate section 487(d)(1)(C)(ii) of the HEA, which states that an institution can apply funds provided under a contractual arrangement with a Federal, State, or local government agency for the purpose of providing job training to select individuals to satisfy a student's tuition, fees, or other institutional charges before it applies Federal funds to those charges. The commenters further stated that we have long recognized that WIOA funds fit this definition because WIOA funds are provided under a job training contract funded for the purpose of providing job training to dislocated workers and individuals who are unemployed, underemployed, or disabled. They opined that the Department has long permitted proprietary institutions to apply WIOA-type funds to tuition and fees prior to applying title IV funds. The commenters suggested that even under the ARP, an institution must continue to apply first any WIOA-type funds to a student's tuition, fees, or other institutional charges. One commenter concluded that categorizing WIOA-type funds as Federal education assistance funds and as job training funds applied first would render the presumption rule superfluous as to WIOA-type funds, in violation of Supreme Court precedent.[8]

*Discussion:* Institutions can apply non-Federal portions of WIOA-type funds to tuition, fees, and other institutional charges. Section 487(d)(1)(C)(ii) of the HEA refers to the application of funds that the institution receives from a contract. The section does not categorize those funds as Federal and non-Federal. It would be inconsistent with the statutory change enacted by the ARP, which states that institutions must include all Federal education assistance funds in the numerator of their 90/10 calculation, to continue to allow institutions to first apply Federal portions of WIOA-type funds to tuition, fees, and other institutional charges before applying other Federal funds.

*Changes:* None.

[8] The comment cited *McNeill* v. *United States,* 563 U.S. 816, 822 (2011) citing *United States* v. *Wilson,* 503 U.S. 329, 334 (1992) (''[A]bsurd results are to be avoided'')

**Revenue Generated From Institutional Aid (§ 668.28(a)(5))**

*Institutional Loans*

*Comments:* Many commenters supported the Department's proposal to clarify that only principal payments on institutional loans count as non-Federal for 90/10 purposes. One commenter also supported the Department clarifying that institutional scholarships defined in § 668.28(a)(5) exclude funds from the institution, its owners, or affiliates.

*Discussion:* We thank the commenters for their support. We clarified appendix C to show how institutions should record this when calculating 90/10. We modified the line item for institution loans in appendix C to show how institutions should notate the full amount they received from students repaying institutional loans in the first column, but institutions should calculate and only include the principal payment amount in the second adjusted amount column.

*Changes:* We revised the line item showing institutional loans in appendix C.

*Income Share Agreements*

*Comments:* Many commenters generally supported the Department's proposed guardrails that institutions must abide by in order to include revenue from ISAs in their 90/10 calculation. Many of these commenters also supported not allowing institutions to count proceeds from the sale of ISAs in their 90/10 calculation.

*Discussion:* The Department thanks these commenters for their support.

*Changes:* None.

*Comments:* Several commenters opposed the proposed requirement that only the portion of cash payments that represent ''principal payments'' on ISAs or alternative financing agreements should be included in 90/10 calculations. These commenters stated that because ISAs do not have principal balances or charge interest, and because the amount that students may ultimately pay under an ISA (if any) is indeterminable until after the end of the end of the ISA, no portion of any student's payment is a payment of principal, and there is no established methodology for imputing or inferring what amount of a student's payment can reasonably be attributed to ''principal.'' These commenters stated that, in its current form, the proposed rule unreasonably fails to provide sufficient guidance to proprietary institutions that provide ISAs to comply with the proposed requirements. They recommended that we should count the entirety of each payment until the total amount of payments exceeds the amount financed and any amount exceeding the amount financed should not count as non-Federal revenue.

A few other commenters requested additional clarification on whether the principal payments on the income share agreement or other financing agreement must be aligned with current institutional charges, or whether principal payments made following matriculation, but still related to an institutional charge, may be counted. The commenters stated that this would arise in a situation in which the borrower has graduated, but the terms of the payment extend beyond the completion date.

*Discussion:* The Department does acknowledge the commenters' assertions that ISAs may be structed differently than traditional private loans and may use different terminology than ''principal'' and ''interest'' for similar concepts. In the normal course of business, an entity must record what portion of payments they receive from students is considered profit and what portion is considered a return of capital. For 90/10 purposes, a portion of student payments must be allocated to profit, and a portion must be allocated as a return of capital. Institutions must limit the return of capital included in their 90/10 calculation to the amount of capital originally applied to tuition, fees, and other institutional charges according to the application of payments for the 90/10 calculation. We revised our terminology to be broader in two paragraphs and also revised the ISA line item in appendix C to reflect that the total amount of student payments that an institution receives is not the same amount that it counts in its 90/10 calculation. We modified § 668.28(a)(5)(ii)(B) to provide that the agreement clearly identifies the maximum time and maximum amount a student would be required to pay, including the implied or imputed interest rate, any fees, and any revenue generated for a related third-party, the institution, or any entity described above for that maximum time period, and § 668.28(a)(5)(ii)(C) to provide that all payments must be applied with a portion allocated to the return of capital and a portion applied to profit and that revenue, interest, or fees would not be included in the calculation.

We continue to believe that institutionally-issued ISAs and other alternative financial products should be treated the same as institutional loans in the 90/10 calculation. Institutions may only count in their 90/10 calculation the principal payments made on private institutional loans, and it is appropriate

to have similar requirements for ISAs. If the Department allowed an institution to include the full payments on ISAs up to the amount of institutional charges, this may incentivize the use of ISAs because institutions would be able to count the student's full payment amount in their 90/10 calculation rather than only a portion of the payment.

The Department, the Truth in Lending Act (TILA), and its implementing Regulation Z [9] require that institutions provide numerous disclosures on private institutional loans so that borrowers can make an informed financial choice. Students should be able to make meaningful comparisons between ISAs and traditional loans. ISAs and other alternative financial products should be required to provide similar disclosures so that students can compare the various financial options available to them. The Department declines to remove the disclosure requirements and believes that institutions base the imputed or implied interest rate it discloses based on the maximum time and amount that a student would be required to repay. These requirements only apply to revenue from ISAs or other alternative financing agreements that institutions wish to count in their 90/10 calculation, and these regulations do not apply to ISAs or alternative financing agreements that institutions do not wish to include in their 90/10 calculation or to ISAs or alternative financing agreements financed by an unrelated third-party that does not meet any of the criteria described in § 668.28(a)(5)(ii).

In response to questions about the application to tuition, fees, and other institutional charges, the Department clarifies that ISAs and other alternative financing products should be treated like institutional loans. This means that the relevant tuition, fees, and other institutional charges that the institution should identify in its agreement and consider when determining the portion of a student's payment that counts in its 90/10 calculation are those at the time the student signs the agreement. Institutions are also required to take into consideration the amount of payments for tuition and fees that were allocated to payments of Federal funds under the presumption in § 668.68(a)(4). The institution is responsible for keeping track of the relevant tuition, fees, and other institutional charges that were not deemed to be paid for with title IV funds to ensure that when the student begins making payments on the product, the institution does not count in its 90/10 calculation payments that exceed the tuition, fees, and other institutional charges that were not paid by title IV funds. We have clarified that regulation to convey more clearly which institutional charges are relevant to the agreement.

*Changes:* We clarified § 668.28(a)(5)(iii)(A) to better communicate what stated institutional charges the agreement must not exceed. The Department revised § 668.28(a)(5)(iii)(B) to provide that the agreement clearly identifies the maximum time and maximum amount a student would be required to pay, including the implied or imputed interest rate and any fees and revenue generated for a related third-party, the institution, or any entity described above, for that maximum time period, and § 668.28(a)(5)(ii)(C) to provide that all payments are applied with a portion allocated to the return of capital and a portion allocated to profit and that revenue, interest, and fees are not included in the calculation. We also revised the line item in appendix C showing how institutions should count payments on ISAs covered by § 668.28(a)(5)(ii) in their 90/10 calculation.

*Comments:* Commenters stated that the Department lacks the legal authority to establish an interest rate limit, either real or imputed, on ISAs for 90/10 purposes or for any other purpose. These commenters stated that, even if the Department has such authority, the proposed regulation is arbitrary and favors more traditional private student loans over ISAs without any countervailing policy benefits. The commenters further suggested that, if the Department is correct in its concurrence with the Consumer Financial Protection Bureau's (CFPB's) assertion that ISAs are private education loans, then the Department has no more authority to restrict the imputed interest rates of ISAs then it has to restrict interest rates for more traditional private education loans. These commenters stated that interest rate limits on ISAs are regressive and opined that the regulation fails to fully define ISAs or alternative financing mechanisms. A couple of commenters asked if an institution could subsidize the interest rate if so that it would, in effect, be same as or lower than the comparable Direct Loan interest rate.

A few commenters stated that ineligible programs, by definition, are not eligible for title IV funding and noted there are situations in which individual students may not be eligible for title IV funds. Thus, they questioned the Department's rationale for requiring that the implied or imputed interest rate of ISAs not exceed the interest rate on comparable Federal loans since students may not be eligible for those loans. They also recommended that we amend the section governing interest rates for ISAs to include all borrower types, and not just undergraduates and graduates.

*Discussion:* In light of the comments the Department received regarding the structure of ISAs, we have removed the proposed limit on the interest rate that ISAs can assess if they are included in an institution's 90/10 calculation. We have decided to remove this proposed requirement because, as commenters noted, the rate will vary from student to student and at various times over a students' payment trajectory if their income changes.

*Changes:* The Department removed the proposed limit on the interest rate for an ISA that an institution must disclose to a student if the ISA funds are included in its 90/10 calculation in § 668.28(a)(5)(ii)(D). As a technical change, we moved proposed § 668.28(a)(5)(iii) to § 668.28(a)(6)(vii), redesignated proposed § 668.28(a)(5)(iv) as § 668.28(a)(5)(iii), and redesignated proposed § 668.28(a)(6)(vii) as § 668.28(a)(6)(viii). We moved this paragraph because this provision is more appropriately included in the paragraph that outlines what funds must be excluded from an institution's 90/10 calculation.

*Comments:* A few commenters requested clarification on whether § 668.28(a)(5), specifically the paragraph about ISAs, applies to both eligible and non-eligible programs. These commenters observed that the example in appendix C of revenue generated from ineligible programs does not include an example of these payments. A few commenters urged the Department to be mindful of student affordability concerns and allow institutions to include payments on ISAs or other alternative financing agreements in their 90/10 calculations with appropriate guardrails.

*Discussion:* Institutions can generate non-Federal revenue from payments on ineligible programs from sources identified under § 668.28(a)(5). As previously stated, appendix C is an example and is not intended to reflect every line item an institution may include. Finally, we believe these regulations align with commenters who urged us to allow institutions to include ISAs with appropriate guardrails.

*Changes:* None.

*Comments:* A couple of commenters asked us how we would evaluate the relationship between a vendor and an institution and if the term limitation applies to both ISAs and private loans.

[9] 12 CFR part 1026.

*Discussion:* We revised § 668.28(a)(5)(ii) to clarify the relationships covered by these regulations. The Department would evaluate if the relationship between a vendor and an institution meets these criteria to determine if the ISA or alternative financing agreement is covered by this section. ISAs and private loans must meet the Department's established criteria for private loans, and those would be the applicable term limitation for them. (See 34 CFR part 601.) We also note that TILA and Regulation Z outline additional requirements for private education loans.

*Changes:* The Department revised the relationships covered by § 668.28(a)(5)(ii) to include agreements with the institution only or with any entity or individual in the institution's ownership tree, or with any common ownership of the institution and the entity providing the funds, or if the entity or another entity with common ownership has any other relationships or agreements with the institution.

*Comments:* A few commenters asked the Department what we would consider to be an ISA or alternative financing agreement.

*Discussion:* We would generally consider an agreement with a student or prospective student that is not a traditional loan but involves the institution or related party, as defined in § 668.28(a)(5)(ii), paying or reducing tuition, fees, or other institutional charges with the anticipation that a student will repay that entity later using other defined repayment terms as an ISA or other alternative financing agreement.

*Changes:* None.

*Institutional Scholarships*

*Comment:* One commenter argued that the Department should include ''tuition discount'' in its definition of allowable revenue from institutional scholarships because that is included in section 487(a)(1)(D)(iii) of the HEA, which describes allowable revenue from institutional scholarships.

*Discussion:* The commenter is correct about the content of this HEA section. However, section 487(d)(1)(a) of the HEA requires that proprietary institutions calculate their revenue for purposes of 90/10 through cash basis accounting. Tuition discounting is not a cash payment on a student's ledger, and therefore it would not be able to be counted as allowable institutional revenue using this method of accounting.

*Changes:* None.

**Funds Excluded From Revenues (§ 668.28(a)(6))**

*Institutional Matches and Returned Federal Funds*

*Comments:* One commenter asked the Department to clarify if institutional matching funds for Federal programs that are not title IV programs are excluded from a proprietary institution's 90/10 calculation. The commenter stated that they assumed the Department means to treat institutional matching funds the same for both title IV and Federal programs. The commenter also requested that the Department clarify if it intends for proprietary institutions to exclude all Federal funds that are required to be refunded or returned, or if the Department intends only for institutions to exclude title IV funds that must be returned under § 668.22. Similarly, the commenter stated that they assume the Department means to treat Federal funds the same as title IV funds for purposes of exclusions.

*Discussion:* The commenter is correct, and we have changed § 668.28(a)(6)(iii) and (iv) to clarify our intent. The final rule excludes from the proprietary institutions' revenue calculation all funds provided by the institution as matching funds for all Federal programs. The exclusion is not limited to just title IV programs. However, we clarify that if institutions use any qualified outside funds, such as state grants, to satisfy institutional matching requirements for Federal funds, institutions can include those qualified funds in their 90/10 calculation. This is consistent with what we allow for institutional matching funds for title IV programs.

Likewise, the final rule excludes from proprietary institutions' 90/10 calculation the amount of all Federal funds, not just title IV funds, that must be returned to their respective granting agencies.

*Changes:* The Department changed § 668.28(a)(6)(iii) to provide that, for the fiscal year, the institution does not include the amount of institutional funds used to match Federal funds. Further, the Department changed § 668.28(a)(6)(iv) to provide that, for the fiscal year, the institution does not include the amount of Federal funds refunded to students or returned to the Secretary under § 668.22 or required to be returned to the applicable program.

*Sale of Accounts Receivable*

*Comments:* Several commenters supported the Department's proposal to exclude proceeds from selling accounts receivable in an institution's 90/10 calculation. Several other commenters supported allowing proprietary institutions to count proceeds from accounts receivable as non-Federal revenue in their 90/10 calculation. Many of these commenters indicated that the HEA does not authorize the Department to deny an institution from taking accelerated tuition payments, which they stated is what proceeds from the sale of accounts receivable represent. A few commenters observed that institutions are currently allowed to count revenue from accounts receivable in their 90/10 calculation and asked the Department to explain its rationale for changing current practice. A few commenters requested clarification whether § 668.28(a)(6) is intended to exclude any amount of this revenue, or only the portion of the sale that is not tied back to tuition, fees, and institutional charges.

*Discussion:* The Department disagrees with commenters that the proceeds from sales of accounts receivable represent payments of tuition, fees, or other institutional charges for the purposes of education or training. As stated in the NPRM, through program reviews and oversight activities, the Department has observed instances where sales of institutional loans were made at inflated prices to entities that were later identified as being parties to other business relationships with the institution.[10] Even instances where the sales of accounts receivables are to unrelated business entities, the Department has determined that those proceeds should be excluded because they are not for tuition and fees provided by the institution that should be counted in the 90/10 revenues. These payments are from entities that are purchasing assets in an expectation that they may be able to profit from collecting on those debts. Since these sales to other parties are not made to pay tuition and fees for students, excluding these proceeds from the institution's revenues for the 90/10 calculation is consistent with intent of the statute.

*Changes:* None.

**Sanctions (§ 668.28(c))**

*Requirement That a Proprietary Institution Notify Students if It Fails 90/10*

*Comments:* Many commenters supported the Department's proposed regulations to require an institution to notify students if it does not pass 90/10. A few commenters recommended that the Department not require institutions

[10] 87 FR 45459.

to notify students because it might encourage students to prematurely leave the school when the failure may be minor or a calculation error. One commenter recommended that § 668.28(c)(3) note that proprietary institutions, when informing students of the institution's 90/10 failure for a particular fiscal year, may also provide a statement about the institution's remedial plan for seeking to achieve 90/10 compliance in the next fiscal year. One commenter asked the Department to define what it considers a notification.

*Discussion:* We appreciate support from commenters who agree that an institution should notify students if it fails 90/10 in a fiscal year. The Department disagrees with commenters that do not think an institution should be required to notify students because students should have timely information about a potential loss of title IV eligibility at that institution so that they can make informed enrollment decisions. Nothing in the Department's requirement that institutions notify students prohibits institutions from describing the steps that they are taking or will take to address the 90/10 failure.

Institutions are the best judge of how to communicate information to their students, but we would generally expect that a notification would be published on an institution's website, emailed to students, and communicated in some medium that all students can and do access. Additionally, the notification should use plain language and clearly communicate that a consecutive failure would mean that students are no longer able to use their title IV funds at the school.

*Changes:* None.

*Notifying the Department if an Institution Later Determines That It Failed 90/10*

*Comments:* A few commenters requested clarification of § 668.28(c)(4) and what the Department considers immediate notification that the institution obtained additional information and calculated that it had failed the 90/10 calculation more than 45 days past the fiscal year end date. A few commenters recommended we include a timeframe with a specific number of business days instead of requiring an ''immediate'' notification.

*Discussion:* We decline to include a certain number of business days that an institution must notify the Department because we recognize that institutions may obtain new information under different circumstances, and it is more appropriate to maintain the flexibility to determine if the institution provided an immediate notification. Generally, we would interpret the plain language reading to mean that institutions notify the Department as soon as they obtain this additional information.

*Changes:* None.

*Liability for Title IV Funds Disbursed After Losing Eligibility Due to 90/10 Failure*

*Comments:* A few commenters opposed the Department's proposal to institute full liability for title IV funds disbursed after an institution fails 90/10 and encouraged us to continue our current practice of using the estimated loss formula to assess liability. These commenters observed that initial determinations of 90/10 compliance made in good faith may be overturned months later after many loan disbursements have been made based on additional information the institution obtains. These commenters argued that if the institution acted in good faith, the Department should not gain a double recovery on loan payments from students and punish the school. One commenter opined that this proposal seems designed to close any proprietary institution that loses title IV eligibility due to failing 90/10.

Several commenters requested clarification for when an institution's liability begins. A few commenters stated that an institution can only be liable for funds it disburses after it determines that it failed 90/10.

*Discussion:* The Department clarified § 668.28(c)(5) that institutions are liable for title IV funds that they disburse beginning on the first day of the fiscal year immediately following their second consecutive 90/10 failure. Instituting full liability beginning on the first day of the fiscal year after an institution loses title IV eligibility due to two consecutive 90/10 failures will better protect the integrity of taxpayer dollars. Based on the Department's experience, institutions monitor their compliance with 90/10 throughout the fiscal year and are aware when they are going to fail, or are close to failing, the standards. Establishing full repayment liability is necessary to discourage institutions from disbursing title IV funds after losing eligibility or delaying conducting their 90/10 calculation in order to prolong title IV eligibility where the institution would otherwise benefit by having its students being responsible to repay the ineligible loan funds that the institution received on their behalf. The decision to continue disbursing funds when there is a loss of eligibility, or a high risk of a loss of eligibility, falls solely with the institution and therefore the institution should solely be responsible for the repayment of those funds. The Department disagrees with commenters that claimed that we do not have the authority to assess liability for any part of a fiscal year before the institution determines that it fails 90/10. Section 487(d) of the HEA establishes that a failure of the 90/10 revenue requirements for two consecutive years makes the institution ineligible. The regulations try to mitigate any liabilities for title IV funds provided to ineligible institutions by requiring the institutions to monitor and report promptly when an institution fails the 90/10 requirement for a fiscal year. Institutions that are at-risk of losing title IV eligibility for a second consecutive 90/10 failure should monitor their funding closely, including making inquiries of students about the sources of aid they may be receiving from Federal sources. Further, institutions are required to submit their 90/10 calculation within 45 days of the end of their fiscal year and, in most situations, institutions know or should know within that window if they failed 90/10.

*Changes:* The Department added language to § 668.28(c)(5) clarifying when liability begins.

**Change in Ownership (§§ 600.2, 600.4, 600.20, 600.21, and 600.31) (HEA Sections 101, 102, 103, 410, and 498)**

**General Support**

*Comments:* A few commenters offered unqualified support for the Department's suggested changes to the change in ownership (CIO) regulations. Many commenters offered some support, if only for our intent to clarify and improve the CIO regulations and the need to create regulations to address what commenters described as significant problems, while also offering suggestions for or objections to some of the proposed changes.

*Discussion:* The Department thanks commenters for their support. We have attempted to clarify and otherwise improve the CIO process for all concerned parties.

*Changes:* None.

**General Opposition**

*Comments:* Some commenters expressed concern that the Department is over-regulating since CIOs are uncommon and suggested this overreach is a result of some large, prominent, and disruptive failed transactions. Commenters disagreed that the regulations would provide greater clarity as the Department argued. Other commenters expressed opposition to individual components of the CIO regulations. One commenter

recommended that, rather than promulgate these regulations, the Department should work with Congress to clarify the CIO provisions as Congress works to reauthorize the HEA.

*Discussion:* There are several reasons for the Department pursuing these changes to the CIO regulations, including to provide greater clarity in, and codification of, current practice, as well as address distinct problems identified by the referenced Government Accountability Office (GAO) report at https://*www.gao.gov/products/gao-21-89.* As noted in the NPRM, and as reported in 2020 by the GAO, between January 2011 and August 2020, of 59 changes of ownership (involving 20 separate transactions) involving a conversion from a for-profit entity to a nonprofit entity, one entire chain that comprised 13 separate institutions was granted temporary continued access to title IV, HEA aid but ceased operations prior to the Department reaching a decision on whether to approve the requested conversion to nonprofit status. Three-fourths were sold to a nonprofit entity that had not previously operated an institution of higher education, increasing the risk that students may not get the educational experience for which they are paying. One-third had what GAO termed ''insider involvement'' in the purchasing of the nonprofit organization (*i.e.,* someone from the former for-profit ownership was also involved with the nonprofit purchaser), suggesting greater risk of impermissible benefits to those insiders. Altogether, the 59 institutions that underwent a change in ownership resulting in a conversion received more than $2 billion in taxpayer-financed Federal student aid in Award Year 2018–19.

Given the high impact that will likely result from these transactions, we believe these regulations are necessary to carry out our statutory obligation to prudently implement and oversee the title IV, HEA student assistance programs. We respond to specific comments about pieces of the CIO regulations in the appropriate sections.

*Changes:* None.

*Comments:* Some commenters requested further clarification regarding what they described as the insufficiency of the current regulatory framework and requested the Department provide further explanation of, and justification for, the regulatory changes. These commenters stated that the amended definitions do not provide sufficient clarity and that the definitional changes could result in profound disruption to institutions undergoing the CIO process. These commenters further stated the Department does not sufficiently justify under the APA the need for the changes to the definitions and should provide actual, realistic, and evidence-based justifications.

*Discussion:* The GAO report on nonprofit conversions is sufficient justification for these regulatory changes. It demonstrated both a significant increase in the number of CIOs, as well as significant title IV funds flowing to institutions involved in CIOs (and as specifically reviewed in the report, conversions to nonprofit status). Moreover, in reviewing numerous CIO applications, we believe these regulations will provide necessary clarity about what will and will not lead to a successful CIO process. This clarity will in turn help institutions undertaking a CIO to meet the standards in these regulations more easily. We disagree that the definitions are unclear; for example, the amended definition of ''nonprofit institution'' adds a description of institutional characteristics that do not generally meet the definition, which will ensure that institutions do not reach an inaccurate interpretation. We also disagree that these amended definitions will contribute to the disruption of institutions going through changes in ownership. Instead, the regulations create a more structured process that includes deadlines for when the Department must receive certain information and clarifies the standards for what constitutes a CIO. We also increase the percentage of ownership interest that will, by definition, constitute a change of ownership and control, sparing institutions that previously may have had to undergo lengthy CIO reviews for certain ownership changes that did not in fact represent a change in control. Finally, 20 U.S.C. 1221e–3 and 3474 authorize the Secretary to promulgate regulations relating to programs administered by the Department and as the Secretary determines necessary and appropriate to administer and manage the functions of the Department.

*Changes:* None.

*Value of CIOs*

*Comments:* Some commenters emphasized that CIOs are often in the best interests of schools and taxpayers in that they allow for new investment in institutions or the continued healthy operations of institutions. These commenters further stated that CIOs typically occur because an interested buyer has more resources to inject into the school to strengthen it, the current owner is planning to retire or leave the industry, or an investment fund has timed out. These commenters added that CIOs can prevent the closure of institutions that may be struggling, thereby preventing disruption to students' educational programs, and saving both taxpayers and institutions from covering the cost of avoidable closed school discharges.

*Discussion:* The changes will not preclude CIOs, and the Department acknowledges, as some commenters have stated, that a CIO can be beneficial for a school. That is true in some, but not all circumstances, so the changes also strive to protect students and taxpayers.

*Changes:* None.

*Regulatory Implementation*

*Comments:* In response to questions from the Department about when to implement these regulations, several commenters recommended at least one full academic year to allow institutions an appropriate amount of time to implement the regulations. A few commenters suggested delaying the rule up to 3 years. Other commenters requested clarity on how the new regulations would apply to institutions currently in the process of a CIO. They argued that these regulations should not apply to transactions currently in process. Several other commenters argued for the need to address this pressing problem without commenting on a specific implementation date.

*Discussion:* In considering the implementation question further, the Department believes it is appropriate to follow the master calendar provision in section 482 of the HEA and have these regulations take effect on July 1, 2023. The Department is concerned that as the number of applications for CIOs continues to grow it is important to put in these rules clarifying the process as soon as possible. Doing so will help institutions put together transactions that are reviewed in a more efficient manner. We disagree with waiting one or as many as three years for the implementation of these regulations. Given that these regulations consider the structuring of transactions rather than the way institutions operate, we do not believe that institutions will need significant time to adjust the way they administer the title IV programs to meet these requirements. As such, we see no need to delay the implementation date.

Regarding CIOs that are underway, because these regulations will go into effect on July 1, 2023, any transaction that is slated to close on or after July 1, 2023, would be subject to the requirements in this regulation. However, the 90-day advance notice requirement would not go into effect

until July 1, 2023, as well. That means any transaction that is scheduled to close between July 1, 2023, and October 1, 2023, would not be subject to this 90-day requirement since that would require submitting a notice prior to the effective date of the regulations.

*Changes:* None.

*GAO Report and Risk*

*Comments:* Commenters requested clarification on the types of transactions that have proven extremely risky for students and taxpayers. Some commenters requested clarification on how the referenced GAO report that focused on nonprofit conversions informed the Department's approach to transactions that do not involve conversions.

Commenters stated that risk is an unavoidable part of any transaction and asked what level of risk we would be willing to accept. Commenters further stated that the Department provides no evidence of assessments of ''imminent or excessive risk'' to students and taxpayers and requested examples of previous transactions that constituted an unacceptable amount of risk.

*Discussion:* The GAO report explains the kind of risk that conversions entail and has been linked to. As noted above, the GAO report deals with conversions. However, all CIOs—whether they involve conversions or not—involve risk. When a new entity takes control of an institution, we are concerned with whether the institution has the ability and financial resources to operate the school. We have seen instances where a new institution either lacked the financial resources or was too burdened with debts or other obligations (whether to former owners or other creditors) to succeed. In other instances, an entity that has never operated a school struggles to maintain a school, or an entity that has operated a smaller school struggles to operate a larger school or to integrate additional campuses and locations into their operations. Because the concerns vary and are often case-specific, the Department believes that the regulations lay out a concrete process that will ensure we receive the information we need to make a thorough review of a CIO, discourage the instances that have been the most concerning in the past, and provide flexibility for institutions that may previously have been subject to a CIO review because they met the current 25 percent threshold, but the proposed transaction did not actually involve a change in control.

Evidence that we could adduce to support regulating in this instance is based on Department experience with a wide variety of CIOs—each of which is fact-specific—and does not lend itself to exposition in this final rule.

*Changes:* None.

**Definitions (§ 600.2)**

*Comments:* Some commenters expressed concern related to the amended definitions for ''additional location'' and ''branch campus'' and asked why those definitions refer to ''physical'' facilities. These commenters questioned what impact these changes have on the definition of ''prison education programs,'' which are considered additional locations but can be offered through distance education.

Commenters requested further clarification regarding these definitions on the inclusion of ''separate'' from the main campus when ''geographically apart'' is a more precise term. Some commenters asked what a location is called that has less than 50 percent of an academic program.

Finally, commenters suggested the Department define ''ownership structure.''

*Discussion:* We refer to additional locations and branch campuses as physical locations to emphasize that they are ''brick and mortar'' places of education. PEPs are similar in that they consist of actual locations where students are collectively located and receiving education together even if that is just, for example, a computer lab dedicated to distance education.

We agree that some precision might have been lost in the change to the word ''separate'' and have added back the word ''geographically'' in the definition of ''additional location'' and ''branch campus.''

''Ownership structure'' refers to the entities and individuals involved in the ownership of an institution.

We do not define in regulation a special term for a location that offers less than 50 percent of a program.

*Changes:* We have changed ''separate'' to ''geographically separate'' in the definitions of ''additional location'' and ''branch campus'' in § 600.2.

**Distance Education (§ 600.2)**

*Comments:* Commenters stated that the amended definition of ''distance education'' is ambiguous and asked whether it is only relevant to the Department's internal reporting systems. These commenters contended that requiring distance education programs to be offered and approved from the main campus would create significant disruptions to students and unnecessary costs for institutions without a discernable benefit.

These commenters further stated that institutions have used the flexibility afforded under current regulatory guidance to offer distance education programs from locations that will benefit the most students and some students will lose eligibility for State grant funds if a distance education program can only be offered from a main campus that is in a different State.

Some commenters stated that requirements related to distance education should not be included in CIO regulations and should instead be promulgated in a distance education rulemaking package to ensure that affected institutions are aware of the proposed changes. Commenters recommended that we allow distance education programs to be offered from branch campuses. Some commenters recommended that if the proposed changes to the definition of ''distance education'' are finalized, we should alleviate institutional burden by grandfathering existing distance education programs and delaying the effective date for three years to allow students to graduate from existing programs. Some commenters also referred to waiving fees and costs whenever possible, presumably referring to fees that some States and accrediting agencies charge, because the Department does not charge fees.

Commenters stated the regulation does not take into account the varying State standards related to physical presence. They noted that many States have physical presence triggers that describe these standards, and whether institutions are physically located in a State or offer instruction in a State may or may not trigger a State licensure requirement under applicable State laws. Commenters requested clarification that an institution only needs to provide CIO approvals from States in which its operations trigger a license requirement and greater clarity on how ''physically located'' will be interpreted.

*Discussion:* As described in the NPRM, the Department's primary goal for updating the definition of distance education is to ensure equitable treatment to students enrolled in distance education, including for closed school discharges. However, we are persuaded by the commenters that the change we proposed could create significant unintended challenges for students and institutions that requires additional consideration. We also believe that there could be other ways to address programs that are offered fully through distance education programs. Therefore, we removed the proposed addition to the regulations

stipulating that distance education must be associated with an institution's main campus. However, we do not plan to change the Department's longstanding practice of associating distance education with an institution's main campus that we sought to codify in these regulations. Institutions should report to the Department any distance education programs offered that are not associated with the institution's main campus. The Department intends to explore this issue further.

*Changes:* We have removed proposed paragraph (6) from the definition of ''distance education.''

**Nonprofit Institution (§ 600.2)**

*Comments:* Some commenters supported the Department's position that we do not exclusively rely on the IRS to determine whether an institution is a nonprofit, as the IRS framework is not designed to implement title IV and fails to further title IV goals in certain respects. These commenters recommended that to reduce uncertainty, we should articulate a clearer rationale for the definition of a nonprofit institution. Other commenters expressed concerns that the expanded definition is beyond what is currently in statute.

Some commenters stated that only the IRS has the ability to determine the tax-status of an organization. Commenters further requested clarification on the statutory justification under the HEA for the Department to make a determination on the tax-status of an institution. Similarly, some commenters argued that we should not adopt tests on excess benefits that are more stringent than what the IRS requires. In addition, commenters requested clarification on the Department's experience making these determinations. Commenters also questioned whether we have legal authority to make a determination on the tax-status of an institution under *W. Virginia* v. *EPA,* 142 S. Ct. 2587, 2608 (2022). Some commenters requested clarification on how we plan to treat institutions that do not meet the nonprofit definition but are owned by nonprofit entities under State law and are considered tax-exempt organizations for IRS and State tax purposes.

Some commenters stated ''net earnings'' in paragraph (1) is inconsistent with the statutory definition of nonprofit. Commenters also stated that the term ''private shareholder'' implies that the benefit can occur only between a nonprofit, tax-exempt entity and a for-profit entity, or between a nonprofit, tax-exempt entity and an individual. These commenters suggested statutory and regulatory definitions demonstrate that it is improper to define a nonprofit institution by excluding an institution if any part of its net earnings ''benefits'' any ''private entity'' if that ''private entity'' is another 501(c)(3) organization.

*Discussion:* We agree with the commenters that it would not be appropriate to rely solely on IRS determinations of tax-exempt status to decide if an institution is nonprofit. Although tax-exempt status under the Internal Revenue Code (IRC) and the definition of nonprofit institution under the regulations for purposes of participation in HEA programs are related, these are not the same concepts. The Department does not determine the tax status of institutions or their owner entities. Having 501(c)(3) status is only one element of the definition of a nonprofit under the regulations. However, when we determine whether the institution's revenues provide an impermissible private benefit, we are also guided—but not bound—by authority developed by the IRS, as well as the tax court and other courts addressing the issue of private or excess benefit transactions. Through this final definition, we clarified what qualifies as a nonprofit institution for the purpose of HEA program participation and do so under the authority provided to the Secretary under 20 U.S.C. 1221e–3 and 3474 to promulgate appropriate regulations.

The Department is concerned about excess benefit transactions even when they benefit another nonprofit entity, because they remove funds from the institution that should benefit its students. We will consider these on a case-by-case basis.

*Changes:* None.

*Comments:* Some commenters asked for clarification on how we would treat a situation where an institution is deemed to be nonprofit at the state level but not by the Department. They asked if such an institution met a State-level requirement for nonprofit institutions but not for proprietary institutions, would the Department consider that institution to be out of compliance?

*Discussion:* The Department cannot determine that an institution is a nonprofit without the State also concluding that under its laws. However, the Department could conclude that an institution deemed a nonprofit under State law should still be treated as a proprietary institution for title IV aid. In either situation, the institution would need to abide by the State requirements for a nonprofit institution, and there is no conflict.

*Changes:* None.

*Comments:* Commenters argued that the HEA definition of a nonprofit institution borrowed language from the Internal Revenue Code to define a nonprofit, with the exception of an additional clause to say that no part of the net earnings ''may lawfully inure'' to the private benefit of a shareholder or individual. Commenters argued that the proposed definition of a nonprofit institution adopts a different test of what constitutes private inurement than what is contemplated in the HEA.

*Discussion:* The 501(c)(3) tax exempt status conferred by the IRS, while a single requirement under the regulations, is not the only requirement for nonprofit status to participate in the HEA programs.

*Changes:* None.

*Comments:* Commenters raised concerns that the lack of a definition of ''entity'' and requested greater clarity. One commenter argued that the lack of a definition could result in the Department fighting with more institutions about their tax status.

*Discussion:* The proposed changes to these regulations will provide greater clarity without including a definition for entity and we disagree this will foment disagreements. The Department refers to ''entity'' in its regulations at § 600.31 to mean a legal entity and does not believe there will be any confusion.

*Changes:* None.

*Comments:* A commenter suggested that the definition of a nonprofit should be revised to state that ''nonprofits formerly structured as proprietary institutions cannot have net earnings that benefit a private entity or person.'' They argued that because the excess revenue is used for the mission of a nonprofit institution that a range of stakeholders at private nonprofit institutions, including parents, faculty, staff, board members, and others can have a beneficial stake in the revenue.

*Discussion:* The Department does not think it would be appropriate to limit the definition only to institutions that were previously proprietary institutions. We review many CIOs that are not conversions from proprietary to nonprofit status, and we believe we must have consistent rules for all of these reviews. The situation described by the commenters differs from what the Department addressed with net earnings requirements. An institution that invests excess net earnings in the improvement of its educational enterprise or building an endowment is not specifically benefiting a private individual in the ways described in paragraphs (2) through (4) of the definition. In addition, institutions that newly apply

to participate in HEA programs must also meet the definition.

*Changes:* None.

*Comments:* Some commenters thought that the word ''generally'' in the lead phrase ''For example, a nonprofit institution is generally not an institution that . . .'', presents a loophole that would permit some institutions to maintain improper debts and arrangements with former owners after a change in ownership. Some commenters argued that including the word ''generally'' provided enough flexibility for the Department to address some limited situations where an institution should be approved as a nonprofit and that adding specific clarifications of what those situations could be in the rest of the definition created too many carve outs. Other commenters suggested that any agreement with a former owner, current or former employee, or board member should disqualify the institution from the definition of nonprofit, regardless of whether the payments and terms are reasonable. Along similar lines, commenters recommended removing carve-outs that permit revenue-sharing and other contractual arrangements with affiliates of former owners. A commenter also argued that we should further explain the instances in which we would not find this general definition. One commenter suggested that we add the same language to paragraph (2)(i) that is included in paragraph (2)(iii)(C) to allow for debt owed to a former owner of the institution or a natural person or entity related to or affiliated with the former owner in cases where the Secretary determines that the payments and terms under the agreement are comparable to payments and terms in an arm's-length transaction at fair market value. The commenter also suggested clarifying in paragraphs (2)(ii)(C) and (2)(iii)(C) that the provision applies specifically to paragraphs (2)(ii)(A) and (B) and (2)(iii)(A) and (B), respectively. The commenter suggested these changes stating that they would strike a better balance between ensuring the transaction benefits students, institutions, and taxpayers without impeding the evolution of institutions. One commenter asked the Department to clarify whether nonprofit institutions may have debt arrangements with their former owners as long as they are reasonable based on the fair market value, and if so, whether we could explain the standards we will apply in evaluating those arrangements.

*Discussion:* We intentionally used the word ''generally'' in the proposed definition for nonprofit institution. The Department has denied requests to convert to nonprofit status where debts to former owners are based on inflated or unsupportable valuations and, therefore, do not permit an institution to meet the definition of a nonprofit.

As to the prohibition on a debt owed to a former owner, we have seen that those kinds of arrangements allow continuing direct or indirect control by that former owner. As such, we do not think the suggestion of applying a fair market test would be appropriate for that type of relationship.

A review may include a variety of factors when to assess whether there is an impermissible benefit to a private entity. These depend on the details of the transaction and what types of agreements are involved, particularly as to debt financing or servicing agreements. It would be imprudent to try to list them all or to codify them in the regulations at the risk of omitting some or giving the impression that those listed will necessarily be used and those left out will not. However, providing some specificity as to what those items may be is important for granting clarity, and we identified them in the regulatory language. The Department believes the additional paragraphs that follow the lead-in language that uses the word ''generally'' provide sufficient detail to clarify that exceptions to these requirements will be limited and unusual.

*Changes:* None.

*Comments:* Some commenters argued that the proposed definition of a nonprofit institution is internally inconsistent with other regulatory requirements for a CIO. They noted that becoming a nonprofit institution is the triggering event for the CIO process, but the proposed definition of a nonprofit would involve the Department determining if the institution is nonprofit. They argued this created inconsistency since the nonprofit status would trigger the CIO review, but the CIO review is now needed to determine the nonprofit status.

*Discussion:* The Department review is to determine whether the institution will be recognized as a nonprofit for purposes of the HEA programs, and this is not inconsistent having a CIO review triggered when a nonprofit entity under state law with an IRS tax-exempt status acquires an institution, or if the existing owner of an institution converts under state law from a for-profit corporation (or other legal entity) to a non-profit corporation (or other legal entity), without the institution actually undergoing a change in ownership through, for example, an asset sale or a membership interest or stock sale.

*Changes:* None.

*Comments:* Commenters stated that Congress did not intend for public institutions of higher education to be categorized as nonprofit institutions and the Department's existing definition appropriately reflects that intention. These commenters further stated that if public institutions are included as ''private shareholders,'' we need to clarify the prohibition with former owners in paragraph (2) because public institutions do not have former owners. Similarly, these commenters suggested clarifying that paragraph (3) does not apply to public institutions.

*Discussion:* The Department disagrees. HEA section 101(a)(4) specifically defines an ''Institution of higher education'' as a public or ''other'' nonprofit. In referring to ''other'' nonprofit organizations, Congress made clear that the public institutions it was referring to were also nonprofit organizations. We also disagree that paragraphs (2) and (3) should not apply to public institutions. It is possible that there could be prior owners if an institution converts from proprietary to public status.

*Changes:* None.

*Comments:* One commenter argued that the Department should refer to nonprofit institutions as being ''controlled'' rather than ''owned or operated'' since nonprofit entities are not typically owned. They argued that it is more common for one nonprofit entity to exercise control over another rather than own it.

*Discussion:* Institutions are owned by entities regardless of whether a nonprofit entity that owns an institution is owned by others.

*Changes:* None.

*Comments:* One commenter recommended that if an institution can show that the transaction has been reviewed by a State agency that oversees nonprofit entities, this should suffice as proof that no excess benefit was provided to former owners. This commenter further stated that a fairness opinion that looks at transactions holistically should provide the Department with sufficient comfort that there is no excess benefit and that the transactions contemplated are at fair market value. The commenter provided suggested regulatory text for their suggestions.

*Discussion:* The Department disagrees with the commenter. The commenter provided an indication of one State that does such reviews. It is unclear, however, if that State's review would examine the same situations that concern us. We seek to ensure that an institution is a nonprofit solely for the

purposes of the HEA programs that we administer. It is also unclear how many States conduct similar reviews.

The Department also disagrees with simply accepting a fairness opinion. The fairness opinion would not guarantee that it addresses all the issues that we need to consider in our review of the CIO for title IV purposes. We have sufficient expertise and resources to review and analyze materials submitted in support of a transaction (including market valuation or appraisals) and do not currently plan to defer to conclusions reached by outside parties.

*Changes:* None.

*Comments:* Several commenters argued for providing additional limitations on the situations in which agreements with prior owners would not be acceptable. They argued that the excess benefit should have to be material or provided to an owner who had a certain percentage ownership stake in the institution. Another commenter argued that there could be situations in which the net earnings of the institution benefit a prior owner, but it should not be unlawful. They provided an example of transactions in which a buyer pays the seller back over time or finances the purchase.

*Discussion:* If the relationship with the prior owner is a debt obligation, it precludes nonprofit status. Other agreements will be evaluated in the context of market rates or actual costs for any services and whether the agreement is at arm's length.

*Changes:* None.

*Comments:* Commenters requested clarification whether the Department will apply the same reasonableness standard to evaluate the revenue-sharing arrangements with the persons or entities referenced at paragraphs (2)(ii)(A) and (2)(iii)(A) and paragraphs (2)(ii)(B) and (2)(iii)(B). Some commenters requested clarification regarding why we use a different standard for market analysis of revenue-sharing arrangements than the standard for market analysis of leases and other agreements. These commenters also requested clarification on what each standard means and how the standards differ.

*Discussion:* The difference in the language between paragraphs (2)(ii)(A) and (2)(iii)(A) and paragraphs (2)(ii)(B) and (2)(iii)(B) is due to the difference between revenue-sharing agreements and other types of agreements. The same reasonableness standard will apply in both cases, but the differences in the types of agreements will affect the factors we review in making our determination.

*Changes:* None.

*Comments:* Commenters recommended excluding charitable grants and contributions from consideration as revenue sharing agreements, as fundraising can extend to personal financial contributions. They raised concerns that conditional pledges or matching commitments might be considered revenue sharing. Additionally, according to these commenters, board members and former employees can gift conditional contributions such as matching gifts, donor-advised funds, and split-interest agreements to nonprofit institutions.

*Discussion:* It is not clear why charitable grants and contributions would be considered revenue-sharing agreements, but we will review all relevant information when determining whether an institution meets the definition of nonprofit.

*Changes:* None.

**Fair-Market Value Assessment (§ 600.2)**

*Comments:* We received a number of comments related to determining fair market value, including how that relates to restrictions on agreements with former owners.

Some commenters stated the Department needs to further strengthen oversight over market price. Other commenters requested clarification on how we will determine ''market price,'' what factors we will to do so, what evidence we will use to evaluate reasonableness or fair market value, as well as to provide the relevant statutory authority. Some requested that we include the factors used to determine market price in the regulations. Relatedly, commenters recommended that institutions be able to submit specific documentation such as valuations, appraisals, and market studies to demonstrate fair market value while another asked for clarity on what documentation schools will be required to submit.

Some commenters suggested that the market assessment would pose a barrier to future business relationships or mergers between proprietary institutions and nonprofit or public institutions.

Some commenters recommended that the regulations should not require the Secretary to determine market price for arrangements or transactions between existing nonprofit institutions. These commenters stated the application of these regulations to existing nonprofit institutions outside the context of conversions will have a chilling effect on transactions between existing nonprofit institutions. They further recommended that all such agreements can be deemed permissible if there is a determination that the terms are reasonable.

*Discussion:* As already noted, we have performed and will continue to perform a review of materials submitted by parties to a transaction so we can ensure that the transaction does not violate the Department's definition of nonprofit. To restrict our consideration to tangible assets alone is not tenable because intangible assets affect an institution's value and the reasonableness of consideration paid for a transaction. However, we will continue to carefully scrutinize inflated intangibles when analyzing valuation studies submitted to support requests for nonprofit status.

The Department does not intend to halt all valuations before further considering the GAO report. Moreover, the GAO report found that we had strengthened our CIO process. Additionally, there are no current processes for the IRS to engage with us on specific cases when we conduct our review to determine whether an institution is a nonprofit for the purposes of participating in programs under the HEA. As noted in the GAO report, we have conducted a rigorous and substantive analysis since 2016 to determine whether an institution is a nonprofit for the purpose of participation based on the pertinent regulations and does not depend solely on whether an institution is a 501(c)(3) organization under the IRC—which is only one of the requirements under the existing regulations.

To remove the allowance for market-value agreements between institutions and affiliates of former owners would eliminate the possibility for arrangements that are beneficial for all parties, so we will retain that allowance.

The Department sees no persuasive evidence that expecting parties engaged in a CIO ensure that the sums being paid represent a fair market valuation will chill beneficial and appropriate requests for nonprofit status. Taking control of an institution can carry significant expense. Overpaying for a transaction in the short-term or through long-term could hamper the ability of the new owner to make any necessary investments in educational instruction and quality. We see no evidence that requiring parties to a transaction to demonstrate that the transaction is based on an assessment of fair value is a burdensome requirement. Moreover, this comports with standard expectations for due diligence in an arm's length transaction. We are eager to review ownership changes and requests for nonprofit status in a way that is fair and beneficial for all parties in the

transaction, as well as for students and taxpayers.

*Changes:* None.

*Comments:* Commenters argued that if the agreement is determined to be offered at or below the fair-market value the Department should not restrict how that price is financed. They argued that if the former owner offers better financial terms on a fair-market price transaction we should allow it, and the word ''generally'' should permit such cases and not rule out all debts to former owners.

*Discussion:* It is not unusual to see the pricing for a CIO to be structured in a way that long-term value accrues to the former owner through financing arrangements or through restrictive service agreements. While we will not approve owner-financed arrangements as nonprofit, we intend to evaluate other arrangements between the parties that impact the valuation of the CIO, including longer-term requirements that may limit an institution's resources or inhibit its ability to enter into arm's-length transactions with other parties.

*Changes:* None.

*Comments:* Commenters argued that the Department should not simply assume that a revenue-sharing agreement between an institution and a former owner is acceptable just because it is offered at a fair-market value. They argued that the concern about revenue sharing is not just the price, but the incentives it creates for the institution with respect to its former owner. They argued that the regulations should specifically state that there could be certain circumstances when revenue-sharing agreements that are at a fair-market price could still not be allowed. The commenters also suggested explicitly stating that debt agreements that are related to an institution's profits or revenues are not allowable, nor would debt instruments that limit the institution's ability to set policy or priorities be allowable.

*Discussion:* We agree that evaluating long-term arrangements between the seller and purchaser in a CIO is essential to evaluating the transaction. The examples the commenter highlighted are why the regulatory language intentionally uses the market price as an instance that may allow for an agreement for a prior owner. Because this language is not definitive it would provide the flexibility that the commenter requests for denying such arrangements if a thorough review of the specific details of the CIO merits it.

*Changes:* None.

*Comments:* Some commenters argued that the limitations on revenue sharing with prior owners should also be extended to cover successor owners or assignees. They argued that without this criterion, a former owner would simply sell the agreement to another entity and continue to profit.

*Discussion:* We disagree with the commenters that any regulatory changes are needed to address this issue. The regulatory text captures any relationship with the prior owner. This would capture the assignment of the contract to another individual or entity.

*Changes:* None.

*Comments:* Commenters argued that the Department should apply a fair market test to all other agreements used by schools to ensure they are reasonable. One commenter pointed to agreements with football coaches who may be receiving private inurement and excess benefits as an example of a transaction to evaluate.

*Discussion:* We do not believe the commenters' examples are analogous to other types of arrangements captured in the definition of a nonprofit. The commenter offers no evidence that the arrangements with football coaches would represent a revenue-sharing agreement or an obligor to a debt owed to a former owner.

*Changes:* None.

*Comment:* One commenter argued that we should eliminate the option for an allowable revenue sharing agreement with a former owner if it is based upon market price. They argued that the Department should specify that it be the *nonprofit* market price if we retain this option.

*Discussion:* We disagree with the proposal to eliminate the consideration of agreements based upon market price. With respect to the nonprofit market price, we do not think such a requirement is appropriate. We believe the requirement that the terms of the revenue-sharing agreement are reasonable based upon the market price and that price bears a reasonable relationship to the cost of the services or materials provided provides us enough flexibility to ensure that institutions are unable to engage in the kind of transactions we have seen in the past that has allowed former owners to impermissibly profit from a CIO.

*Changes:* None.

**90-Day Reporting Requirement (§ 600.20)**

*Comments:* Some commenters supported the addition of a 90-day notice requirement. Others requested further clarification on how the Department determined the 90-day window for the notice requirement. Some commenters suggested that 90 days would not provide the Department sufficient notice and adequate time to review proposed transactions. One of these commenters suggested that notice should be provided 120 days in advance. Commenters requested clarification on the elements, requirements, and provisions required for notifications to be compliant.

Other commenters requested clarification on the consequences of an institution failing to submit a notice or meet other application timelines.

Some commenters supported the 90-day notice requirement but wanted further clarification on how the Department will respond once it has received notice. Commenters requested clarification on whether this pre-acquisition review would be an abbreviated pre-acquisition review (APAR) or comprehensive pre-acquisition review (CPAR) and what happens if we do not respond within the 90-day period. Commenters asked how this requirement would alleviate the issues the Department has raised with regard to staffing and making timely decisions on transactions. Commenters also asked why we settled on 90 days as the amount of requested advance notice.

Commenters recommended that the Department issue a pre-acquisition review letter prior to the proposed closing date that identifies whether the new owner will be required to post a letter of credit and identifies any impediments to the approval of the change and conditions that the Department might impose if it approves the school's eligibility under the new ownership or structure. Commenters suggested that having this information prior to closing benefits the current and future owners as well as students who may be harmed by adverse actions taken by the Department that may have been avoided if information was provided to parties prior to closing.

Commenters recommended that to avoid disputes occurring after a CIO has been closed, issues such as qualifications of a business appraiser, the appropriateness of a valuation methodology and then the acceptability of the results of a valuation process are all matters that a nonprofit buyer should be able to present to the Department in advance of the closing of the nonprofit buyer's purchase of the assets of an institution without resetting the 90-day clock. The commenters also argued that these items should be added to a pre-closing validation review process. Some commenters stated that the proposed process has the potential to greatly prolong the transaction review and recommended the 90-day timeframe should only reset for a substantive

change. Another suggested that the clock should not reset if there is a change to the ownership structure.

One commenter suggested that the Department should provide a contingency that allows the waiving of the 90-day advance notice requirement for an institution that is in financial distress.

*Discussion:* The purpose of the 90-day notice is to prevent an institution from being in a situation where there is little time for the Department to consider the change in ownership and the institution is put into a title IV-ineligible status, even if temporarily. Ninety days is not the amount of time in which we will conduct a review of the proposed CIO. We believe the 90-day period is important for adding structure to the CIO process and setting proper expectations. Too often to date the Department has reviewed numerous proposed CIO options with an institution over a period of months, only to be presented with a completely new proposal just days before (or even after) a transaction closes. It is not unusual for an institution or its counsel to ask us for guidance on a proposed CIO just a few weeks or even days before a scheduled closing. Such an approach wastes resources for the Department and the institutions. It can also cause confusion over what elements have or have not been reviewed. Providing clearer structure and having institutions give the Department 90 days advance notice will make the CIO process work better for all involved. Failing to provide this timely notice could result in a period of title IV ineligibility for an institution.

Institutions that wish to have more information about what the Department expects may also submit a preacquisition review request separately from the 90-day notice—and may do so well in advance of the notice. Because we have ended CPARs, this would be an abbreviated review. See the September 15, 2022, Electronic Announcement on *https://fsapartners.ed.gov/knowledge-center* for more information. The abbreviated review would inform institutions whether a new owner letter of credit will be required to meet the requirements of a materially complete application.

The Department declines to provide any exceptions for the 90-day advance notice. In the Department's experience, it is highly unusual for an institution to face financial distress where the CIO plans are solidified at least 90 days prior to the CIO. The institutions that have financial struggles typically have been in situations where the CIO structure was unsettled prior to the transaction taking place.

The required elements for the 90-day notice are provided in paragraphs (g)(1)(i) and (iii) of § 600.20.

Institutions should include all relevant information available to them when they provide their initial notice. This will prevent the 90-day clock from resetting and prolonging the process; an institution would have an incentive to submit rough proposals that end up not resembling the ultimate transaction, which would defeat the purpose of the advance notification.

*Changes:* None.

*Comments:* A few commenters stated the 90-day advance notice and requiring the institution and its new owners to provide the materially complete application within 10 days after the CIO are duplicative. Commenters argued that some of the information requested for the 90-day advance notice is more detailed than it needs to be at this stage of the process. The commenters noted that we currently request a lot of detailed information even though we only evaluate if we are going to request a letter of credit based upon the new owner's financial statements. Similarly, a commenter argued that the Department should more clearly specify what we need for the 90-day advance notice versus the post-acquisition application. They also argued that information provided on the 90-day advance notice should not need to be duplicated on the post-acquisition application. For example, they argued that if the institution provided evidence of its State license in the 90-day advance notice then the post-acquisition should only need to show that such license remained in effect as of the day before the change in ownership.

*Discussion:* The Department does not think it is necessary to change to the regulatory text any further. Where an institution provides the same information on the 10-day post-acquisition application that it provided on the 90-day advance notice, it could submit copies of what it already provided. We do not think it would difficult or burdensome for an institution to resubmit documentation that it has already provided. Additionally, it establishes that any changes to that information must be reported and ensures that all necessary documentation is in one place.

*Changes:* None.

**Student Notification (§ 600.20(g)(4))**

*Comments:* Some commenters stated that providing notice to students of a potential CIO would cause undue stress and confusion, noting most students are unaware of school ownership and are not interested in that information. Commenters further stated that students may interpret the notice as negative news about the institution and therefore choose not to enroll or to withdraw without completing their program. These commenters recommended that the institution receiving a preacquisition review letter provide evidence to the Department within 10 days that it has either notified students of the proposed CIO or formally notified the Department that the proposed transaction is being terminated. Institutions often do not continue with the CIO, which according to these commenters, is another reason not to require student notification so early in the process. Other commenters recommended notice be provided on the earlier of 10 days prior to the CIO or within 10 days after receipt of any required pre-closing accreditation approval and receipt of a pre-acquisition review response. Another commenter suggested that the Department require notice to students closer to when the transaction will be completed but did not specify a date. A different commenter suggested the institution should inform the Department no later than 2 business days before closing and provide proof of student notification at the same time. Some commenters recommended that the Department eliminate any student notification requirement or require the notification after the transaction is complete.

Commenters also asked if a banner or other type of announcement on an institution's website would be sufficient to notify students.

*Discussion:* We disagree with the commenters that a notification to students is inappropriate. While many students may not be concerned with who owns their school, some are. We believe this notification is as necessary as those made to consumers who receive a notification that their mortgage is being transferred to a new lender. Students have a right to know where their money is going and, in this case, who owns the school they attend.

We appreciate the suggestions from the commenters about multiple options for when to require notice to students. However, we disagree with the suggestions to provide notice either after the transaction or just a few days before it occurs. Providing notice so late in the process diminishes the usefulness of the notification, would act as an unfair surprise to students, and would provide them little time to consider whether it affects their plans for enrollment.

We believe that it is best to align the student notification requirements with those for notifying the Department. Doing so ensures that institutions

provide consistent information and that students have more time to consider their options. As articulated elsewhere in this final rule, part of our goal with these regulations is to ensure that there is a more structured process for CIOs and fewer instances in which institutions have to resolve significant issues before closing transactions. We believe this approach will mean that agreements will be further along by the time institutions approach the Department and will contain greater detail than they might have in the past. This will also reduce the likelihood that institutions need to inform students about CIOs that do not occur.

Regarding the requirements for making the student notification, institutions must inform students individually via email or some other method of the proposed change in ownership. Electronic notifications provided directly to individual students would be acceptable, but a simple message on a web page would not be sufficient.

*Changes:* None.

**Temporary Provisional Program Participation Agreements (§ 600.20)**

*Comments:* Commenters supported clarifying the Department's ability to withdraw title IV eligibility based on a review of a change in ownership. They also supported the Department adding conditions to an institution's TPPPA when a prospective owner of the institution does not have sufficiently acceptable audited financial records. Commenters recommended that we include additional financial and regulatory conditions, such as heightened cash monitoring 1 or 2, into TPPPAs. Commenters further recommended that when for-profit institutions convert to nonprofit status, we should continue to consider them as for-profit institutions until the Department has made a decision on the conversion. The commenters noted that this should include being subject to 90/10 and meeting the statutory requirement to show that their programs prepare students for gainful employment in a recognized occupation. Some commenters recommended an institution may only participate under a provisional PPA for a total consecutive period of 3 years and at the expiration, the institution must have executed a non-provisional PPA with the Department.

Other commenters argued that institutions must know what conditions they would be subject to before an acquisition is completed and should receive notice of any TPPPA conditions prior to the transaction closing. They said institutions would not be able to plan for unknown conditions and said such a situation would have a chilling effect on transactions. These commenters expressed concern that more limited pre-transaction review will only lead to more prolonged post-transaction review before ultimately issuing a provisional PPA. These commenters recommended institutions not subject to growth restrictions due to a CIO, or institutions that were subject to growth restrictions but have since provided acceptable new owner financial statements, may apply to remove such restrictions while the post-transaction review is pending. These commenters further recommended that we should review and act on substantive change applications in the ordinary course and without waiting to complete our CIO review.

*Discussion:* The nature of CIO reviews and the contents of TPPPAs depend on the unique aspects of each case. Because of this, automatic inclusion of certain conditions is not justified. However, the Department agrees that it makes sense that for-profit institutions seeking to convert to nonprofit status should remain as for-profit until we approve a conversion. The Department amended § 600.31(d)(7) accordingly. Making this change will result in any conditions that are associated with being a private for-profit institution, such as the 90/10 rule or demonstrating that programs provide gainful employment in a recognized occupation, will continue.

We believe it is beneficial to be able to issue new TPPPAs after the initial TPPPA for a CIO approval has ended on a case-by-case basis if the situation warrants it.

As we improve the CIO review process through these regulations, institutions should see increased efficiency and clarity in the process. The goal of these regulations is that by providing more detail in the regulations, the Department will be able to direct its resources toward reviews that result in a transaction ultimately occurring. This is in opposition to our current practice where it is not uncommon for the Department to conduct detailed reviews of multiple proposals for a single institution, none of which end up being what the final transaction looks like. Spending less time on reviews that do not result in a transaction will free up resources to expedite the overall review process and address the concerns of commenters about added delays.

As we discuss in various places in this rule, the CIOs the Department receives are increasingly complicated and require a significant amount of time to review. Accordingly, it would not be feasible for us to inform institutions about what TPPPA conditions we might require based solely on the application received 90 days before closing. The Department notes the risks institutions mention here are no different than what exists today, where we must currently decide whether title IV aid should continue after the transaction and there is a possibility that we could terminate Federal financial aid after the transaction occurred.

We disagree with commenters that institutions that are subject to growth restrictions or request a substantive change should be able to apply to have those restrictions removed or the change approved while the post-acquisition review is ongoing. We are concerned that removing a growth restriction or approving such a change that may not ultimately allow title IV aid to continue would risk increasing the number of students who must then find another institution that accepts Federal aid or that institutions might then try to argue that disapproving aid would be unfair to the newly enrolled and existing students. Institutions are not entitled to operate at a particular size or make substantive changes while we review their CIO application.

*Changes:* We clarify in § 600.31(d)(7) that for-profit institutions undergoing a change in status to nonprofit will remain in for-profit status until the review is complete.

**State Authorization and Accreditation Approvals (§ 600.20)**

*Comments:* Commenters agreed with having the most recently granted State and accrediting agency approvals readily available for the Department's review of a materially complete application. However, they stated that the requirement to provide this information as of the day before the CIO is overly burdensome and may be hard to obtain from States or accreditors. Commenters recommended the Department require institutions certify that approvals they submitted are current, up-to-date, and not withdrawn.

Commenters requested clarification on what constitutes acceptable supplemental documentation demonstrating an approval was in effect the day before a CIO occurred. Commenters suggested a signed letter on agency letterhead would suffice, but the 10-day requirement would pose difficulties. Commenters recommended meeting this requirement with either an email from the agency or a screenshot from the agency's website obtained no earlier than the day before the CIO. Other commenters raised concerns about the ability to obtain this

documentation from multiple states since some require approval to be obtained after the transaction goes through. They provided regulatory text to address this concern.

Some commenters argued that the Department should only have to provide evidence of the most current grant of accreditation or State licensure. Others argued for an extension if the institution could show it tried to get the documentation but has yet to receive it from the agency.

*Discussion:* The Department will consider whatever documentation is presented by institutions to show the requisite approvals have been met. Section 600.20.(g)(3)(i) states that the day-before evidence of approval supplements the documentation the institution submits as part of a materially complete application.

We believe the commenter concerned with different State and accrediting agency approvals misunderstood the requirement. The Department is requiring documentation that the institution has the required State approval and accreditation as of the day before transaction—not documentation reflecting the CIO. The concerns about post-acquisition approval should not be relevant.

We believe the documentation showing the State licensure (or equivalent authorization) and accreditation were in effect the day before the transaction is critical to maintain. Doing so provides safeguards regarding the institution's eligibility that would not be present if such approvals had lapsed.

We disagree that we should provide for any extension if an institution attempts but has yet to obtain documentation. A CIO involves the potential continued flow of as much as tens of millions of taxpayer dollars a year. Institutions should obtain and submit all necessary documentation timely.

*Changes:* None.

**Audited Financial Statements (§ 600.20)**

*Comments:* One commenter argued that the requirement to submit audited financial statements for the last two completed fiscal years would force transactions to only occur during a set period. The commenter argued that institutions would not have audits finished until several months after the end of the fiscal year, depending on if the auditing schedule was under the institution's control. The commenter recommended instead that we require the two most recently completed financial statements plus an audited current balance sheet if the Department desired.

*Discussion:* We disagree with the commenter. We are not persuaded that it is more important for an institution to be able to complete a transaction when it wants than for the Department to ensure that the continued flow of potentially tens of millions of taxpayer dollars is going to institutions in sufficient financial shape. Accepting the commenter's proposal would risk receiving financial statements that are months and perhaps close to a year out of date. For institutions that are highly dependent upon tuition and meeting enrollment targets, that time gap could result in a meaningfully different financial picture. Moreover, except in very rare cases where an institution is at risk of a precipitous closure, there is no reason to rush a change of ownership transaction. The CIO process will be better served if transactions are well thought through and developed. If doing so means waiting to ensure we have up-to-date financial information, we see no significant downside.

*Changes:* None.

**Financial Protection (§ 600.20)**

*Comments:* Commenters stated the Department should provide the elements, bases, and factors to determine the amount of financial protection. Commenters further stated the Department should provide the factors used to determine when a 25 percent or 10 percent surety is insufficient.

Several commenters recommended requiring at least a 50 percent letter of credit when an owner does not have prior audited financial statements. One commenter argued that it is legally required to ask for a 50 percent letter of credit. Commenters recommended raising letter of credit requirements from 25 percent to 50 percent for owners who cannot demonstrate financial responsibility.

Some commenters stated the proposed financial protections and past practices are unlawful because of financial responsibility requirements elsewhere in the HEA. These commenters stated neither 10 percent nor 25 percent equal the fifty 50 percent requirement set forth in the HEA, presumably referring to the 50 percent requirement for financial responsibility set forth in section 498(c)(3) of the HEA, which bases the surety amount on ''prior year volume of title IV aid'' rather than on ''annual potential liabilities.'' One commenter said that the 10 percent or 25 percent amount for an LOC fails to account for the true costs of potential discharges, which often span well beyond the ''prior year'' volume of title IV aid. Another commenter argued that the Department should require at least a 25 percent letter of credit for institutions that had one but not two years of audited financial statements and a 50 percent letter of credit for institutions that had no audited financial statements.

Other commenters argued that the Department should not allow for the possibility of requiring additional letters of credit after a transaction closes because it would chill transactions. They argued that the Department was not clear if institutions that have a CPAR or APAR pending or submitted after the rule change will be notified of an additional letter of credit during the pre-acquisition review.

Some commenters also objected to basing letters of credit on the volume of title IV aid received by institutions under common ownership. They argued that those institutions are not related to the transaction and that those other institutions are already subject to financial responsibility requirements.

*Discussion:* The 10 percent and 25 percent protection amounts codify the current practice by the Department to specifically address a new owner who does not have acceptable financial statements to meet the audited financial statement requirements for a materially complete application following a CIO. As noted in the NPRM, the Department believes that there may be situations where additional financial surety is needed to ameliorate financial or administrative risk based upon a case-by-case determination. This would reflect situations such as when a much smaller institution acquires a much larger one. For situations like that, a letter of credit requirement based only on the title IV volume of the smaller institution would severely underestimate the financial risk that the transaction presents. With respect to the comment that said the minimum requirement must be 50 percent, the financial protection addressed in the regulation is not the financial protection required when an institution fails to meet the financial ratios described in the HEA. As such, the Department does not consider the requirement to be either unlawful or insufficient—it requires a separate element of surety when a new owner does not have two years of financial statements to meet the requirements of a materially complete application. A failure to meet the financial ratios is addressed in the financial responsibility regulations in subpart L.

There is significant variation in CIOs, as no two deals will have the same

terms, ownership structures, or other elements. The variability in CIOs thus necessitates a more flexible approach than might exist for other situations, such as what kinds of conditions the Department should enforce when an institution fails a financial responsibility score. As a result, adding financial conditions, including heightened cash monitoring, depends on individual cases and is not appropriate for a rule that applies more broadly.

*Changes:* None.

**Updating Application Information—5 Percent Reporting Requirement (§ 600.21)**

*Comments:* Commenters suggested that the 5 percent ownership reporting requirement is unlikely to result in more meaningful visibility. Commenters requested further clarification on the determination that the cost of the reporting burden will be minimal. They stated that there are frequent and inconsequential changes to owners of institutions with low percentages of ownership, and such owners typically have no role in the operations of the institution. Commenters further stated that the low threshold of the reporting requirement will create compliance issues and additional administrative burden to update electronic applications. These commenters recommended that the requirement not apply to passive investors such as those individuals or entities who invest in a fund that is actively managed by a partnership. These commenters stated these investors have no role in the control or operations of an institution or any entity in an institution's ownership structure and recommended the Department maintain the current 25 percent reporting requirement. One commenter suggested that the 5 percent requirement should only apply to voting ownership. One commenter noted that such minor changes could occur a few times a month. Other commenters recommended the reporting requirement should be increased to 10 percent to better capture voting interests and not require reporting of purely financial interests.

Some commenters recommended the alignment of §§ 600.21 and 600.31 by incorporating details on change in control into § 600.31. The commenters suggested that the reporting requirements in § 600.21 could simply cross-reference the events described in § 600.31 that the Department wants an institution to report.

Commenters asked what specific evidence and experience the Department relies on about CIOs that institutions seek to evade Department oversight.

*Discussion:* As has been noted, we expect the new 5 percent reporting requirement will increase visibility into the ownership of institutions in a way that is not burdensome. This will allow the us to obtain more information without greatly increasing burden on schools. When combined with the considerable decline in burden from the change to the 50 percent review threshold, we will have more insight while allowing for an overall burden reduction.

The Department disagrees with suggestions to limit reporting to non-passive investors or those with voting interests. We believe that would increase burden as it could result in arguments between schools and the Department about what constitutes a passive owner. Moreover, the Department believes a more complete view of all ownership is important. This type of reporting will also make it possible for the Department to see acquisition of ownership over time, such as someone who steadily acquires shares until they become a 50 percent owner.

While the Department maintains that this information is important, we agree that it is not critical to obtain it on the same timeline as other information mentioned in this rule. Accordingly, we are adjusting the reporting timeline for these types of changes to require institutions to report them every quarter.

*Changes:* We adjusted § 600.21(a)(6)(i) to shift the 10-day reporting requirement to quarterly based on the institution's fiscal year for changes representing at least 5 percent but under 25 percent (either on a single or combined basis). However, when an institution plans to undergo a change in ownership, all unreported ownership changes of 5 percent or more in the existing ownership must be reported prior to submission of the 90-day notice. Thereafter, any changes of 5 percent or more in the existing ownership must be reported within the 10-day deadline, up through the date of the change in ownership.

**Automatic Recertification (§ 600.20)**

*Comments:* Commenters requested clarification on the interaction between the proposed changes to § 600.20(h), which explains the requirements for an extension of a temporary provisional program participation agreement and § 668.13(b)(3), which provides an automatic recertification. Commenters stated the Department proposed deleting § 668.13(b)(13) in negotiated rulemaking, but the deletion was not included in the proposed regulation.

*Discussion:* The month-to-month extension of the temporary approval for the duration of the review of the CIO application is unrelated to the provisional certification periods in § 668.13.

*Changes:* None.

**Fifty Percent CIO Review Threshold (§ 600.31)**

*Comments:* Commenters recommended the Department maintain the 25 percent CIO review threshold. These commenters stated that the Department should maintain the current review threshold because there are so few CIOs and owners might try to purposefully avoid scrutiny by acquiring an ownership interest just below the 50 percent threshold. They expressed concern that even at or below 25 percent, an owner or group of owners could exert effective control over an institution as long as no other owner has a similarly large ownership share. Other commenters stated that to determine whether any of the transactions at the 50 percent or above threshold are really hiding a genuine change of control, the Department will need to review them anyway and may not find the heightened limits alleviate the workload or sharpen the focus.

Some commenters stated that the Department has not sufficiently explained why the 50 percent threshold is appropriate. These commenters also noted that the assertion that a 25 percent threshold is too burdensome is not sufficient to justify a 50 percent threshold.

Although these commenters expressed concern related to loosening the standards, they recommended a 35 percent threshold, standing alone, or combined with a 20-percent standard for related parties, which is in line with the IRS. Other commenters recommended that we amend the regulations to better capture written voting agreements and include language to not include temporary proxies given for a particular meeting or part of a meeting.

Other commenters supported the 50 percent threshold and recommended eliminating the addition or removal of an entity that submits financial statements to satisfy financial responsibility requirements as an automatic CIO resulting in a change in control.

*Discussion:* It has been the Department's experience that changes in control typically do not occur at the 25 percent level. Therefore, we can eliminate considerable unnecessary

burden for the Department and institutions by increasing this threshold to 50 percent. This standard comports more with our experience than the current 25 percent standard or the suggested 35 percent IRS standard. Voting agreements and proxies are considered on a case-by-case basis. Moreover, the 50 percent threshold only mandates when a CIO review must occur. The regulations make clear that levels below 50 percent will be subject to the CIO regulations when a change of control occurs despite being under the 50 percent threshold. The enhanced reporting requirements under § 600.21 will allow the Department to monitor these potential shifts in control more closely.

The entity that submits financial statements is key to the financial strength of the institution. That is typically the highest level of unfractured ownership, but we want to ensure that we maintain flexibility for other circumstances.

*Changes:* None.

**Executive Orders 12866 and 13563**

*Regulatory Impact Analysis*

Under Executive Order 12866, the Office of Management and Budget (OMB) must determine whether this regulatory action is ''significant'' and, therefore, subject to the requirements of the Executive order and subject to review by OMB. Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities in a material way (also referred to as an ''economically significant'' rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

The Department estimates the quantified annualized economic and net budget impacts to be $835 million, consisting of an $879 million net increase in Pell Grant transfers and $-44.3 million reduction in loan transfers among students, institutions, and the Federal Government, including annualized transfers of $82.7 million at 3 percent discounting and $81.9 million at 7 percent discounting. Most of these transfers are due to statutory changes made by Congress that are addressed by these regulations. Additionally, we estimate annualized quantified costs of $3.4 million related to paperwork burden and $1.1 million of administrative costs to the government. Therefore, this final action is ''economically significant'' and subject to review by OMB under section 3(f) of Executive Order 12866. Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as a ''major rule,'' as defined by 5 U.S.C. 804(2). Notwithstanding this determination, based on our assessment of the potential costs and benefits (quantitative and qualitative), we have determined that the benefits of this regulatory action will justify the costs.

We have also reviewed these regulations under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only on a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include ''identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.''

We are issuing these final regulations to address inadequate protections for students and taxpayers in the current regulations and to implement recent changes to the HEA. In choosing among alternative regulatory approaches, we selected those approaches that maximize net benefits. Based on the analysis that follows, the Department believes that these regulations are consistent with the principles in Executive Order 13563.

We have also determined that this regulatory action would not unduly interfere with State, local, and Tribal governments in the exercise of their governmental functions.

As required by OMB Circular A–4, we compare these final regulations to the current regulations. In this regulatory impact analysis, we discuss the need for regulatory action, potential costs and benefits, net budget impacts, and the regulatory alternatives we considered.

1. Need for Regulatory Action

The Department has identified a significant need for regulatory action to address inadequate protections for students and taxpayers in the current regulations and to implement recent changes to the HEA.

Pell Grants for Confined or Incarcerated Individuals

In the Consolidated Appropriations Act, 2021, Congress added a new provision allowing confined or incarcerated individuals to access Pell Grants for enrollment in approved PEPs. Regulatory changes are necessary to implement the law and to ensure access to high-quality postsecondary programs for incarcerated individuals. Among existing higher education programs in prisons, there is considerable variation in available resources, operational requirements, and the depth of stakeholder partnerships they have established.[11] Research shows that high-quality prison education programs increase learning and skills among incarcerated students, and increase the likelihood of stable employment post-incarceration.[12] Individuals who were

[11] Castro, E.L., Hunter, R.K., Hardison, T., & Johnson-Ojeda, V. (2018). ''The Landscape of Postsecondary Education in Prison and the Influence of Second Chance Pell: An Analysis of Transferability, Credit-Bearing Status, and Accreditation.'' *The Prison Journal, 98*(4), 405–26. *https://doi.org/10.1177/0032885518776376.*

[12] Ibid.

formerly incarcerated face significant challenges in finding employment when returning to their communities. Many lack vocational skills and have little or no employment history, leading to high rates of unemployment and low wages for these individuals.[13] In a study funded by the U.S. Department of Justice, researchers found that postsecondary correctional education programs are highly cost-effective, and can help incarcerated individuals reenter the employment arena and reduce recidivism.[14]

The Department has explored postsecondary education for incarcerated individuals through its Second Chance Pell experiment, first announced in 2015.[15] The goal of the experiment has been to learn about how Federal Pell Grant funding expands postsecondary educational opportunities for incarcerated individuals and explore how such funding fosters other positive outcomes.[16] Data reported to the Department indicate that recipients of Second Chance Pell Grants successfully completed a high percentage of the credits they attempted.[17] The institutions participating in the Second Chance Pell experiment reported that their programs had positive effects related to public safety, as well as safe working and living conditions in their carceral facilities. Further research has illustrated that correctional education programs contribute to successful rehabilitation and subsequent reentry for those who were incarcerated, thereby improving safety within the facilities that offer postsecondary programming and recidivism and public safety outcomes overall.[18]

Correctional education can offer rehabilitation to incarcerated individuals, because the programs are able to capitalize on acquired education and skills. Soft skills in particular, such as communication and interaction with others, are a significant benefit of correctional education.[19] In one study of correctional education in Delaware, the surveyed participants noted that the program provided ''credentialing and a variety of skills . . . that they may not otherwise have obtained due to lack of confidence, missing opportunities to participate in educational programs offered in the community, [and] incapability of making time to commit to such programs outside of incarceration.'' [20]

The Department's framework for PEPs will clarify and implement statutory requirements for the benefit of incarcerated individuals and other stakeholders, including correctional agencies and institutions, postsecondary institutions, accrediting agencies, and related organizations. Our final regulations clarify definitions of confined or incarcerated individuals and PEPs that align with the statute. These regulations clarify the processes that the oversight entity (including a State department of corrections or the Bureau of Prisons) will follow in determining whether a PEP is operating in the best interests of the students. Consistent with the statute, the final regulations will prevent proprietary institutions or institutions subject to certain adverse actions from offering PEPs. These final regulations also provide protections for incarcerated individuals against programs that do not satisfy applicable licensure or certification requirements or where such students are typically prohibited under Federal or State law from employment in the field due to the nature of a student's conviction. Under the final rule, institutions must disclose whether their program is designed to lead to occupations in which formerly incarcerated individuals typically face barriers in other States. These final regulations are designed to clarify how oversight entities can meet statutory requirements, and to guide PEP educational institutions and practitioners on access to, and eligibility for, Federal Pell Grants.

90/10 Rule

The ARP amended section 487 of the HEA to require that proprietary institutions count all Federal funds used to attend the institution as Federal revenue in the 90/10 calculation, rather than only counting title IV, HEA program funds. In FY 2021, proprietary institutions were eligible to receive funding from at least 26 non-title IV Federal programs. The largest two non-title IV, Federal programs with documented funding provided to proprietary institutions were Post-9/11 GI Bill education benefits, which accounted for approximately $1.3 billion in FY 2021, and the DOD Tuition Assistance program, which accounted for $185 million in that year. Some proprietary institutions have aggressively recruited service members and veterans in order to use funds from GI Bill education benefits and DOD Tuition Assistance to comply with the current 90/10 requirement since these funds helped offset title IV, HEA program funds in the calculation.[21]

In addition, the changes to § 668.28 modify allowable non-Federal revenue in the 90/10 calculation to better align the regulations with statutory intent and to address practices proprietary institutions have used to alter their 90/10 calculation or inflate their non-Federal revenue percentage. These combined changes include:

(1) Creating a new requirement for when proprietary institutions must request and disburse title IV, HEA program funds to prevent delaying disbursements to the subsequent fiscal year in order to reduce their Federal revenue percentage for the preceding fiscal year. The changes to the disbursement rules in § 668.28(a)(2) will prevent such practices.

(2) Clarifying the regulatory requirements that ineligible programs must meet in order to be included in the 90/10 calculation. The Department is concerned that these sources of non-Federal revenue may provide an incentive for institutions to create, offer, and market programs with little oversight or few consumer protections, or to create programs that bear little, if

[13] Coady, N.M. (2021). A Qualitative Evaluation of Prison Education Programs in Delaware: Perceptions of Adult Male Returning Citizens. *ProQuest Dissertations Publishing.* Retrieved from *www.proquest.com/openview/af55946da2d8d2213f500ffaa89a3102/1.pdf.*

[14] Davis, L., et al. ''How Effective is Correctional Education, and Where Do We Go From Here?'' Rand Corp. (2014). *www.rand.org/pubs/research_reports/RR564.html.*

[15] Department of Education Experimental Sites Initiative site, Updated June 8, 2022, *https://www2.ed.gov/about/offices/list/ope/pell-secondchance.pdf.*

[16] Second Chance Pell Fact Sheet. (n.d.). In *U.S. Department of Education. https://www2.ed.gov/about/offices/list/ope/pell-secondchance.pdf.*

[17] U.S. Department of Education. (2020, August). *Experimental Sites Initiative Second Chance Pell: Evaluation Report for Award Years 2016–2017 and 2017–2018.* Federal Student Aid. Retrieved from *https://experimentalsites.ed.gov/exp/pdf/20162018SecondChancePellESIReport.pdf.*

[18] Chesnut, K., & Wachendorfer, A. (2021, April). *Second Chance Pell: Four Years of Expanding Access to Education in Prison.* Vera Institute of Justice. Retrieved from *www.vera.org/publications/second-chance-pell-four-years-of-expanding-access-to-education-in-prison.*

[19] Bennett, B. (2015). ''An Offender's Perspective of Correctional Education Programs in a Southeastern State.'' *Walden Dissertations and Doctoral Studies.* 457. *https://scholarworks.waldenu.edu/dissertations/457.*

[20] Coady, N.M. (2021). A Qualitative Evaluation of Prison Education Programs in Delaware: Perceptions of Adult Male Returning Citizens. *ProQuest Dissertations Publishing.* Retrieved from *www.proquest.com/openview/af55946da2d8d2213f500ffaa89a3102/1.pdf.*

[21] See, for example, Hollister K. Petraeus, ''For-Profit Colleges, Vulnerable G.I.'s,'' *The New York Times* (Sept. 21, 2011), *www.nytimes.com/2011/09/22/opinion/for-profit-colleges-vulnerable-gis.html;* and For-Profit Higher Education: The Failure to Safeguard the Federal Investment and Ensure Student Success, U.S. Senate, Health, Education, Labor and Pensions Committee, Majority Committee Staff Report (Jul. 30, 2012), *www.help.senate.gov/imo/media/for_profit_report/PartI-PartIII-SelectedAppendixes.pdf.*

any, relationship to eligible programs subject to the 90/10 revenue requirement in order to increase the amount of non-Federal funds proprietary institutions receive in a fiscal year to comply with 90/10. The changes to § 668.28(a)(3) will prevent such revenue from being included to inflate the amount of non-Federal funds.

(3) Creating guardrails for ISAs and other financing agreements between students and proprietary institutions. Payments made by students or former students on institutional loans or alternative financing agreements currently count as non-Federal revenue in a proprietary institution's 90/10 calculation, and thus some proprietary institutions may have an incentive to encourage students to utilize these products, which may be more costly to borrowers and lack the same consumer protections as Federal student loans.[22] The addition of § 668.28(a)(5)(ii) will mitigate incentives for institutions to use these products to meet the 90/10 revenue calculation.

(4) Modifying revenue that must be excluded from the 90/10 calculation. The Department is modifying allowable revenue generated from institutional aid and funds that cannot be included in the 90/10 calculation to prohibit proprietary institutions from including revenue from the sale of ISAs, alternative financing agreements, or institutional loans in their 90/10 calculation. The revenue to the institution from these transactions is for an asset sale and not a payment by that party for the education provided by the institution as intended under the 90/10 revenue requirement. Thus, the Department does not consider funds generated from these sales as representative of funds paid to the institution for the purposes of education and training. The addition of § 668.28(a)(6)(vi) and (vii) will explicitly exclude proceeds from such sales from being counted as non-Federal revenue in the 90/10 calculation.

Finally, we also remove several outdated provisions, such as those related to the Ensuring Continued Access to Student Loans Act (ECASLA) of 2008.

Changes in Ownership

The Department has received a growing number of CIO applications in recent years. We processed over 150 transactions from October 2018 through the end of 2021; dozens more remain pending. Moreover, the CIO applications that we received and reviewed have been increasingly complex and require significant effort and expertise to review, particularly given that the current regulations are not always clear for institutions or the Department. Some of these CIOs include institutions converting from proprietary to nonprofit status, which further complicates the Department's review and presents a greater risk to students and taxpayers. Given this changing landscape of CIO applications, the Department needs to further clarify and define the CIO process to better protect students and taxpayers from potentially risky transactions, restrain profit-motives at the expense of student outcomes, and to provide the Department and institutions with clearer processes and regulations to mitigate loss and noncompliance. These improvements will enable the Department to identify high-risk transactions and require financial protection as needed.

Accordingly, these final regulations clarify the requirements for institutions undergoing CIOs, including by requiring adequate advance notice of such transactions to ensure the Department can assess the requirements of continued participation in the title IV, HEA programs prior to completion of the transaction. Further, these regulations will increase transparency into CIOs to better enable the Department to identify individuals with control over the institution, while reducing the burden of reviewing transactions in which a change in ownership is unlikely to result in a change in control. These final regulations also clarify that the Department may apply terms for continued participation in the Federal financial aid programs to ensure that we are able to take appropriate steps to protect students and taxpayers from risky transactions. Changes to the definition of a ''nonprofit institution'' will clarify the requirements for operating such institutions to prohibit enrichments to private parties, ensuring that proprietary institutions are not able to receive approval as nonprofit institutions without sufficiently addressing their business practices and the profit interests of former owners.[23]

To provide additional clarity to institutions and ensure consistency in the application of the regulations, the Department is also finalizing some technical changes to adjust the definitions of additional locations and branch campuses of the institution to conform with current practice and clarify how the Department views such locations.

2. Summary of Comments and Changes From the NPRM

| Provision | Regulatory section | Description of change from NPRM |
|---|---|---|
| **Pell Grants for Confined or Incarcerated Individuals** | | |
| Participation Percentage | § 600.7(c)(4)(i)(B) | Following the period described in paragraph (c)(4)(i)(A), no more than 75 percent of the institution's regular enrolled students may be confined or incarcerated. |
| Waiver | § 600.7(c) | Waiver will now be split into paragraphs separately addressing waiver grant and waiver denial. |

[22] See, for example, Loonin, D. (2011). Piling On: The Growth of Proprietary School Loans and the Consequences for Students. Student Loan Borrower Assistance Program at the National Consumer Law Center. Received from *www.studentloanborrowerassistance.org/wp-content/uploads/File/proprietary-schools-loans.pdf* and Consumer Financial Protection Bureau (Jan 20, 2022). Consumer Financial Protection Bureau to Examine Colleges' In-House Lending Practices. Retrieved from *www.consumerfinance.gov/aboutus/newsroom/consumer-financial-protection-bureau-to-examine-colleges-in-house-lending-practices.* Ritter & Weber 2021 *The Emergence of Income Share Agreements* Chapter 14 in Social Finance, Inc., Federal Reserve Bank of Atlanta, and Federal Reserve Bank of Philadelphia, Workforce Realigned: How New Partnerships are Advancing Economic Mobility. Risks identified include ''deceptive marketing, high implied annual percentages rates in the event of high realized incomes, potentially insufficient protections for low incomes or disruptive life events or low incomes, and potentially burdensome aggregate income shares for individuals who take on multiple ISAs or combine ISAs with loans.'' Retrieved from *https://socialfinance.org/wp-content/uploads/Workforce-Realigned-Full-Book.pdf* on October 8, 2022.

[23] Shireman, R. (2020). How For-Profits Masquerade as Nonprofit Colleges, The Century Foundation. *https://tcf.org/content/report/how-for-profits-masquerade-as-nonprofit-colleges/.*

| Provision | Regulatory section | Description of change from NPRM |
|---|---|---|
| Institution Location | § 668.238(a) | Following our initial approval of an institution's PEP, additional PEP offered by the same institution at the same location may be determined eligible without further approval from the Secretary except as required by § 600.7, § 600.10, § 600.20(c)(1), or § 600.21(a), as applicable, if such programs are consistent with the institution's accreditation or its State approval agency. |
| Documentation | § 668.238(b)(4) | Documentation detailing the methodology including thresholds, benchmarks, standards, metrics, data, or other information the oversight entity used in approving the PEP and how the information was collected. |
| Limitation or Termination of Approval | § 668.240 | The Secretary may limit or terminate or otherwise end the approval of an institution to provide an eligible prison education program if the Secretary determines that the institution violated any terms of the subpart or that the institution submitted materially inaccurate information to the Secretary, accrediting agency, State agency, or oversight entity. |
| Best Interest Determination | § 668.241 | Revised so all outcome indicators are optional but maintain that the current input indicators as mandatory to assess and removed ''barring exceptional circumstances surrounding the student's conviction'' from the assessment of transferability of credits. |
| Best Interest Final Evaluations | § 668.241(e)(1) | After its initial determination that a program is operating in the best interest of students under paragraph (a), the institution must obtain subsequent evaluations of each eligible prison education program from the responsible oversight entity not less than 120 calendar days prior to the expiration of each of the institution's Program Participation Agreements, except that the oversight entity may make a determination between subsequent evaluations based on the oversight entity's regular monitoring and evaluation of program outcomes. |
| Period Following Best Interest Determination. | § 668.241(e)(2)(i) | Include the entire period following the prior determination and be based on the applicable factors described under paragraph (a) for all students enrolled in the program since the prior determination. |
| **90/10** | | |
| ISA | § 668.28(a)(5)(ii) | Clarified ISA agreements covered by the requirements in § 668.28(a)(5)(ii)(A) through (C). |
| Covered Institutional Charges | § 668.28(a)(5)(ii)(A) | Clarified ISA or alternative financing agreement must identify what institutional charges the agreement covers, and those charges cannot be more than the stated institutional charges at the time the student signs the agreement. |
| Required Disclosures | § 668.28(a)(5)(ii)(B) | Clarified that the ISA or alternative financing agreement must disclose: the maximum time and amount a student would be required to repay, the maximum amount a student would be required to repay, the implied or imputed interest rate, and any fees or revenue generated for a third-party. |
| 90/10 Calculation | § 668.28(a)(5)(ii)(C) | Clarified that revenue, interest, and fees are not included in the 90/10 calculation. |
| ISA Interest Rate | § 668.28(a)(5)(ii)(D) | Removed the proposed limit on the interest rate for an ISA that an institution must disclose to a student if the ISA funds are included in its 90/10 calculation. |
| Federal Funds | § 668.28(a)(6)(iii)<br>§ 668.28(a)(6)(iv) | Revised funds to be the amount of institutional funds used to match Federal funds.<br>Revised language to state the amount of Federal funds refunded to students or returned to the Secretary under § 668.22 or required to be returned to the applicable program. |
| Institutional Loans and ISAs | Appendix C | Revised the line item for institutional loans to show that institutions should count the full payment amount in the amount column and only the amount of principal payment in the adjusted amount column.<br>Revised the line item for payments on ISAs counted under institutional aid to show that institutions should count the full payment amount in the amount column and only the payment amounts that represent a return of capital in the adjusted amount column. |
| **Change in Ownership** | | |
| Definitions | § 600.2 | Eliminated proposed paragraph (6) from the ''distance education'' definition. |
| Definitions | § 600.2 | Revised definition of additional location and branch campus from ''separate'' to ''geographically separate.'' |
| State authorization and accreditation approvals. | § 600.20 | Clarified that for-profit institutions undergoing a change in status to nonprofit will remain in the former until the review is complete. |
| Reporting changes | § 600.21 | Clarified that certain ownership changes at the 5 percent level can be reported quarterly instead of within 10 days. |

3. Discussion of Costs and Benefits

3.1 *Pell Grants for Confined or Incarcerated Individuals:*

From the 1990s until the amendments made by the Consolidated Appropriations Act, 2021, the HEA prohibited students who are incarcerated in a Federal or State penal institution from participating in the Federal Pell Grant program, which provides need-based grants to low-income undergraduate and certain post-baccalaureate students to promote access to postsecondary education. This restriction prevents many otherwise eligible incarcerated individuals from accessing financial aid and benefiting from the postsecondary education and training that can be crucial to their successful reentry into society and their communities upon the completion of their sentences. The HEA was amended to eliminate this restriction for students who meet the definition of confined or incarcerated individuals and who enroll in eligible PEPs. The Department is implementing the statutory requirement to extend Federal Pell Grant eligibility to incarcerated individuals and increase their participation in high-quality educational opportunities.

*Costs of the Regulatory Changes:*

These final regulations will impose some additional costs on the Department, educational institutions, oversight entities, and accrediting agencies.

First, adding eligible Pell Grant recipients as provided for by Congress will expand the costs of the Pell Grant program for the Federal government. The Department expects these costs to be more than offset by the benefits noted in the benefits section, however, especially in the form of lower recidivism rates and increased employment opportunities. Research has found that the average cost to incarcerate an inmate in the United States totals more than $33,000 per year.[24] However, participating in correctional postsecondary education programs reduces a former inmate's recidivism risk by 28 percent.[25]

Second, the educational institutions offering in-prison instruction will face some additional costs of achieving and maintaining compliance with new, higher standards. Thus far, correctional education programs have not had to comply with the same requirements as programs that receive title IV and Federal Pell Grant funding, although institutions that participate in the Second Chance Pell experiment have already met some of the program requirements for incarcerated individuals. Additional costs of meeting the higher standards may include the cost of seeking and obtaining approval of initial PEP offerings from the accrediting agency and the Secretary, as well as the costs of providing the data necessary for the oversight entity to determine whether the PEP is operating in the best interests of students. Correctional facilities may also face some increased costs related to providing appropriate facilities and resources, including staffing, to support the PEP as they partner with higher education institutions. Both institutions and correctional facilities would also face increased costs associated with required support services for their students, including appropriate academic and career counseling, as well as support to help prospective students complete the Free Application for Federal Student Aid®.

Additionally, oversight entities may incur additional costs to oversee the development and operation of eligible PEPs. For example, under §§ 668.236 and 668.241, the oversight entity must develop an appropriate process to approve PEPs and determine if they are operating in the best interest of students. The ''best interest'' determination will require assessment of several identified inputs and outcomes and will require collaboration with relevant stakeholders. All of these steps will increase costs for the oversight entity.

With the expansion of PEPs, additional costs will be incurred by the oversight entities to ensure that the programs are providing quality education and opportunities for incarcerated individuals. With more programs to evaluate, the oversight entities will need to account for additional time and complexity of the review process, as well as the potential need for new staff to accommodate a higher volume of PEP reviews and additional monitoring tasks related to the enhanced metrics that PEPs must submit. Additional costs may also arise from having to implement technological solutions to accommodate the higher and more in-depth review process and program monitoring, especially as PEPs continue to expand.

Accrediting agencies may also face costs related to the approval of PEPs and the required site visit. However, the accrediting agency may, in turn, require the institution of higher education to cover the additional costs associated with the final regulations, transferring these costs from the accrediting agencies to institutions.

Finally, the Department will incur some additional burden and cost associated with its obligation to oversee PEPs and to support oversight entities and institutions. For instance, we offered to provide a significant amount of data to the oversight entities to assist them in making the best interest determination. The Department also intends to provide needed technical assistance to the field. We estimate that the costs of systems changes needed to reflect the regulatory requirements, oversight to ensure institutional compliance through program review functions, and training support to provide technical assistance to the field will total approximately $1.1 million.

*Benefits of the Regulatory Changes:*

Many of the individuals in the growing prison population have lower levels of educational attainment compared to the general population. Research finds that ''only 15 percent of incarcerated adults earn a postsecondary degree or certificate either prior to or during incarceration, while almost half (45 percent) of the general public have completed some form of postsecondary education''. The same study notes that about two-thirds of incarcerated adults have a high school diploma or equivalent.[26] This creates an opportunity for significant expansion of correctional education programs, including postsecondary educational programs, which would begin to address those unmet needs.

Extending Pell Grants to eligible PEPs will provide numerous economic and public safety benefits to incarcerated individuals, to their communities when they return, and to States and the Federal government in the form of more successful rehabilitation of imprisoned individuals, lower recidivism rates, higher employment rates, increased earnings, greater contribution to the economy, and ultimately cost savings for the government. These effects and benefits are enabled through increased educational attainment.

Numerous studies have shown that providing education programs to incarcerated individuals is a significant factor in successful rehabilitation and subsequent reentry. First, research demonstrates that correctional education is associated with higher self-confidence and self-worth for confined

[24] *www.vera.org/downloads/publications/the-price-of-prisons-2015-state-spending-trends.pdf.*

[25] Bozick, R., Steele, J., Davis, L., & Turner, S. Does providing inmates with education improve postrelease outcomes? A meta-analysis of correctional education programs in the United States. *J. Experimental Criminology* 14, 389–428 (2018). *https://doi.org/10.1007/s11292-018-9334-6.*

[26] Ositelu, M., Equipping Individuals for Life Beyond Bars, New America (November 2019), *www.newamerica.org/education-policy/reports/equipping-individuals-life-beyond-bars/.*

or incarcerated individuals, which can lead confined or incarcerated individuals who attend postsecondary education to engage in fewer instances of misconduct than those who did not attend.[27] Postsecondary education programs in prisons also improve incarcerated individuals' cognitive skills, especially for individuals with learning disabilities, by teaching critical thinking skills, encouraging debate, and helping students apply course lessons to their own lives, all of which may help them better adjust to social values and expectations upon reentry.[28] This is a critical benefit, given that an estimated 30 to 50 percent of the adult prison population has a learning disability.[29] Correctional education programs also improve literacy levels for incarcerated individuals with limited past educational experience, which increases their post-release chances of furthering their studies and securing employment.[30] One of the most critical benefits correctional education programs provide to incarcerated individuals is the development of skills necessary for post-release employment. Those adults who participate in postsecondary education or job training programs while incarcerated are more likely to have higher literacy and numeracy proficiency than their peers who do not participate in such programs, helping to close the gaps in literacy and numeracy skills between the incarcerated population and the general public.[31] A study conducted by the Education Division of the Indiana Department of Correction (IDOC) comparing the outcomes of incarcerated individuals who participated in a postsecondary education program in the correctional facility with those who did not found that employment rates and time employed following release was much higher for those who participated in the program. Their incomes were also higher.[32]

In addition to the benefits provided to PEP participants, there are also significant public safety benefits for their communities. Over the last two decades, numerous studies have been conducted on the impact of prison education on post-release outcomes for previously incarcerated individuals.[33] The recidivism rate represents the rate at which individuals who were previously incarcerated re-offend and are re-admitted to correctional facilities and is often used as a measure of success for correctional education programs. Aggregating the findings from 57 studies published or released between 1980 and 2017, one study found that confined or incarcerated individuals participating in correctional postsecondary education programs are 28 percent less likely to recidivate when compared with confined or incarcerated individuals who did not participate in correctional education programs.[34]

Reducing recidivism also reduces economic, public safety, and personal costs, and correspondingly increases benefits in those categories, for correctional facilities, governments, and our Nation as a whole. Using a hypothetical pool of 100 inmates, a 2014 RAND study illustrated the powerful economic benefit of correctional education programs by comparing the direct costs of such correctional education programs with the costs of reincarceration. The study found that the direct costs of reincarceration were far greater than the direct costs of providing correctional education. For a correctional education program to be cost-effective or ''break-even,'' it would need to reduce the 3-year reincarceration rate by between 1.9 and 2.6 percentage points. The study's findings indicate that participation in correctional education programs is associated with a 13-percentage-point reduction in the risk of reincarceration in the 3 years following release, far exceeding the break-even point thereby generating real benefits to society.[35]

3.2 *90/10:*

The ARP amended section 487 of the HEA by modifying which Federal funds proprietary institutions must count in the numerator of their 90/10 calculation. The final regulations amend § 668.28 to reflect statutory requirements implemented in the ARP.

Additionally, these regulations modify allowable non-Federal revenue in the 90/10 calculation to better align the regulations with the statutory intent of the 90/10 calculation and address practices proprietary institutions have used or may be incentivized to use to alter their 90/10 calculation or inflate their non-Federal revenue percentage. Examples of such practices include: delaying disbursements to avoid failing 90/10 in two consecutive years, offering ineligible programs with little or no oversight or programs unnecessary to the education or training of students, and selling institutional loans or ISAs to count the proceeds from the sale in their 90/10 calculation. These regulations also create accountability protections and disclosure requirements. For instance, the regulations require proprietary institutions to notify students if the institution fails the 90/10 calculation in a fiscal year and notify students that they may lose title IV eligibility at that institution after another year of failing the calculation. These regulations also promote consumer protection and close potential loopholes related to ISAs and other alternative financing agreements. These changes will result in costs to certain proprietary institutions. Institutions unable to generate sufficient non-Federal revenues may seek to generate revenue to meet 90/10 requirements through such methods as creating programs that are not title IV eligible, a permissible source of revenue as long as these ineligible programs meet the requirements established in the regulations. They could also try to recruit more students who can pay without needing title IV financial aid. Students at proprietary institutions that fail the 90/10 calculation may no longer be able to attend due to lack of aid or school closure. However, according to research on similar sanctions, most of the students diverted from proprietary institutions will likely enroll in other institutions, often community colleges, which are typically lower cost.[36]

[27] Lahm, K.F. (2009). Educational participation and inmate misconduct. *Journal of Offender Rehabilitation,* 48, 37–52. *www.tandfonline.com/doi/abs/10.1080/10509670802572235*.

[28] Vandala, N.G. (2019). The transformative effect of correctional education: A global perspective. *Cogent Social Sciences,* 5(1). *https://doi.org/10.1080/23311886.2019.1677122*.

[29] Koo, A. (2015). Correctional education can make a greater impact on recidivism by supporting adult inmates with learning disabilities. *J. Crim. L. & Criminology,* 105. *https://scholarlycommons.law.northwestern.edu/jclc/vol105/iss1/6*.

[30] Jones Young, N.C., & Powell, G.N. (2015). Hiring ex-offenders: A theoretical model. *Human Resource Management Review,* 25(3), 298–312. *www.sciencedirect.com/science/article/abs/pii/S1053482214000692?via%3Dihub*.

[31] Ositelu, M.O. ''Equipping Individuals for Life Beyond Bars.'' *New America,* 4 Nov. 2019, *www.newamerica.org/education-policy/reports/equipping-individuals-life-beyond-bars/*.

[32] Nally, J., Lockwood, S., Knutson, K., & Ho, T. (2012). An evaluation of the effect of correctional education programs on post-Releasrecidivism and employment: An empirical study in Indiana. *Journal of Correctional Education* (1974–), 63(1), 69–89. *www.jstor.org/stable/26507622*.

[33] Bozick, R., Steele, J., Davis, L., & Turner, S. Does providing inmates with education improve postrelease outcomes? A meta-analysis of correctional education programs in the United States. *J. Experimental Criminology* 14, 389–428 (2018). *https://doi.org/10.1007/s11292-018-9334-6*.

[34] Ibid., 389–428.

[35] Davis, L.M., et al., ''How Effective Is Correctional Education, and Where Do We Go from Here? The Results of a Comprehensive Evaluation.'' Santa Monica, CA: RAND Corporation, 2014. *www.rand.org/pubs/research_reports/RR564.html*.

[36] Cellini, S.R., Darolia, R., & Turner, L.J. (2020). Where do students go when for-profit colleges lose Federal Aid? *American Economic Journal: Economic Policy,* 12(2), 46–83, *http://doi.org/10.1257/pol.20180265*.

Moreover, the study finds evidence that borrowing and default decline after students switch sectors. We anticipate that most students, proprietary institutions that provide programs that attract more non-Federal investment, public and nonprofit institutions, taxpayers and the Department will benefit from these regulations. Proprietary institutions that attract greater amounts of non-Federal investment, possibly because their programs are of greater value, will benefit because institutions that cannot secure as much non-Federal investment will either have to leave the title IV programs or need to refocus on providing better programs instead of devoting as much efforts to aggressively recruiting service members so they can manage their 90/10 rate. Similarly, public and private nonprofit institutions will benefit from not having to compete with institutions that are focused on avoiding issues with their 90/10 ratio, leading instead to greater competition over who offers programs with better returns. Taxpayers and the Department will benefit because ensuring greater levels of non-Federal investment in proprietary institutions will exert greater market forces on these institutions to deliver better value. The result is that the Federal investment will produce better returns.

*Costs of the Regulatory Changes:*

We expect that the changes to the 90/10 regulations will result in costs to the Department and proprietary institutions in several areas.

First, the regulations will result in some additional burden and compliance costs for proprietary institutions. For example, proprietary institutions will be responsible for identifying and counting more sources of Federal funds in their 90/10 calculation, including Federal funds delivered directly to students. These institutions will also need to adjust their 90/10 revenue sources and measures based upon the changes in the regulations. Additionally, institutions may need to make changes to programs to align with the new regulations, which will result in extra compliance costs for proprietary institutions. The Department expects that proprietary institutions seeking to meet the 90/10 requirements may improve the overall quality of their programs to attract and enroll more students who pay for courses with sources other than Federal funds. These improvements may include making changes to improve the quality and visibility of their programs; or partnering with employers willing to pay institutions with their own funds, ensuring alignment with labor market needs. Further, institutions may create programs that are not eligible for title IV, HEA funds or other Federal funds to generate revenue to comply with the final 90/10 rule. As noted in the NPRM, we are concerned that allowing institutions to count funds from these ineligible programs may serve as an incentive for proprietary institutions to create and market low-quality ineligible programs.

Second, proprietary institutions that are unable to meet the 90/10 requirements will lose eligibility for Federal aid after failing for two consecutive years. This may cause an interruption in the academic program for some students. These students may also incur additional costs and burdens associated with identifying other educational opportunities and transferring across institutions, including searching for institutions that offer their desired program of study, paying to have their transcript sent to the new institution, and possibly losing progress toward their credential if the new institution does not accept all their previous coursework. However, the Department believes that—as in other cases where institutional accountability rules were strengthened—students are likely to transfer to higher-quality, and possibly more affordable, programs at other institutions.[37]

Lastly, these regulations include other sources of Federal funds in addition to title IV, HEA funds as Federal sources of revenue for the purposes of calculating 90/10. Rather than specifying all Federal funding sources in the regulations, the Department opts to identify non-title IV, HEA Federal education assistance funds that must be included in the numerator of the 90/10 calculation in a notice published in the **Federal Register**, with updates as needed. We will incur minimal additional administrative costs related to the salary expenses of staff who identify Federal funds and update the **Federal Register** notice as needed.

*Benefits of the Regulatory Changes:*

The 90/10 rule benefits multiple groups of stakeholders, particularly military-connected students, proprietary institutions that offer programs of value to students and employers, public and non-profit institutions, and taxpayers.

First, military-connected students receive the most significant and immediate benefits from the regulations. The ARP amendment aimed to end some allegedly predatory practices to recruit service members and veterans because their GI Bill and DOD Tuition Assistance education benefits could help proprietary institutions meet their non-Federal revenue requirements under the current 90/10 regulations.[38] Approximately 33 institutions would have failed the 90/10 requirements in 2018–19 if DOD and VA dollars were included as Federal funds. Seventeen institutions would have failed for two years in 2019–20, which would have resulted in their loss of title IV program eligibility. Most institutions (about 1,740 of approximately 1,800 institutions) would have passed in both years. Under these regulations, proprietary institutions at risk of failing the calculation no longer have an incentive to aggressively target GI Bill and DOD Tuition Assistance recipients because these programs are counted as Federal funds for purposes of 90/10. This revision also provides service members and veterans greater opportunities to consider their enrollment options at various institutions without potential undue influence or aggressive recruiting from proprietary institutions. Without such aggressive recruiting, military-connected students might be more likely to choose higher-value programs, generating potentially better employment and earnings gains for this population. This is especially true in light of the lower earnings gains for proprietary institutions noted elsewhere.

Other students who are considering enrolling in proprietary institutions will also benefit. For example, proprietary institutions will not be able to use temporary measures, such as delaying disbursements or selling institutional loans, to mask potential challenges with meeting the 90/10 requirements or to avoid losing eligibility following a failure of the 90/10 calculation during the fiscal year. All students will also benefit from the Department's assessment of institutional liability for all title IV funds disbursed after an institution becomes ineligible due to two consecutive 90/10 failures. This disincentivizes institutions to continue disbursing title IV funds after they lose eligibility. Consequently, students are less likely to receive title IV aid that

[37] Cellini, S.R., Darolia, R., & Turner, L.J. (2020). Where do students go when for-profit colleges lose Federal aid? *American Economic Journal: Economic Policy,* 12(2), 46–83, *http://doi.org/10.1257/pol.20180265.*

[38] See, for example, *www.nytimes.com/2011/09/22/opinion/for-profit-colleges-vulnerable-gis.html; www.help.senate.gov/imo/media/for_profit_report/PartI-PartIII-SelectedAppendixes.pdf; www.chronicle.com/article/for-profit-college-marketer-settles-allegations-of-preying-on-veterans/; www.insidehighered.com/quicktakes/2015/10/09/defense-department-puts-u-phoenix-probation; https://oag.ca.gov/news/press-releases/attorney-general-becerra-announces-settlement-itt-tech-lender-illegal-student;* and *https://files.eric.ed.gov/fulltext/ED614219.pdf.*

their school should not have disbursed. This preventive effort will also benefit taxpayers by decreasing improper payments that would occur if we were unable to collect the liability from the institution.

Next, the final regulations will promote consumer protection for prospective and currently enrolled students by requiring certain disclosures in institutional financing agreements. This provides additional protections for students accessing ISAs or alternative financing arrangements by increasing transparency about the terms of the arrangement and, in some cases, may result in better terms offered by the institution.

Lastly, students and taxpayers benefit when we more closely align allowable non-Federal revenue with the statutory intent of the HEA. By requiring proprietary institutions to bring in at least 10 percent of their revenue from non-Federal sources, such as tuition revenue, the final regulations require institutions to demonstrate a willing market beyond taxpayer-financed Federal education assistance and reduce their reliance on Federal subsidies. Institutions may have to attract more students who are willing to pay a greater share of program expenses with their personal funds, form more partnerships with employers, or take other steps to make non-Federal actors willing to invest their own money. Greater non-Federal investment could improve the return on Federal investments as the competition to attract non-Federal revenue will encourage better value. Institutions that do not comply with the 90/10 regulations lose eligibility for title IV, HEA funds. This may save some taxpayer dollars, depending on where the students who would have attended those institutions enroll and the relative price of those other institutions. These proprietary institutions will then need to operate without access to title IV, HEA financial aid dollars; identify and enroll students who pay with funds other than title IV funds, including by making any necessary changes to better market their programs; or partner with employers willing to pay institutions with their own funds, ensuring alignment with labor market needs and reducing the reliance on taxpayer dollars. Furthermore, a loss of access to title IV aid may also result in lower tuition prices at these institutions, as prior research has shown that proprietary schools that participate in title IV have higher tuition than similar programs at institutions that do not participate.[39]

3.3 *Change in Ownership (CIO):*

With the growing complexity of CIO transactions in recent years, the Department is finalizing regulations to ensure a clearer, more streamlined process for CIOs that ensures compliance with the HEA and related regulations. Addressing CIOs is important because they can affect the financial structure of institutions in ways that can limit their ability to invest in educational success. They can also affect the accountability structures that may or may not be attached to an institution that receives millions or tens of millions of dollars a year. Among the riskiest of those transactions for students and taxpayers are conversions from proprietary to nonprofit status. Between 2011 and 2020, there have been 59 such conversions, involving 20 separate transactions.[40] Of these, three-fourths of the institutions were sold to an entity that had not previously operated an institution of higher education; 13 institutions with a common ownership structure closed before we were able to decide whether to approve or deny the request for conversion.

A full, comprehensive CIO review—which can take between 7 months and 1 year, on average, for a CIO that includes a conversion, and 6 months for a CIO that does not—is a significant administrative burden for both the institution and the Department. Some institutions close transactions for the sale to a new owner but are unprepared to meet the regulatory requirements for a CIO, resulting in emergency situations where there is a potential loss of institutional eligibility and precipitous closure. These final regulations seek to reduce that risk by ensuring adequate notice is given prior to the sale closing date so that we can assess whether the institution can meet the regulatory requirements under the time constraints of § 600.20(g) and (h). This also provides sufficient time for the Department to request a letter of credit if the new owner does not have audited financial statements that satisfy the requirements of § 600.20(g)(3)(iv). In addition, these final regulations clarify the requirements for approval of a CIO application and establish appropriate documentation requirements.

In addition to revising the CIO regulations, the ownership and control reporting regulations, and the definition of a nonprofit, these regulations also modify or add to definitions set forth in § 600.2. These regulations clarify definitions related to campus locations, such as ''main campus,'' ''branch campus,'' and ''additional location.''

*Costs of the Regulatory Changes:*

The primary sources of costs with the CIO portion of these final regulation are increased burden for institutions from provisions that would enhance the Department's review of CIOs and institutional participation in the Federal student aid programs. This final rule also provides for increased oversight of proprietary institutions seeking to convert to nonprofit status and increased reporting requirements for CIOs. The Department is not anticipating significant transfers to the Department from the CIO regulations, as this rule considers the structure under which an institution that is already participating in the title IV programs may continue to operate. Though a CIO could result in the Department not continuing title IV aid, we more often impose conditions. Where there is a requested conversion to nonprofit status, arrangements with outside parties preclude approval of nonprofit status.

Some of these regulatory provisions will not impose additional burden on affected institutions. For instance, although institutions must expend resources to submit a required notice to the Department at least 90 days in advance of the transaction, the information provided is principally the same as the information required for a materially complete application which must be submitted 10 business days following the closing of the transaction. Providing earlier notice will enable us to provide faster determinations related to any potential letter of credit requirement, and to avoid losses of eligibility for institutions that would be unable to meet the requirements of § 600.20(g) and (h) immediately after the transaction, as required by the regulations. Other aspects of the regulations simplify and codify existing Department practice, which do not increase burden to institutions.

However, some provisions require institutions undergoing CIOs after the effective date of the regulations to submit additional documentation and meet new requirements. For example, institutions must provide notice to their students of a forthcoming CIO at least 90 days in advance, requiring the

[39] Cellini, Stephanie Riegg, and Claudia Goldin. 2014. ''Does Federal Student Aid Raise Tuition? New Evidence on For-Profit Colleges.'' American Economic Journal: Economic Policy, 6 (4): 174–206.

[40] Government Accountability Office (GAO), Higher Education: IRS and Education Could Better Address Risks Associated with Some For-Profit College Conversions, December 2020. *www.gao.gov/products/gao-21-89*.

development of communications and resources for students. In addition, we currently require transactions to be reported to the Department only if the transaction affects at least a 25 percent ownership interest. These final regulations lower the reporting threshold for a CIO to cover changes of ownership interest of 5 percent or more. Accordingly, a greater number of institutions will need to meet these reporting requirements and affected institutions will incur some costs to meet them. We anticipate these costs will be modest as the process for reporting such a change will not be difficult or time consuming. However, these final regulations limit reviews of changes in control, which are more burdensome for the institution, generally to those involving a transfer of at least 50 percent control, rather than the current 25 percent. The Department believes that this will provide additional transparency benefits, while reducing the burden on institutions from more onerous changes in control reviews under circumstances where a change in control likely has not occurred. We believe these savings will outweigh the expense from the additional reporting. The Department anticipates the reporting burden cost range will be minimal due to the limited number of these events that occur and the minimal cost of the reporting. Additionally, any costs from the CIO regulations will only be associated with those institutions undergoing a CIO, which are relatively uncommon compared to the total number of institutions that participate in the title IV programs. The Department anticipates that the administrative costs to the agency of implementing these changes will be very limited, given the relatively small number of such transactions and the fact that many of these requirements are consistent with current practice.

*Benefits of the Regulatory Changes:*

The Department believes that the benefits and burden reduction that will result from the CIO regulations will outweigh these new costs. We anticipate the regulations will significantly benefit students, taxpayers, institutions, and the Department.

Students, taxpayers, institutions, and the Department will all benefit from the regulatory changes for CIOs, including those involving oversight of proprietary institutions converting to nonprofit status. Changes in ownership and control pose significant risk, especially when the transaction involves a significant amount of debt, a burdensome servicing agreement, the acquisition of a large institution or chain, or a conversion to nonprofit status with ongoing and burdensome obligations to a former owner or other entity. Some cases resulted in school closures (and associated closed school discharges), requiring the investment of enforcement and oversight resources by States and the Federal government, and improperly exempting some institutions from regulations governing proprietary institutions—such as the 90/10 rule. Students, taxpayers, and the Department will benefit from increased transparency around a proposed transaction, providing more time for the Department to conduct oversight and ensure the transaction is properly conducted and does not result in an interruption of title IV, HEA funds. Institutions will also benefit from an earlier submission that allows us to provide feedback on whether the institution will be able to meet the requirements of a materially complete application before the CIO occurs. Knowing whether the Department requires an institution to submit a new owner letter of credit as part of the transaction can be critical. This advanced notice enables institutions to obtain a letter of credit with less time constraints and may also impact whether the institution will have a CIO.

Students and taxpayers will benefit from greater assurances that schools are complying with regulatory requirements in CIO transactions and meeting the definition of a ''nonprofit institution.'' Current and prospective students will benefit from the requirement that the institution provide notice to students at least 90 days prior to a CIO because the requirement will ensure that students receive important information that may impact their education in a timely manner, and that they are able to make future education decisions based on that knowledge. Students and taxpayers will also benefit from increased oversight of proprietary institutions converting to nonprofit status, including requiring that proprietary institutions continue to comply with regulatory requirements such as 90/10 unless and until they have met the requirements to be approved as a nonprofit institution by the Department. Taxpayers benefit from additional financial protection such as letters of credit when the required audited financial statements of a new owner are not available (consistent with current practice), as well as from any additional financial protections that may be deemed necessary by the Secretary based on the risk of the transaction.

Educational institutions will benefit from greater clarity as to how the rules apply to CIO transactions. The revised definition of ''nonprofit institutions'' will ensure that institutions seeking such a designation are not using business arrangements that improperly benefit related parties. This can occur, for example, when a prior owner retains control of the institution through a contractual relationship, or when the prior owner continues to enjoy revenues generated by the institution through a debt obligation or a servicing agreement. This clarification will aid institutions in knowing how to comply, and complying, with the statutory and regulatory requirements for title IV HEA programs.

These final regulations will also enable a proprietary institution that seeks to convert to nonprofit status to understand the factors considered by the Department more clearly prior to submitting an application. As these institutions assess potential transactions, they will more easily be able to identify permissible and impermissible contracts and agreements with other private parties. The 90-day notice will also benefit institutions by ensuring that the Department can review owners' audited financial statements to determine whether we require a letter of credit (or other financial surety) prior to the transaction closing. The Department may also provide notice prior to the CIO that we require additional financial surety to minimize financial or administrative risk that the institution may present to taxpayers on a case-by-case basis.

The Department will also benefit from clearer regulations and processes that are more easily interpreted and applied. Clearer definitions related to distance learning, including for ''main campus,'' ''branch campus,'' and ''additional location,'' will simplify and reduce the Department's reviews of institutions and of CIO transactions by ensuring greater consistency. The Department will also benefit from the changes made to the reporting requirements, as lowering the threshold from 25 percent to 5 percent will increase transparency and enable more oversight of changes in control. This greater visibility into voting blocs and lower-level ownership changes will enable the Department to determine where institutions may have undergone a change in control, warranting greater scrutiny by the Department. These regulations will require reporting regardless of the type of corporate structure of the institution. These CIOs do not occur often, limiting the added burden from the reporting requirement. The Department will also experience less burden as a result of the change in the threshold for a change in control review from all changes in ownership

over 25 percent to a 50 percent or greater change in ownership and control or where we have reason to believe a change in control has occurred.

4. Net Budget Impacts

These final regulations are estimated to have a net Federal budget impact in savings of $-44.3 million for loan cohorts 2025 to 2032, and $879 million in net changes to Pell Grants. A cohort reflects all loans originated in a given fiscal year. Consistent with the requirements of the Credit Reform Act of 1990, budget cost estimates for the student loan programs reflect the estimated net present value of all future non-administrative Federal costs associated with a cohort of loans. For the final regulations, the baseline was updated to include modifications for the PSLF waiver, the IDR waiver, the payment pause extension to December 2022, and the August 2022 announcement that the Department will discharge up to $20,000 in Federal student loans for borrowers who make under $125,000 as an individual or $250,000 as a family. This did not affect the net budget impact of these regulations as the impact on loans of the 90/10 provisions in these final regulations affects future cohorts only and the modifications affect past loan cohorts. Pell Grant estimates also affect future awards and were not directly affected by the modifications in question. The budgetary effects of the regulations are primarily attributable to providing Pell Grants to confined or incarcerated individuals in qualifying prison education programs. The Department does not anticipate significant budgetary impacts related to the change in ownership provisions and anticipates a small Federal budgetary savings due to the 90/10 provisions. The specific effects for each provision are described in the following subsections covering the relevant topics.

*Pell Grants for Confined or Incarcerated Individuals*

The changes to the Pell Grant program to allow Pell Grants for confined or incarcerated individuals, as provided for by Congress, are expected to increase educational opportunities for confined or incarcerated individuals, while maintaining appropriate guidelines for program quality and requiring reporting for tracking the extent and performance of PEPs.

To estimate the potential increase in Pell Grant awards related to these changes, the Department assumed, based on current figures and previous experience with Pell Grant availability for incarcerated individuals, that 2 percent of the incarcerated population of approximately 1.6 million individuals will participate in eligible PEPs. The size of the incarcerated population fluctuates and there are differing estimates of the number of incarcerated individuals, which is also affected by the pandemic. For example, the Department of Justice's Bureau of Justice Statistics estimates a population of 1.4 million as of year-end 2019 with a decline to 1.2 million as of year-end 2020,[41] while the Vera Institute of Justice estimates there are 1.8 million in prisons and jails as of mid-2020 and 1.77 million as of mid-2021.[42] Given the uncertainty, the Department chose 1.6 million as a midpoint between estimates. We expect that most participating individuals will not have an opportunity to enroll full time due to the limited availability of courses in carceral settings. Due to these enrollment intensity constraints, incarcerated Pell recipients are unlikely to receive the maximum grant available. Based on experience from the Second Chance Pell experiment, where average awards were nearly 60 percent of the maximum award, the average award used to develop the estimate was prorated to approximately $3,800 in the first year, generating the estimated costs in Table 1.

TABLE 1—ESTIMATED FINANCIAL TRANSFER EFFECTS OF PEPS

[$millions] [43]

| Cost of Expanding Pell Eligibility to Incarcerated Individuals (PB23 Assumptions) | | | | | | |
|---|---|---|---|---|---|---|
| | Academic year (AY) 2023–24 | AY 2024–25 | AY 2025–26 | AY 2026–27 | AY 2027–28 | AY 2028–29 |
| Discretionary Program Cost | 96 | 100 | 101 | 101 | 102 | 103 |
| Mandatory Program Cost | 23 | 22 | 22 | 22 | 22 | 23 |
| Total Program Cost | 119 | 122 | 123 | 123 | 124 | 126 |
| | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 | FY 2028 |
| Discretionary Outlays | 32 | 63 | 99 | 101 | 101 | 102 |
| Mandatory Outlays | 11 | 23 | 22 | 22 | 22 | 22 |
| Total Outlays | 43 | 86 | 121 | 123 | 123 | 124 |
| | | AY 2029–30 | AY 2030–31 | AY 2031–32 | AY 2032–33 | 10-year total |
| Discretionary Program Cost | | 104 | 104 | 105 | 104 | 1,020 |
| Mandatory Program Cost | | 23 | 23 | 23 | 23 | 226 |
| Total Program Cost | | 127 | 127 | 128 | 127 | 1,246 |
| | | FY 2029 | FY 2030 | FY 2031 | FY 2032 | 10-year total |
| Discretionary Outlays | | 103 | 104 | 104 | 104 | 913 |

[41] Bureau of Justice Statistics, Prisoners in 2020—Statistical Tables, December 2021, available at Prisoners in 2020—Statistical Tables (*ojp.gov*).

[42] Vera Institute of Justice, People in Jail and Prison, Spring 2021, available at *www.vera.org/downloads/publications/people-in-jail-and-prison-in-spring-2021.pdf.*

[43] The Federal Pell Grant program has discretionary costs associated with the maximum award set in the annual appropriation and mandatory costs associated with the additional award amount determined by statute. These changes affect both mandatory and discretionary costs.

| | AY 2029–30 | AY 2030–31 | AY 2031–32 | AY 2032–33 | 10-year total |
|---|---|---|---|---|---|
| Mandatory Outlays | 23 | 23 | 23 | 23 | 214 |
| Total Outlays | 126 | 127 | 127 | 127 | 1,127 |

Based on these assumptions, the estimated cost of the regulatory changes related to Pell Grants for confined or incarcerated individuals is approximately $1.1 billion over 10 years. The amount of Pell Grants awarded based on these changes will depend heavily on the number of institutions that choose to participate and the number of students that they enroll. Another factor that will affect the increase in transfers is how quickly institutions begin to offer PEP programs. We assume a fast roll-out since institutions will have been aware of these changes for several years before the regulations take effect, but the ramp-up could be more gradual, shifting the timing back and reducing the overall transfers.

*90/10 Rule*

To help estimate the effect of the final 90/10 regulations, the Department analyzed information about additional Federal aid received by institutions subject to the 90/10 requirements and found that an additional 92 institutions with $524.8 million in Pell grants and $1.09 billion in loan volume in AY 2019–20 would be above the 90 percent threshold, and 49 institutions would be above the 90 percent threshold for both 2018–19 and 2019–20, risking eligibility for title IV, HEA funds. The baseline update included the modifications for the Public Service Loan Forgiveness (PSLF) waiver, the Income-Driven Repayment (IDR) waiver, the payment pause extension to December 2022, and the August 2022 announcement that the Department will discharge up to $20,000 in Federal student loans for borrowers who make under $125,000 as an individual or $250,000 as a family. However, these modifications did not affect the net budget impact of the 90/10 provisions. These final regulations affect future cohorts only and the modifications affect past loan cohorts.

However, the Department recognizes that institutions have historically managed to meet the 90/10 threshold, and we expect most institutions will be able to adapt to the new requirements. Additionally, students will still qualify for similar levels of aid even if they choose to attend a different institution or shift sectors. Therefore, we do not expect a 100 percent loss of loan volume and aid awarded for those institutions that we would otherwise estimate would be out of compliance under the final regulations. We estimate that the inclusion of additional types of Federal aid in the 90/10 calculation will decrease Pell Grants awarded by −$248 million from AY 2024–25 to AY 2032–33 and have a net budget impact of $−44.3 million from reduced loan volumes for cohorts 2025–2032.

The following tables demonstrate the expected change in Pell Grants awarded and loan volumes that resulted in the estimated net budget impact of $−292 million. Our estimates are based on institutional data, including Post-9/11 GI Bill benefits and DOD Tuition Assistance programs. They do not account for funds that go directly to students to cover tuition, fees, or other institutional charges, and they do not include other sources of Federal funds disbursed by State or local entities.

To estimate the reduction in loan volume related to the change in the 90/10 regulations, the Department assumed that institutions with a 90/10 rate over 95 percent under the final regulations would not be able to reduce their rate below 90. While institutions in the 2018–19 and 2019–20 90/10 files used for this estimate did not have the same motivations that will exist under the final regulations because the 90/10 calculation was different for them, no institution with a 90/10 rate above 95 in the first year was under 90 in the second year in the Department's analysis. Seventeen institutions with $94.9 million in Pell Grants and $194.1 million in loans were above the 95 percent rate, representing between 0.2 percent to 3.3 percent of proprietary volume depending on the institution's 2-year or 4-year level classification and grant or loan type. Student choice will affect the potential reduction, as students will be eligible to receive similar title IV amounts if attending a different institution. The Department has generally assumed a high percentage of students at schools that close or close programs because of 90/10 would pursue education and receive aid elsewhere. Additionally, a previous study has found that 60–70 percent enrollment losses at proprietary institutions due to sanctions were offset by increased enrollment at community colleges.[44] For this estimate, we assume that 60 percent of students would pursue their education elsewhere if their initial choice were not available due to the changes to the 90/10 regulations. Finally, we anticipate that the reduction in volume will decrease over the years as institutions over the threshold no longer participate and others adapt to the new threshold. To account for this, we reduced the percentage applied to the Pell Grant and loan volume by 30 percent in 2027–28 and 2028–29, 40 percent in 2029–30 and 2030–31, and 50 percent in 2031–32 and 2032–33. Table 2 shows the effect on Pell Grants of the final regulations.

TABLE 2—ESTIMATED REDUCTION IN PELL GRANT TRANSFERS FROM 90/10 REGULATIONS

| | AY 2023–24 | AY 2024–25 | AY 2025–26 | AY 2026–27 | AY 2027–28 | AY 2028–29 |
|---|---|---|---|---|---|---|
| PB23 Baseline: | | | | | | |
| Discretionary Cost ($m) | 24,342 | 27,581 | 28,041 | 28,509 | 28,994 | 30,385 |
| Mandatory Cost ($m) | 5,310 | 5,670 | 5,754 | 5,840 | 5,934 | 6,246 |
| Total Cost ($m) | 29,652 | 33,251 | 33,795 | 34,349 | 34,928 | 36,631 |
| Recipients | 6,380,000 | 6,990,000 | 7,113,000 | 7,237,000 | 7,372,000 | 7,656,000 |
| | AY 2023–24 | AY 2024–25 | AY 2025–26 | AY 2026–27 | AY 2027–28 | AY 2028–29 |

[44] Cellini, S.R., Darolia, R., & Turner, L.J. (2020). Where do students go when for-profit colleges lose Federal Aid? *American Economic Journal: Economic Policy,* 12(2), 46–83, *http://doi.org/10.1257/pol.20180265.*

TABLE 2—ESTIMATED REDUCTION IN PELL GRANT TRANSFERS FROM 90/10 REGULATIONS—Continued

| | AY 2023–24 | AY 2024–25 | AY 2025–26 | AY 2026–27 | AY 2027–28 | AY 2028–29 |
|---|---|---|---|---|---|---|
| PB23 Baseline: | | | | | | |
| Total Cost | 29,652 | 33,251 | 33,795 | 34,349 | 34,928 | 36,631 |
| % of Pell Grants at Institutions with 90/10 rates over 95 after 60% student adj applied | | 0.000% | 0.134% | 0.134% | 0.094% | 0.094% |
| Total Policy Cost | | | (45) | (46) | (33) | (34) |
| Discretionary Policy Cost | | | (38) | (38) | (27) | (29) |
| Mandatory Policy Cost | | | (8) | (8) | (6) | (6) |
| | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 | FY 2028 |
| Discretionary Outlays | | | (13) | (24) | (34) | (32) |
| Mandatory Outlays | | | (4) | (8) | (7) | (6) |
| Total Outlays | | | (17) | (32) | (41) | (38) |

The reduction in loan volume was processed as a reduction in the baseline volumes by loan type and risk group. Student loan model risk group is a combination of institutional control and academic level with 2-year or less proprietary, 2-year or less private non-profit and public, 4-year first-year/sophomore, 4-year junior/senior, and graduate students as the groups. In assigning the volume associated with 4-year programs to a risk group, we assumed 66 percent of volume will be in the 4-year first year/sophomore risk group and 34 percent in of volume the 4-year junior/senior risk group. Application of the adjustment factors to the loan volumes in the President's budget for FY 2023 baseline with modifications for the PSLF and IDR waivers, the December payment pause extension, and broad-based debt relief shown in Table 3 resulted in the $-44.32 million loan estimate shown in Table 4.

TABLE 3—LOAN VOLUME ADJUSTMENT FACTORS

| Cohort range | 2025–2026 % | 2027–2028 % | 2029–2030 % | 2031–2032 % |
|---|---|---|---|---|
| 2-year proprietary: | | | | |
| Subsidized | 0.645 | 0.452 | 0.387 | 0.323 |
| Unsubsidized | 0.632 | 0.443 | 0.379 | 0.316 |
| PLUS | 0.265 | 0.185 | 0.159 | 0.132 |
| 4-year FR/SO: | | | | |
| Subsidized | 0.112 | 0.078 | 0.067 | 0.056 |
| Unsubsidized | 0.144 | 0.101 | 0.086 | 0.072 |
| PLUS | 0.004 | 0.002 | 0.002 | 0.002 |
| 4-year JR/SR: | | | | |
| Subsidized | 0.112 | 0.078 | 0.067 | 0.056 |
| Unsubsidized | 0.144 | 0.101 | 0.086 | 0.072 |
| PLUS | 0.004 | 0.002 | 0.002 | 0.002 |
| GRAD: | | | | |
| Unsubsidized | 0.075 | 0.053 | 0.045 | 0.038 |
| Grad Plus | 0.008 | 0.005 | 0.005 | 0.004 |

TABLE 4—ESTIMATED 90/10 EFFECT ON LOANS

[$mns]

| | 2025 | 2026 | 2027 | 2028 | 2029 | 2030 | 2031 | 2032 | Total |
|---|---|---|---|---|---|---|---|---|---|
| Subsidized | −2.35 | −3.18 | −2.63 | −2.50 | −2.28 | −2.21 | −1.96 | −1.89 | −18.99 |
| Unsubsidized | −2.58 | −4.31 | −3.76 | −3.60 | −3.30 | −3.15 | −2.81 | −2.72 | −26.22 |
| PLUS | 0.13 | 0.18 | 0.13 | 0.11 | 0.10 | 0.09 | 0.08 | 0.08 | 0.90 |
| Total | −4.79 | −7.31 | −6.26 | −5.99 | −5.48 | −5.26 | −4.69 | −4.54 | −44.32 |

These reductions in transfers depend on institutional and student responses that are uncertain. In deciding whether to continue their education, students will depend on the availability of programs of interest at other institutions that fit their commuting or other constraints. Fewer institutions may be able to get their rate below 90 or more students may decide not to pursue their education if the institution they would have chosen is not available. Both of those scenarios would further reduce Pell Grant and loan transfers. For example, if the 49 institutions with rates above 90 under the final regulations in both years were assumed to not be able to get below the threshold, the estimated savings in Pell would be −$521 million and in loans −$84 million for a total of $605 million in reduced transfers to

students. The mix of institutions and the volume they represent means the assumption about what rate or which institutions could adapt and get below the threshold does have a significant effect on the net budget impact.

*Change in Ownership*

The final regulations clarify the definitions of ''additional location'' and ''branch campus,'' which will promote clearer reporting and a common understanding regarding ownership structures within postsecondary education. The final CIO regulations will also increase reporting to ensure greater transparency into CIO transactions and strengthen the Department's review of changes in control. Increased oversight of CIO transactions and changes to the definition of a ''nonprofit institution'' may affect the distribution of title IV aid across sectors, as the Department will approve conversions from for-profit status to non-profit status only when institutions have met the requirements of a ''nonprofit institution,'' and some students' choice of institution may be affected. However, the Department does not expect a significant budgetary impact from the CIO provisions and would not estimate one without additional data demonstrating a clear effect.

5. Accounting Statement

As required by OMB Circular A–4, we have prepared an accounting statement showing the classification of the expenditures associated with these final regulations. This table provides our best estimate of the changes in annual monetized transfers as a result of these final regulations. Expenditures are classified as transfers from the Federal government to affected student loan borrowers.

TABLE 5—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

[In millions]

| Category | Benefits | |
|---|---|---|
| Increased access to educational opportunities for incarcerated individuals | Not quantified. | |
| Increased protection of military-connected students from aggressive recruitment and greater exertion of market forces on proprietary institutions. | Not quantified. | |
| Improved information about changes in ownership | Not quantified. | |
| **Category** | **Costs** | |
| Discount Rate | 7% | 3% |
| Costs of compliance with paperwork requirements | $3.4 | $3.4 |
| Increased administrative costs to Federal government to update systems to implement the regulations | $11.1 | $11.1 |
| **Category** | **Transfers** | |
| | 7% | 3% |
| Reduced Pell Grants and loan transfers to students as some institutions lose eligibility from revised 90/10 | $−27.1 | $−28.3 |
| Increased Pell Grant transfers to institutions providing educational opportunities to incarcerated individuals | $109 | $111 |

6. Alternatives Considered

As part of the development of these regulations, the Department engaged in a negotiated rulemaking process in which we received comments and proposals from non-Federal negotiators representing numerous impacted constituencies. These included higher education institutions, consumer advocates, students, financial aid administrators, accrediting agencies, and State attorneys general. Non-Federal negotiators submitted a variety of proposals relating to the issues under discussion. Information about these proposals is available on our negotiated rulemaking website at *https://www2.ed.gov/policy/highered/reg/hearulemaking/2021/index.html.*

In response to comments received and further internal consideration of these final regulations, the Department reviewed and considered various changes to the proposed regulations detailed in the NPRM. We described the changes made in response to public comments in the Analysis of Comments and Changes section of this preamble. We summarize below the major proposals that we considered but ultimately chose not to implement in these regulations. In developing these final regulations, we contemplated the budgetary impact, administrative burden, and anticipated effectiveness of the options we considered.

6.1. *Pell Grants for Confined or Incarcerated Individuals:*

With regard to Pell Grants for confined or incarcerated individuals, the Department considered establishing regulations that merely restated the statutory requirements. However, because the requirements were new to institutions, oversight entities, and other stakeholders, we believed the field would benefit from greater clarity and detail in the regulations. As a result, we opted to negotiate on the specific requirements in the regulations and were pleased to reach consensus on those items.

With regard to an oversight entity's holistic determination that a PEP is operating in the best interest of students, the Department considered a variety of metrics, both from the HEA and those more widely used within the higher education system.

The Department received many comments on the proposed regulations opposing the best interest determination made by the oversight entity. Many commenters contended that the best interest determination focused too much on outcomes and not enough on inputs. Commenters were concerned that the oversight entity would not have the expertise to assess outcomes, and that the assessment would be overly burdensome, complex, and costly. In response to these comments, in the final regulations, the Department changed the best interest determination to make an assessment of outcomes (earnings, continuing education, and job placement post release) permissive rather than mandatory. The Department believes that a review of inputs and an optional review of outcomes strikes a better balance between ensuring high-quality PEPs and minimizing undue burden on oversight entities.

The Department also considered allowing institutions to enroll students in eligible PEPs that lead to occupations that typically involve prohibitions on licensure and employment for formerly incarcerated individuals, if the affected individuals attest that they are aware of the restrictions. We are concerned, however, that such programs would not generally be a productive use of students' limited Pell Grant eligibility or time, or of taxpayer dollars. While we acknowledge that some individuals may be able to meet such restrictive licensure requirements, if the typical student in such a program would not be able to find employment or obtain licensure, we are concerned that students may enroll in programs that exhaust their Pell Grant lifetime eligibility before they are able to complete a credential that would allow them to earn a job in the field. The Department is aware that many States have engaged in efforts to reduce barriers to employment for formerly incarcerated individuals, which we strongly encourage. Our regulations ensure that institutions must regularly re-review State requirements to ensure they keep up with any such changes and make potential students aware.

6.2. *90/10 Rule:*

In addressing the statutory changes to the 90/10 requirements made by the ARP, the Department considered including only DOD and Department of Veteran Affairs (VA) funds as additional Federal funds considered for 90/10 calculations, since these are the two largest programs with data that demonstrate a significant amount of funds flow to some proprietary institutions outside of title IV, HEA funds and because military-connected students have been targeted by some proprietary institutions in the past. The Department also considered including other large sources of Federal funds, such as WIOA, but excluding smaller sources. However, the Department determined to include all Federal education assistance programs, with the exception of funds that go directly to students that expressly cover costs outside of tuition, fees, and other institutional charges. The Department took this approach to be consistent with the statutory language in the ARP, which refers to ''Federal education assistance funds'' and because Federal appropriations for education assistance programs and disbursements to institutions may change from year to year. Consequently, the Department does not want to inadvertently create a new loophole where proprietary institutions identify a large source of Federal funds, such as WIOA, and target students that receive this funding.

The Department considered including only Federal funds that go directly to proprietary institutions, to eliminate any burden on proprietary institutions to obtain timely information about funds that go directly to students, especially if a student needs to pay back an agency for funds received due to dropping a class, enrollment intensity decreasing, or other reasons. The Department also considered including all student funds, including those earmarked for purposes other than tuition and fees, such as housing. However, to be consistent with the ARP and HEA, the Department decided to include funds that go directly to students for tuition, fees, and other institutional charges. The Department did not include funds that go directly to students that are earmarked for purposes other than tuition, fees, and other institutional charges because this funding does not apply to institutional charges, as required by the HEA.

The Department considered listing all Federal educational assistance programs in the regulations. However, these programs and the underlying facts that determine institutional eligibility may change over time, so the Department instead decided to identify sources of funds that are to be included in a **Federal Register** notice, which gives greater flexibility to account for changes over time and can be updated as needed.

6.3. *Change in Ownership:*

The Department considered establishing a definition of ''nonprofit institution'' that would preclude all revenue-based or other agreements with a former owner, as opposed to just those that exceed reasonable market value. However, we determined that there could be agreements with a former owner that should not disqualify an institution from nonprofit status.

The Department considered maintaining the current definitions that require the Department to evaluate whether there has been a change of control at 25 percent of a change in ownership interest, rather than 50 percent, as under the final regulations. However, in general we have found that control below 50 percent is relatively rare. To accommodate concerns that institutions might begin to establish changes of control at, for example, 49 percent to evade the CIO requirements, we lowered the threshold for reporting changes in ownership to 5 percent from 25 percent and retained discretion for the Secretary to review and determine a change of control at a threshold below 50 percent based on information available to the Secretary. While the Department also considered requiring reporting of all changes in ownership at any level, we instead determined 5 percent is appropriate to avoid unnecessary reporting on extremely minor changes and to limit unreasonable burden on institutions.

The Department considered whether to maintain the provision that requires the Secretary to continue an institution's participation in the title IV, HEA programs after a CIO with the same terms and conditions that governed its participation before the CIO. However, we are concerned that such terms may not adequately account for the added risk the institution may present to students and taxpayers as a result of the transaction. Based on our past review of CIO applications, we are aware of numerous cases in which the transaction fundamentally altered the operations of the institution. We believe that additional conditions and new terms are more appropriate for institutions undergoing a CIO and are accordingly including language that allows the Department to establish such appropriate terms.

7. Regulatory Flexibility Act

The Secretary certifies, under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), that this regulatory action will not have a significant economic impact on a substantial number of ''small entities.''

The Small Business Administration (SBA) defines ''small institution'' using data on revenue, market dominance, tax filing status, governing body, and population. Most entities to which the Office of Postsecondary Education's (OPE) regulations apply are postsecondary institutions; however, many of these institutions do not report such data to the Department. As a result, for purposes of this final rule, the Department will continue defining ''small entities'' by reference to enrollment,[45] to allow meaningful comparison of regulatory impact across all types of higher education institutions.[46]

[45] Two-year postsecondary educational institutions with enrollment of less than 500 full-time equivalent (FTE) and four-year postsecondary educational institutions with enrollment of less than 1,000 FTE.

[46] In previous regulations, the Department categorized small businesses based on tax status. Those regulations defined ''non-profit organizations'' as ''small organizations'' if they were independently owned and operated and not dominant in their field of operation, or as ''small entities'' if they were institutions controlled by governmental entities with populations below 50,000. Those definitions resulted in the categorization of all private nonprofit organization

Continued

TABLE 6—SMALL INSTITUTIONS UNDER ENROLLMENT-BASED DEFINITION

| Level | Type | Small | Total | Percent |
|---|---|---|---|---|
| 2-year | Public | 328 | 1182 | 27.75 |
| 2-year | Private | 182 | 199 | 91.46 |
| 2-year | Proprietary | 1777 | 1952 | 91.03 |
| 4-year | Public | 56 | 747 | 7.50 |
| 4-year | Private | 789 | 1602 | 49.25 |
| 4-year | Proprietary | 249 | 331 | 75.23 |
| Total | | 3381 | 6013 | 56.23 |

Source: 2018–19 data reported to the Department.

Table 7 summarizes the number of institutions affected by these regulations.

TABLE 7—ESTIMATED COUNT OF SMALL INSTITUTIONS AFFECTED BY THE REGULATIONS

| | Small institutions affected | As percent of small institutions |
|---|---|---|
| Pell Grants for Confined or Incarcerated Individuals | 136 | 4.02 |
| 90/10 | 1,650 | 17.00 |
| Change in Ownership | 203 | 10.00 |

The Department has determined that the economic impact on small entities affected by the regulations will not be significant. As seen in Table 8, the average total revenue at small institutions ranges from $2.3 million for proprietary institutions to $21.3 million at private institutions. These amounts are significantly higher than the $2,953 to $4,593 in estimated costs per small institution for the regulations presented in Table 9.

TABLE 8—TOTAL REVENUES AT SMALL INSTITUTIONS

| Control | Average total revenues for small institutions | Total revenues for all small institutions |
|---|---|---|
| Private | 21,288,171 | 20,670,814,269 |
| Proprietary | 2,343,565 | 4,748,063,617 |
| Public | 15,398,329 | 5,912,958,512 |

**Note:** Based on analysis of IPEDS enrollment and revenue data for 2018–19.

The impact of the PEP regulations will be minimal to small institutions and will involve meeting disclosure requirements and complying with oversight entity and the Department requirements.

The changes to 90/10 will have a minor impact on proprietary institutions. These impacts include calculating the non-Federal revenue and providing a notification to students and the Department if an institution fails to comply with the 90/10 requirement.

While the CIO regulations have the potential to impact small entities, so there will be a minor burden on institutions that undergo a CIO to notify students at least 90 days prior to a proposed CIO. We believe this burden will be minor and the notification can be disseminated electronically. The reduction in the reporting threshold for changes in ownership from 25 to 5 percent will impact more small entities than in the past; however, the burden associated with this increase in reporting is minimal and relatively uncommon. The Department anticipates that lowering the reporting threshold will not result in many institutions having to meet reporting requirements as the Department anticipates that even at the lower threshold, this is still not a common occurrence. In addition, the reporting burden is minimal for those who will have a reporting burden.

as small and no public institutions as small. Under the previous definition, proprietary institutions were considered small if they were independently owned and operated and not dominant in their field of operation with total annual revenue below $7,000,000. Using FY 2017 IPEDs finance data for proprietary institutions, 50 percent of 4-year and 90 percent of 2-year or less proprietary institutions would be considered small. By contrast, an enrollment-based definition applies the same metric to all types of institutions, allowing consistent comparison across all types.

TABLE 9—ESTIMATED COSTS FOR SMALL INSTITUTIONS

| Compliance area | Number of small institutions affected | Cost range per institution ($) | | Estimated overall cost range for small institutions affected ($) | |
|---|---|---|---|---|---|
| Pell Grants for Confined or Incarcerated Individuals disclosure requirement | 44 | 750 | 1,125 | 32,996 | 49,495 |
| 90/10 non-Federal revenue calculation | 1,650 | 750 | 1,500 | 1,237,368 | 2,474,736 |
| 90/10 failure student notification | 11 | 141 | 187 | 1,547 | 2062 |
| CIO notification to students | 71 | 188 | 281 | 13,313 | 19,967 |
| CIO increased reporting burden | 203 | 1,125 | 1,500 | 228,351 | 304,468 |

*Paperwork Reduction Act of 1995*

As part of its continuing effort to reduce paperwork and respondent burden, the Department provides the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This helps ensure that the public understands the Department's collection instructions, respondents can provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the Department can properly assess the impact of collection requirements on respondents.

Sections 600.7, 600.10, 600.20, 600.21, 668.28, 668.43, 668.237, and 668.238 of this final rule contain information collection requirements. These final regulations include requirements for institutions to: obtain a waiver allowing them to enroll more than 25 percent of their students as incarcerated students; obtain approval to offer PEPs; submit an application seeking continued title IV participation for a change in ownership; report changes in ownership or control; and, for proprietary institutions, demonstrate compliance with the 90/10 rule. Under the PRA, the Department has or will at the required time submit a copy of these sections and an Information Collection Request to OMB for its review. For some of the regulatory sections, including those relating to PEPs, PRA approval will be sought via a separate information collection process. Specifically, the Department will publish notices in the **Federal Register** to seek public comment on these collections.

A Federal agency may not conduct or sponsor a collection of information unless OMB approves the collection under the PRA and the corresponding information collection instrument displays a currently valid OMB control number. Notwithstanding any other provision of law, no person is required to comply with, or is subject to penalty for failure to comply with, a collection of information if the collection instrument does not display a currently valid OMB control number. In the final regulations, we will display the control numbers assigned by OMB to the information collection requirements adopted in these final regulations.

*Section 600.7—Conditions of institutional eligibility;*

*Section 600.10—Date, extent, duration, and consequences of eligibility;*

*Section 600.20—Notice and application procedures for establishing, reestablishing, maintaining, or expanding institutional eligibility and certification;*

*Section 600.21—Updating application information; and*

*Section 668.238—Application requirements.*

*Requirements:* Under § 600.7(c)(1), the Secretary will not approve an enrollment cap waiver for a postsecondary institution's Prison Education Program (PEP) until the oversight entity is able to make the ''best interest determination'' described in § 668.241, which will be at least 2 years after the postsecondary institution has continuously provided a PEP.

Section 600.10(c)(1)(iv) requires an institution to obtain approval from the Secretary to offer the institution's first eligible PEP at its first two additional locations at correctional facilities.

Section 600.20(g)(1)(i) requires institutions to notify the Department at least 90 days in advance of a proposed change in ownership. This includes submission of a completed form, State authorization and accrediting documents, and copies of audited financial statements. It also includes reporting any subsequent changes to the proposed ownership structure at least 90 days prior to the date the change in ownership is to occur.

We are amending the reporting requirements in § 600.21(a)(6) to distinguish between reportable changes in ownership and changes of control and between natural persons and legal entities.

Under § 600.21(a)(14), institutions must report initial or additional PEPs and locations for PEPs.

Section 600.21(a)(15) also requires reporting on changes in ownership that do not result in a change of control and that are not otherwise specified on the list of types of changes in ownership that must be reported, to ensure that novel ownership structures are covered under the regulations.

Section 668.238(a) requires postsecondary institution to seek approval for the first PEP at the first two additional locations as required under § 600.10. The application requirements for such PEPs are in § 668.238(b). For all other PEPs and locations not subject to initial approval by the Secretary, postsecondary institutions must submit the documentation outlined in § 668.238(c).

*Burden Calculation:* All of these regulatory changes will require an update to the current institutional application form, 1845–0012. The form update will be completed and made available for comment through a full public clearance package before being made available for use by the effective date of the regulations. The burden changes will be assessed to OMB Control Number 1845–0012, Application for Approval to Participate in Federal Student Aid Programs.

*Section 600.20—Notice and application procedures for establishing, reestablishing, maintaining, or expanding institutional eligibility and certification.*

*Requirements:* Section 600.20(g)(4) requires institutions to notify enrolled and prospective students at least 90 days prior to a proposed change in ownership.

*Burden Calculation:* We believe that this will result in burden for the institution. Based on the GAO report cited earlier, using the 59 institutional changes of ownership over a period of 9 years, we estimate that 7 institutions annually will require 20 hours to develop the required notice and create

and send an email message to all current and prospective students for a total of 140 hours (7 × 20 hours = 140 hours). The burden change will be assessed to OMB Control Number 1845–NEW, Change of Ownership Notification to Students.

CHANGE OF OWNERSHIP NOTIFICATION TO STUDENTS—OMB CONTROL NUMBER: 1845–NEW

| Affected entity | Respondent | Responses | Burden hours | Cost at $46.59 per hour for institutions |
|---|---|---|---|---|
| Proprietary | 7 | 7 | 140 | $6,522.60 |
| Total | 7 | 7 | 140 | 6,522.60 |

*Section 668.28—Non-Federal revenue (90/10).*

*Requirements:* Section 668.28(a)(2) outlines how proprietary institutions calculate the percentage of their revenue that is Federal revenue and creates an end-of-fiscal-year deadline for proprietary institutions to request and disburse title IV funds to students. Additionally, in § 668.28(c)(3) we establish disclosures for proprietary institutions that fail to derive at least 10 percent of their fiscal-year revenues from allowable non-Federal funds.

*Burden Calculation:* We believe that the changes to § 668.28(a)(2) will result in burden for the institution. As of April 2022, there were 1,650 proprietary institutions eligible to participate in the title IV, HEA programs. We believe that all proprietary institutions will be required to perform this calculation. We believe that it will take 1,650 institutions an estimated 24 hours each to gather information about the eligible students and payment information to perform the required calculations and request any required disbursements for a total of 39,600 hours (1,650 institutions × 24 hours = 39,600 hours). The estimated costs for institutions to meet this requirement are $1,844,964.

We believe that the changes to § 668.28(c)(3), which requires institutions to notify students when the institution fails the 90/10 revenue test, will result in a burden for the institution. For the 2019–2020 Award Year, there were 33 institutions that failed to meet the 90/10 revenue test when adding in Post 9–11 GI Bill and DOD Tuition Assistance funds. Using this number of institutions as representative of the number of institutions that would annually fail the 90/10 revenue test, we estimate that 33 institutions will require 4 hours to develop and post the required notice on the institution's intranet and internet sites for a total of 132 hours (33 institutions × 4 hours = 132 hours). The estimated costs for institutions to meet this requirement are $6,150.

The total burden assessed to OMB Control Number 1845–0096 is estimated at 39,732 hours and estimated costs of $1,851,114.

STUDENT ASSISTANCE GENERAL PROVISIONS—NON-TITLE IV REVENUE REQUIREMENTS (90/10)—OMB CONTROL NUMBER: 1845–0096

| Affected entity | Respondent | Responses | Burden hours | Cost at $46.59 per hour for institutions |
|---|---|---|---|---|
| Proprietary | 1,650 | 1,683 | 39,732 | $1,851,114 |
| Total | 1,650 | 1,683 | 39,732 | 1,851,114 |

*Section 668.43—Institutional Information.*

*Requirements:* Under § 668.43(a)(5)(vi), an institution must disclose if an eligible PEP is designed to meet educational requirements for a specific professional license or certification that is required for employment in an occupation (as described in § 668.236(a)(7) and (8)). In that case, the postsecondary institution must provide information regarding whether that occupation typically involves State or Federal prohibitions on the licensure or employment of formerly confined or incarcerated individuals. This requirement applies in the State where the correctional facility is located or, in the case of a Federal correctional facility, in the State where most of the individuals confined or incarcerated in such facility will reside upon release.

*Burden Calculation:* We believe that, of an estimated 400 institutions that will participate in PEPs, 20 percent or 80 institutions will have programs that will require such research and disclosure. We further believe that, of an estimated 800 programs at those institutions, 20 percent or 160 programs will require such research and disclosure. We anticipate that to fully research the licensure requirements in the required State or States and prepare documentation for students in the eligible PEP, an institution will need 25 hours per program for an estimated total burden of 4,000 hours (160 × 25 = 4,000). The burden of 4,000 hours will be assessed to OMB Control Number 1845–0156 with an estimated cost of $186,360.

ACCREDITATION PARTICIPATION AND DISCLOSURES—OMB CONTROL NUMBER: 1845–0156

| Affected entity | Respondent | Responses | Burden hours | Cost at $46.59 per hour for institutions |
|---|---|---|---|---|
| Private, not-for-profit | 14 | 28 | 700 | $32,613 |

ACCREDITATION PARTICIPATION AND DISCLOSURES—OMB CONTROL NUMBER: 1845–0156—Continued

| Affected entity | Respondent | Responses | Burden hours | Cost at $46.59 per hour for institutions |
|---|---|---|---|---|
| Public | 66 | 132 | 3,300 | 153,747 |
| Total | 80 | 160 | 4,000 | 186,360 |

*Section 668.237—Accreditation requirements.*

*Requirements:* Section 668.237 requires program evaluation at the first two additional locations to ensure institutional ability to offer and implement the PEP in accordance with the accrediting agency's standards. The final regulations require the accrediting agency to conduct a site visit no later than one year after the institution has initiated a PEP at its first two additional locations at correctional facilities. Additionally, the final regulations require accrediting agencies to review the methodology used by an institution in determining that the PEP meets the same standards for substantially similar non-PEP programs.

*Burden Calculation:* Of the current 54 recognized accrediting agencies, it is estimated that 18 accrediting agencies may be called upon to perform such required reviews for institutions under their oversight. It is estimated that each of these accrediting agencies will require 8 hours per institution to evaluate the written applications for the first two PEP programs offered or any change in methodology review. With an estimated 400 institutions participating in the PEP program, accrediting agencies will require 3,200 hours to complete this initial review (400 institutions × 8 hours = 3,200 burden hours).

We estimate that, under the final regulations, accrediting agencies will require 50 hours to prepare for the site visit, perform the site visit, and report the findings. With an estimated 400 institutions participating in the PEP program, accrediting agencies will require 20,000 hours to complete this initial review (400 institutions × 50 hours = 20,000 burden hours).

We estimate that accrediting agencies will require an estimated 8 hours to perform the methodology review under the final regulations. With an estimated 400 institutions participating in the PEP program, accrediting agencies will require 3,200 hours to complete this initial review (400 institutions × 8 hours = 3,200 burden hours).

The total estimated burden for accrediting agencies to perform these tasks for the PEP evaluations is 42,400 hours under the OMB Control Number 1840–NEW.

PRISON EDUCATION PROGRAM ACCREDITATION REQUIREMENTS—OMB CONTROL NUMBER 1840–NEW

| Affected entity | Respondent | Responses | Burden hours | Cost $46.59 per hour for institutions |
|---|---|---|---|---|
| Not-For-Profit Private | 18 | 12,000 | 26,400 | $1,229,976 |
| Total | 18 | 12,000 | 26,400 | 1,229,976 |

Consistent with the discussions above, the following chart describes the sections of the final regulations involving information collections, the information being collected, the collections that the Department will submit to OMB for approval and public comment under the PRA, and the estimated costs associated with the information collections. The monetized net cost of the increased burden for institutions and students was calculated using wage data developed using Bureau of Labor Statistics (BLS) data. For institutions, we have used the median hourly wage for Education Administrators, Postsecondary, $46.59 per hour according to BLS as of May 2021. *www.bls.gov/oes/current/oes119033.htm.*

TABLE 10—COLLECTION OF INFORMATION

| Regulatory section | Information collection | OMB control No. and estimated burden | Estimated cost $46.59 institutional unless otherwise noted |
|---|---|---|---|
| §§ 600.7, 600.10, 600.20, 600.21, and 668.238. | § 600.7(c)(1) specifies procedures for the Secretary to approve an enrollment cap waiver for incarcerated individuals at a postsecondary institution.<br>§§ 600.10(c)(1)(iv) and 668.238(a) require an institution to obtain approval from the Secretary to offer the institution's first eligible PEP at its first two additional locations at correctional facilities.<br>§ 600.20(g)(1)(i) requires institutions to notify the Department at least 90 days in advance of a proposed change in ownership.<br>§ 600.21(a)(6) specifies reporting requirements for changes in ownership and changes of control.<br>§ 600.21(a)(14) requires institutions to report on PEPs. | 1845–0012; Burden will be cleared at a later date through a separate information collection for the form. | Costs will be cleared through separate information collection for the form. |

TABLE 10—COLLECTION OF INFORMATION—Continued

| Regulatory section | Information collection | OMB control No. and estimated burden | Estimated cost $46.59 institutional unless otherwise noted |
|---|---|---|---|
| | § 600.21(a)(15) requires reporting on changes in ownership that do not result in a change of control and that are not otherwise specified in the regulations. § 668.238(b) specifies the application requirements for PEPs. For all other PEPs not subject to initial approval by the Secretary, postsecondary institutions must submit the documentation outlined in § 668.238(c). | | |
| § 600.20 | § 600.20(g)(4) requires institutions to notify enrolled and prospective students at least 90 days prior to a proposed change in ownership. | 1845—NEW; 140 hours | $6,522.60. |
| § 668.28 | § 668.28(a)(2) clarifies how proprietary institutions calculate the percentage of their revenue from Federal education assistance programs. § 668.28(c)(3) establishes disclosures for proprietary institutions that fail the 90/10 calculation. | 1845–0096; 39,732 hours | $1,844,964. |
| § 668.43 | § 668.43(a)(5)(vi) requires a disclosure if an eligible PEP is designed to meet educational requirements for a specific professional license or certification that is required for employment in an occupation. | 1845–0156; 4,000 hours | $186,360. |
| § 668.237 | § 668.237 specifies how accrediting agencies will review PEPs.. | 1840—NEW; 26,400 hours | $1,229,976. |

The total burden hours and change in burden hours associated with each OMB Control number affected by the regulations follows:

| Control No. | Total burden hours | Change in burden hours |
|---|---|---|
| 1840–NEW | 26,400 | +26,400 |
| 1845–0096 | 39,737 | +39,732 |
| 1845–0156 | 583,171 | +4,000 |
| 1845–NEW | 140 | +140 |
| Total | 649,448 | +70,272 |

We have prepared Information Collection Requests for these information collection requirements. If you wish to review and comment on the Information Collection Requests, please follow the instructions in the **ADDRESSES** section of this document. *Note:* The Office of Information and Regulatory Affairs in OMB and the Department review all comments posted at *www.regulations.gov*.

In preparing your comments, you may want to review the Information Collection Requests (ICRs), including the supporting materials, in *www.regulations.gov* by using Docket ID ED–2022–OPE–0062. These proposed collections are identified as proposed collections 1840–NEW, 1845–0096, 1845–0156, 1845–NEW.

If you want to review and comment on the ICRs, please follow the instructions provided below. Please note that the Office of Information and Regulatory Affairs and the Department review all comments posted at *www.regulations.gov*.

We consider your comments on these proposed collections of information in—

- Deciding whether the proposed collections are necessary for the proper performance of our functions, including whether the information will have practical use;
- Evaluating the accuracy of our estimate of the burden of the proposed collections, including the validity of our methodology and assumptions;
- Enhancing the quality, usefulness, and clarity of the information we collect; and
- Minimizing the burden on those who must respond. Comments submitted in response to this document should be submitted electronically through the Federal eRulemaking Portal at *www.regulations.gov* by selecting Docket ID ED–2022–OPE–0062. Please specify the Docket ID and indicate ''Information Collection Comments'' if your comment(s) relate to the information collection for this rule.

*For Further Information:* Electronically mail *ICDocketMgr@ed.gov.*

Consistent with 5 CFR 1320.8(d), the Department is soliciting comments on the information collection through this document. OMB is required to make a decision concerning the collections of information contained in these final regulations between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, to ensure that OMB gives your comments full consideration, it is important that OMB receives your comments by November 28, 2022.

**Intergovernmental Review**

This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive Order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

**Assessment of Educational Impact**

In the NPRM we requested comments on whether the proposed regulations would require transmission of information that any other agency or authority of the United States gathers or makes available. Based on the response to the NPRM and on our review, we have determined that these final regulations do not require transmission of information that any other agency or authority of the United States gathers or makes available.

**Federalism**

Executive Order 13132 requires us to ensure meaningful and timely input by State and local elected officials in the development of regulatory policies that have federalism implications. ''Federalism implications'' means substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. The final regulations do not have federalism implications.

*Accessible Format:* On request to one of the program contact persons listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

*Electronic Access to This Document:* The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov*. At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov*. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

**List of Subjects**

*34 CFR Part 600*

Colleges and universities, Foreign relations, Grant programs-education, Loan programs-education, Reporting and recordkeeping requirements, Selective Service System, Student aid, Vocational education.

*34 CFR Part 668*

Administrative practice and procedure, Aliens, Colleges and universities, Consumer protection, Grant programs-education, Loan programs-education, Reporting and recordkeeping requirements, Selective Service System, Student aid, Vocational education.

*34 CFR Part 690*

Colleges and universities, Education of disadvantaged, Grant programs-education, Reporting and recordkeeping requirements, Student aid.

**Miguel A. Cardona,**

*Secretary of Education.*

For the reasons discussed in the preamble, the Secretary amends parts 600, 685, 668, and 690 of title 34 of the Code of Federal Regulations as follows:

## PART 600—INSTITUTIONAL ELIGIBILITY UNDER THE HIGHER EDUCATION ACT OF 1965, AS AMENDED

■ 1. The authority citation for part 600 continues to read as follows:

**Authority:** 20 U.S.C. 1001, 1002, 1003, 1088, 1091, 1094, 1099b, and 1099c, unless otherwise noted.

■ 2. Section 600.2 is amended by:
■ a. Revising the definitions of ''Additional location'' and ''Branch campus''.
■ b. Adding in alphabetical order a definition of ''Confined or incarcerated individual''.
■ c. Removing the definition of ''Incarcerated student''.
■ d. Adding in alphabetical order a definition of ''Main campus''.
■ e. Revising the definition of ''Nonprofit institution''.

The additions and revisions read as follows:

**§ 600.2 Definitions.**

* * * * *

*Additional location:* (1) A physical facility that is geographically separate from the main campus of the institution and within the same ownership structure of the institution, at which the institution offers at least 50 percent of an educational program. An additional location participates in the title IV, HEA programs only through the certification of the main campus.

(2) A Federal, State, or local penitentiary, prison, jail, reformatory, work farm, juvenile justice facility, or other similar correctional institution is considered to be an additional location even if a student receives instruction primarily through distance education or correspondence courses at that location.

* * * * *

*Branch campus:* A physical facility that is geographically separate from the main campus of the institution and within the same ownership structure of the institution, and that also—

(1) Is approved by the Secretary as a branch campus; and

(2) Is independent from the main campus, meaning the location—

(i) Is permanent in nature;

(ii) Offers courses in educational programs leading to a degree, certificate, or other recognized education credential;

(iii) Has its own faculty and administrative or supervisory organization; and

(iv) Has its own budgetary and hiring authority.

* * * * *

*Confined or incarcerated individual:* An individual who is serving a criminal sentence in a Federal, State, or local penitentiary, prison, jail, reformatory, work farm, juvenile justice facility, or other similar correctional institution. An individual is not considered incarcerated if that individual is subject to or serving an involuntary civil commitment, in a half-way house or home detention, or is sentenced to serve only weekends.

* * * * *

*Main campus:* The primary physical facility at which the institution offers eligible programs, within the same ownership structure of the institution, and certified as the main campus by the Department and the institution's accrediting agency.

* * * * *

*Nonprofit institution:* (1) A nonprofit institution is a domestic public or private institution or foreign institution as to which the Secretary determines that no part of the net earnings of the institution benefits any private entity or natural person and that meets the requirements of paragraphs (2) through (4) of this definition, as applicable.

(2) When making the determination under paragraph (1) of this definition, the Secretary considers the entirety of the relationship between the institution, the entities in its ownership structure, and other parties. For example, a nonprofit institution is generally not an institution that—

(i) Is an obligor (either directly or through any entity in its ownership chain) on a debt owed to a former owner of the institution or a natural person or

entity related to or affiliated with the former owner of the institution;

(ii) Either directly or through any entity in its ownership chain, enters into or maintains a revenue-sharing agreement, unless the Secretary determines that the payments and the terms under the revenue-sharing agreement are reasonable, based on the market price and terms for such services or materials, and the price bears a reasonable relationship to the cost of the services or materials provided, with—

(A) A former owner or current or former employee of the institution or member of its board; or

(B) A natural person or entity related to or affiliated with the former owner or current or former employee of the institution or member of its board;

(iii) Is a party (either directly or indirectly) to any other agreements (including lease agreements) under which the institution is obligated to make any payments, unless the Secretary determines that the payments and terms under the agreement are comparable to payments in an arm's-length transaction at fair market value, with—

(A) A former owner or current or former employee of the institution or member of its board; or

(B) A natural person or entity related to or affiliated with the former owner or current or former employee of the institution or member of its board; or

(iv) Engages in an excess benefit transaction with any natural person or entity.

(3) A private institution is a ''nonprofit institution'' only if it meets the requirements in paragraph (1) of this definition and is—

(i) Owned and operated by one or more nonprofit corporations or associations;

(ii) Legally authorized to operate as a nonprofit organization by each State in which it is physically located; and

(iii) Determined by the U.S. Internal Revenue Service to be an organization described in section 501(c)(3) of the Internal Revenue Code (26 U.S.C. 501(c)(3)).

(4) A foreign institution is a ''nonprofit institution'' only if it meets the requirements in paragraph (1) of this definition and is—

(i) An institution that is owned and operated only by one or more nonprofit corporations or associations; and

(ii)(A) If a recognized tax authority of the institution's home country is recognized by the Secretary for purposes of making determinations of an institution's nonprofit status for title IV purposes, is determined by that tax authority to be a nonprofit educational institution; or

(B) If no recognized tax authority of the institution's home country is recognized by the Secretary for purposes of making determinations of an institution's nonprofit status for title IV purposes, the foreign institution demonstrates to the satisfaction of the Secretary that it is a nonprofit educational institution.

* * * * *

■ 3. Section 600.4 is amended by:

■ a. Revising paragraph (a) introductory text; and

■ b. Removing the parenthetical authority citation at the end of the section.

The revision reads as follows:

**§ 600. Institution of higher education.**

(a) An institution of higher education is a public or other nonprofit educational institution that—

* * * * *

■ 4. Section 600.7 is amended by revising paragraph (c) to read as follows:

**§ 600.7 Conditions of institutional eligibility.**

* * * * *

(c) *Special provisions regarding confined or incarcerated individuals.* (1)(i) The Secretary may waive the prohibition contained in paragraph (a)(1)(iii) of this section, upon the application of an institution, if the institution is a nonprofit institution that provides four-year or two-year educational programs for which it awards a bachelor's degree, an associate degree, or a postsecondary diploma and has continuously provided an eligible prison education program approved by the Department under subpart P of 34 CFR part 668 for at least two years.

(ii) The Secretary does not grant the waiver of the prohibition contained in paragraph (a)(1)(iii) of this section if—

(A) For a program described under paragraph (c)(3)(ii) of this section, the program does not maintain a completion rate of 50 percent or greater; or

(B) For an institution described under paragraph (c)(2) or (3) of this section—

(*1*) The institution provides one or more eligible prison education programs that is not compliant with the requirements of 34 CFR part 668, subpart P; or

(*2*) The institution is not administratively capable under 34 CFR 668.16 or financially responsible under 34 CFR part 668, subpart L.

(2) If the nonprofit institution that applies for a waiver consists solely of four-year or two-year educational programs for which it awards a bachelor's degree, an associate degree, or a postsecondary diploma, the Secretary may waive the prohibition contained in paragraph (a)(1)(iii) of this section for the entire institution.

(3) If the nonprofit institution that applies for a waiver does not consist solely of four-year or two-year educational programs for which it awards a bachelor's degree, an associate degree, or a postsecondary diploma, the Secretary may waive the prohibition contained in paragraph (a)(1)(iii) of this section on a program-by-program basis—

(i) For the four-year and two-year programs for which the institution awards a bachelor's degree, an associate degree, or a postsecondary diploma; and

(ii) For the other programs the institution provides, if the confined or incarcerated individuals who are regular students enrolled in those other programs have a completion rate of 50 percent or greater.

(4)(i)(A) For five years after the Secretary grants the waiver, no more than 50 percent of the institution's regular enrolled students may be confined or incarcerated individuals; and

(B) Following the period described in paragraph (c)(4)(i)(A) of this section, no more than 75 percent of the institution's regular enrolled students may be confined or incarcerated individuals.

(ii) The limitations in paragraph (c)(4)(i) of this section do not apply if the institution is a public institution chartered for the explicit purpose of educating confined or incarcerated individuals, as determined by the Secretary, and all students enrolled in the institution's prison education program are located in the State where the institution is chartered.

(5) The Secretary limits or terminates the waiver described in this section if the Secretary determines the institution no longer meets the requirements established under paragraph (c)(1) of this section.

(6) If the Secretary limits or terminates an institution's waiver under paragraph (c) of this section, the institution ceases to be eligible for the title IV, HEA programs at the end of the award year that begins after the Secretary's action unless the institution, by that time—

(i) Demonstrates to the satisfaction of the Secretary that it meets the requirements under paragraph (c)(1) of this section; and

(ii) The institution does not enroll any additional confined or incarcerated individuals upon the limitation or termination of the waiver and reduces its enrollment of confined or

incarcerated individuals to no more than 25 percent of its regular enrolled students.

* * * * *

■ 5. Section 600.10 is amended by revising paragraph (c)(1) to read as follows:

**§ 600.10 Date, extent, duration, and consequence of eligibility.**

* * * * *

(c) * * *

(1) An eligible institution that seeks to establish the eligibility of an educational program must obtain the Secretary's approval—

(i) Pursuant to a requirement regarding additional programs included in the institution's Program Participation Agreement (PPA) under 34 CFR 668.14;

(ii) For the first direct assessment program under 34 CFR 668.10, the first direct assessment program offered at each credential level, and for a comprehensive transition and postsecondary program under 34 CFR 668.232;

(iii) For an undergraduate program that is at least 300 clock hours but less than 600 clock hours and does not admit as regular students only persons who have completed the equivalent of an associate degree under 34 CFR 668.8(d)(3); and

(iv) For the first eligible prison education program under subpart P of 34 CFR part 668 offered at the first two additional locations as defined under § 600.2 at a Federal, State, or local penitentiary, prison, jail, reformatory, work farm, juvenile justice facility, or other similar correctional institution.

* * * * *

■ 6. Section 600.20 is amended by revising paragraphs (g) and (h) to read as follows:

**§ 600.20 Notice and application procedures for establishing, reestablishing, maintaining, or expanding institutional eligibility and certification.**

* * * * *

(g) *Application for provisional extension of certification.* (1) If a private nonprofit institution, a private for-profit institution, or a public institution participating in the title IV, HEA programs undergoes a change in ownership that results in a change of control as described in § 600.31, the Secretary may continue the institution's participation in those programs on a provisional basis if—

(i) No later than 90 days prior to the change in ownership, the institution provides the Secretary notice of the proposed change on a fully completed form designated by the Secretary and supported by the State authorization and accrediting documents identified in paragraphs (g)(3)(i) and (ii) of this section, and supported by copies of the financial statements identified in paragraphs (g)(3)(iii) and (iv) of this section;

(ii) The institution promptly reports to the Secretary any changes to the proposed ownership structure identified under paragraph (g)(1)(i) of this section, provided that the change in ownership cannot occur earlier than 90 days following the date the change is reported to the Secretary; and

(iii) The institution under the new ownership submits a ''materially complete application'' that is received by the Secretary no later than 10 business days after the day the change occurs.

(2) Notwithstanding the submission of the items under paragraph (g)(1) of this section, the Secretary may determine that the participation of the institution should not be continued following the change in ownership.

(3) For purposes of this section, a private nonprofit institution, a private for-profit institution, or a public institution submits a materially complete application if it submits a fully completed application form designated by the Secretary supported by—

(i) A copy of the institution's State license or equivalent document that authorized or will authorize the institution to provide a program of postsecondary education in the State in which it is physically located, supplemented with documentation that, as of the day before the change in ownership, the State license remained in effect;

(ii) A copy of the document from the institution's accrediting agency that granted or will grant the institution accreditation status, including approval of any non-degree programs it offers, supplemented with documentation that, as of the day before the change in ownership, the accreditation remained in effect;

(iii) Audited financial statements for the institution's two most recently completed fiscal years that are prepared and audited in accordance with the requirements of 34 CFR 668.23;

(iv)(A) Audited financial statements for the institution's new owner's two most recently completed fiscal years that are prepared and audited in accordance with the requirements of 34 CFR 668.23, or equivalent financial statements for that owner that are acceptable to the Secretary; or

(B) If such financial statements are not available, financial protection in the amount of—

(*1*) At least 25 percent of the institution's prior year volume of title IV aid if the institution's new owner does not have two years of acceptable audited financial statements; or

(*2*) At least 10 percent of the institution's prior year volume of title IV aid if the institution's new owner has only one year of acceptable audited financial statements; and

(v) If deemed necessary by the Secretary, financial protection in the amount of an additional 10 percent of the institution's prior year volume of title IV aid, or a larger amount as determined by the Secretary. If any entity in the new ownership structure holds a 50 percent or greater direct or indirect voting or equity interest in another institution or institutions, the financial protection may also include the prior year volume of title IV aid, or a larger amount as determined by the Secretary, for all institutions under such common ownership.

(4) The institution must notify enrolled and prospective students of the proposed change in ownership, and submit evidence that such disclosure was made, no later than 90 days prior to the change.

(h) *Terms of the extension.* (1) If the Secretary approves the institution's materially complete application, the Secretary provides the institution with a temporary provisional Program Participation Agreement (TPPPA).

(2) The TPPPA expires on the earlier of—

(i) The last day of the month following the month in which the change of ownership occurred, unless the provisions of paragraph (h)(3) of this section apply;

(ii) The date on which the Secretary notifies the institution that its application is denied; or

(iii) The date on which the Secretary co-signs a new provisional program participation agreement (PPPA).

(3) If the TPPPA will expire under the provisions of paragraph (h)(2)(i) of this section, the Secretary extends the provisional TPPPA on a month-to-month basis after the expiration date described in paragraph (h)(2)(i) of this section if, prior to that expiration date, the institution provides the Secretary with—

(i) An audited ''same-day'' balance sheet for a proprietary institution or an audited statement of financial position for a nonprofit institution;

(ii) If not already provided, approval of the change of ownership from each State in which the institution is

physically located or for an institution that offers only distance education, from the agency that authorizes the institution to legally provide postsecondary education in that State;

(iii) If not already provided, approval of the change of ownership from the institution's accrediting agency; and

(iv) A default management plan unless the institution is exempt from providing that plan under 34 CFR 668.14(b)(15).

* * * * *

■ 7. Section 600.21 is amended by:
■ a. Revising paragraphs (a) introductory text and (a)(6);
■ b. Adding paragraphs (a)(14) and (15); and
■ c. Revising paragraph (b).

The revisions and additions read as follows:

**§ 600.21 Updating application information.**

(a) *Reporting requirements.* Except as provided in paragraph (b) of this section, an eligible institution must report to the Secretary, in a manner prescribed by the Secretary no later than 10 days after the change occurs, any change in the following:

* * * * *

(6)(i) *Changes in ownership.* (A) Any change in the ownership of the institution, whereby a natural person or entity acquires at least a 5 percent ownership interest (direct or indirect) of the institution but that does not result in a change of control as described in § 600.31.

(B) Changes representing at least 5 percent but under 25 percent (either on a single or combined basis) must be reported quarterly (instead of within 10 days) based on the institution's fiscal year. However, when an institution plans to undergo a change in ownership, all unreported ownership changes of 5 percent or more in the existing ownership must be reported prior to submission of the 90-day notice required by § 600.20. Thereafter, any changes of 5 percent or more in the existing ownership must be reported within the 10-day deadline, up through the date of the change in ownership.

(ii) *Changes in control.* A natural person or legal entity's ability to affect substantially the actions of the institution if that natural person or legal entity did not previously have this ability. The Secretary considers a natural person or legal entity to have this ability if—

(A) The natural person acquires, alone or together with another member or members of their family, at least a 25 percent ownership interest (as defined in § 600.31(b)) in the institution;

(B) The entity acquires, alone or together with an affiliated natural person or entity, at least a 25 percent ownership interest (as defined in § 600.31(b)) in the institution;

(C) The natural person or entity acquires, alone or together with another natural person or entity, under a voting trust, power of attorney, proxy, or similar agreement, at least a 25 percent ownership interest (as defined in § 600.31(b)) in the institution;

(D) The natural person becomes a general partner, managing member, chief executive officer, trustee or co-trustee of a trust, chief financial officer, director, or other officer of the institution or of an entity that has at least a 25 percent ownership interest (as defined in § 600.31(b)) in the institution; or

(E) The entity becomes a general partner or managing member of an entity that has at least a 25 percent ownership interest (as defined in § 600.31(b)) in the institution.

* * * * *

(14) Its establishment or addition of an eligible prison education program at an additional location as defined under § 600.2 at a Federal, State, or local penitentiary, prison, jail, reformatory, work farm, juvenile justice facility, or other similar correctional institution that was not previously included in the institution's application for approval as described under § 600.10.

(15) Any change in the ownership of the institution that does not result in a change of control as described in § 600.31 and is not addressed under paragraph (a)(6) of this section, including the addition or elimination of any entities in the ownership structure, a change of entity from one type of business structure to another, and any excluded transactions under § 600.31(e).

(b) *Additional reporting from institutions owned by publicly traded corporations.* An institution that is owned by a publicly traded corporation must report to the Secretary any change in the information described in paragraph (a)(6) or (15) of this section when it notifies its accrediting agency, but no later than 10 days after the institution learns of the change.

* * * * *

■ 8. Add § 600.22 to read as follows:

**§ 600.22 Severability.**

If any provision of this subpart or its application to any person, act, or practice is held invalid, the remainder of the subpart or the application of its provisions to any person, act, or practice will not be affected thereby.

■ 9. Section 600.31 is amended by:
■ a. In paragraph (b), revising the definitions of ''Closely-held corporation'', ''Ownership or ownership interest'', ''Parent'', and ''Person'';
■ b. Revising paragraph (c)(3);
■ c. Removing paragraph (c)(4);
■ d. Redesignating paragraphs (c)(5) through (7) as paragraphs (c)(4) through (6), respectively;
■ e. In newly redesignated paragraph (c)(5), removing the phrase ''paragraph (d)'' and adding, in its place, the phrase ''paragraphs (c)(3) and (d)'';
■ f. Revising paragraphs (d)(6) and (7);
■ g. Adding paragraph (d)(8);
■ h. Revising paragraph (e); and
■ i. Removing the parenthetical authority citation at the end of the section.

The revisions and addition read as follows:

**§ 600.31 Change in ownership resulting in a change in control for private nonprofit, private for-profit and public institutions.**

* * * * *

(b) * * *

*Closely-held corporation.* Closely-held corporation (including the term ''close corporation'') means—

(i) A corporation that qualifies under the law of the State of its incorporation or organization as a statutory close corporation; or

(ii) If the State of incorporation or organization has no statutory close corporation provision, a corporation the stock of which—

(A) Is held by no more than 30 persons; and

(B) Has not been and is not planned to be publicly offered.

* * * * *

*Ownership or ownership interest.* (i) Ownership or ownership interest means a direct or indirect legal or beneficial interest in an institution or legal entity, which may include a voting interest or a right to share in profits.

(ii) For the purpose of determining whether a change in ownership has occurred, changes in the ownership of the following are not included:

(A) A mutual fund that is regularly and publicly traded.

(B) A U.S. institutional investor, as defined in 17 CFR 240.15a–6(b)(7).

(C) A profit-sharing plan of the institution or its corporate parent, provided that all full-time permanent employees of the institution or its corporate parent are included in the plan.

(D) An employee stock ownership plan (ESOP).

*Parent.* The legal entity that controls the institution or a legal entity directly or indirectly through one or more intermediate entities.

*Person.* Person includes a natural person or a legal entity, including a trust.

* * * * *

(c) * * *

(3) *Other entities.* (i) The term ''other entities'' means any entity that is not closely held nor required to be registered with the SEC, and includes limited liability companies, limited liability partnerships, limited partnerships, and similar types of legal entities.

(ii) The Secretary deems the following changes to constitute a change in ownership resulting in a change of control of such an entity:

(A) A person (or combination of persons) acquires at least 50 percent of the total outstanding voting interests in the entity, or otherwise acquires 50 percent control.

(B) A person (or combination of persons) who holds less than a 50 percent voting interest in an entity acquires at least 50 percent of the outstanding voting interests in the entity, or otherwise acquires 50 percent control.

(C) A person (or combination of persons) who holds at least 50 percent of the voting interests in the entity ceases to hold at least 50 percent voting interest in the entity, or otherwise ceases to hold 50 percent control.

(D) A partner in a general partnership acquires or ceases to own at least 50 percent of the voting interests in the general partnership, or otherwise acquires or ceases to hold 50 percent control.

(E) Any change of a general partner of a limited partnership (or similar entity) if that general partner also holds an equity interest.

(F) Any change in a managing member of a limited liability company (or similar entity) if that managing member also holds an equity interest.

(G) Notwithstanding its voting interests, a person becomes the sole member or shareholder of a limited liability company or other entity that has a 100 percent or equivalent direct or indirect interest in the institution.

(H) An entity that has a member or members ceases to have any members.

(I) An entity that has no members becomes an entity with a member or members.

(J) A person is replaced as the sole member or shareholder of a limited liability company or other entity that has a 100 percent or equivalent direct or indirect interest in the institution.

(K) The addition or removal of any entity that provides or will provide the audited financial statements to meet any of the requirements in § 600.20(g) or (h) or 34 CFR part 668, subpart L.

(L) Except as provided in paragraph (e) of this section, the transfer by an owner of 50 percent or more of the voting interests in the institution or an entity to an irrevocable trust.

(M) Except as provided in paragraph (e) of this section, upon the death of an owner who previously transferred 50 percent or more of the voting interests in an institution or an entity to a revocable trust.

(iii) The Secretary deems the following interests to satisfy the 50 percent thresholds described in paragraph (c)(3)(ii) of this section:

(A) A combination of persons, each of whom holds less than 50 percent ownership interest in an entity, holds a combined ownership interest of at least 50 percent as a result of proxy agreements, voting agreements, or other agreements (whether or not the agreement is set forth in a written document), or by operation of State law.

(B) A combination of persons, each of whom holds less than 50 percent ownership interest in an entity, holds a combined ownership interest of at least 50 percent as a result of common ownership, management, or control of that entity, either directly or indirectly.

(C) A combination of individuals who are family members as defined in § 600.21, each of whom holds less than 50 percent ownership interest in an entity, holds a combined ownership interest of at least 50 percent.

(iv) Notwithstanding paragraphs (c)(3)(ii) and (iii) of this section—

(A) If a person who alone or in combination with other persons holds less than a 50 percent ownership interest in an entity, the Secretary may determine that the person, either alone or in combination with other persons, has actual control over that entity and is subject to the requirements of this section; and

(B) Any person who alone or in combination with other persons has the right to appoint a majority of any class of board members of an entity or an institution is deemed to have control.

* * * * *

(d) * * *

(6) A transfer of assets that comprise a substantial portion of the educational business of the institution, except where the transfer consists exclusively in the granting of a security interest in those assets;

(7) A change whereby the institution's ownership changes from an entity that is for-profit, nonprofit, or public to another one of those statuses. However, when an institution's ownership changes from a for-profit entity to a nonprofit entity or becomes affiliated with a public system, the institution remains a proprietary institution until the Department approves the change of status for the institution; or

(8) The acquisition of an institution to become an additional location of another institution unless the acquired institution closed or ceased to provide educational instruction.

(e) *Excluded transactions.* A change in ownership and control timely reported under § 600.21 and otherwise subject to this section does not include a transfer of ownership and control of all or part of an owner's equity or partnership interest in an institution, the institution's parent corporation, or other legal entity that has signed the institution's PPA—

(1) From an owner to a ''family member'' of that owner as defined in § 600.21(f);

(2) As a result of a transfer of an owner's interest in the institution or an entity to an irrevocable trust, so long as the trustees only include the owner and/or a family member as defined in § 600.21(f). Upon the appointment of any non-family member as trustee for an irrevocable trust (or successor trust), the transaction is no longer excluded and is subject to the requirements of § 600.20(g) and (h);

(3) Upon the death of a former owner who previously transferred an interest in the institution or an entity to a revocable trust, so long as the trustees include only family members (as defined in § 600.21(f)) of that former owner. Upon the appointment of any non-family member as trustee for the trust (or a successor trust) following the death of the former owner, the transaction is no longer excluded and is subject to the requirements of § 600.20(g) and (h); or

(4) A transfer to an individual owner with a direct or indirect ownership interest in the institution who has been involved in the management of the institution for at least two years preceding the transfer and who has established and retained the ownership interest for at least two years prior to the transfer, either upon the death of another owner or by transfer from another individual owner who has been involved in the management of the institution for at least two years preceding the transfer and who has established and retained the ownership interest for at least two years prior to the transfer, upon the resignation of that owner from the management of the institution.

* * * * *

## PART 668—STUDENT ASSISTANCE GENERAL PROVISIONS

■ 10. The general authority citation for part 668 is revised to read as follows:

**Authority:** 20 U.S.C. 1001–1003, 1070g, 1085, 1088, 1091, 1092, 1094, 1099c, 1099c–1, and 1231a, unless otherwise noted.

* * * * *

■ 11. Section 668.8 is amended by revising paragraph (n) to read as follows:

### § 668.8 Eligible program.

* * * * *

(n) *Other eligible programs.* For title IV, HEA program purposes, *eligible program* includes a direct assessment program approved by the Secretary under § 668.10, a comprehensive transition and postsecondary program approved by the Secretary under § 668.232, and an eligible prison education program under subpart P of this part.

### § 668.11 [Redesignated as § 668.12]

■ 12. Redesignate § 668.11 as § 668.12.

■ 13. Add a new § 668.11 to subpart A to read as follows:

### § 668.11 Severability.

If any provision of this part or its application to any person, act, or practice is held invalid, the remainder of the part or the application of its provisions to any person, act, or practice will not be affected thereby.

■ 14. Section 668.14 is amended by revising paragraph (b)(16) to read as follows:

### § 668.1 Program participation agreement.

* * * * *

(b) * * *

(16) For a proprietary institution, the institution will derive at least 10 percent of its revenues for each fiscal year from sources other than Federal funds, as provided in § 668.28(a), or be subject to sanctions described in § 668.28(c);

* * * * *

■ 15. Section 668.23 is amended by:

■ a. Revising paragraph (d)(3); and

■ b. Removing the parenthetical authority citation at the end of the section.

The revision reads as follows:

### § 668.23 Compliance audits and audited financial statements.

* * * * *

(d) * * *

(3) *Disclosure of Federal revenue.* A proprietary institution must disclose in a footnote to its audited financial statement the percentage of its revenues derived from Federal funds that the institution received during the fiscal year covered by that audit. The revenue percentage must be calculated in accordance with § 668.28. The institution must also report in the footnote the dollar amount of the numerator and denominator of its 90/10 ratio as well as the individual revenue amounts identified in section 2 of appendix C to this subpart.

* * * * *

■ 16. Section 668.28 is revised to read as follows:

### § 668.28 Non-Federal revenue (90/10).

(a) *General*—(1) *Calculating the revenue percentage.* A proprietary institution meets the requirement in § 668.14(b)(16) that at least 10 percent of its revenue is derived from sources other than Federal funds by using the formula in appendix C to this subpart to calculate its revenue percentage for its latest complete fiscal year. For purposes of this section—

(i) For any fiscal year beginning on or after January 1, 2023, Federal funds used to calculate the revenue percentage include title IV, HEA program funds and any other educational assistance funds provided by a Federal agency directly to an institution or a student including the Federal portion of any grant funds provided by or administered by a non-Federal agency, except for non-title IV Federal funds provided directly to a student to cover expenses other than tuition, fees, and other institutional charges. The Secretary identifies the Federal agency and the other educational assistance funds provided by that agency in a notice published in the **Federal Register**, with updates to that list published as needed.

(ii) For any fiscal year beginning prior to January 1, 2023, Federal funds are limited to title IV, HEA program funds.

(2) *Disbursement rule.* An institution must use the cash basis of accounting in calculating its revenue percentage by—

(i) For each eligible student, counting the amount of Federal funds the institution received to pay tuition, fees, and other institutional charges during its fiscal year—

(A) Directly from an agency identified under paragraph (a)(1)(i) of this section; and

(B) Paid by a student who received Federal funds; and

(ii) For each eligible student, counting the amount of title IV, HEA program funds the institution received to pay tuition, fees, and other institutional charges during its fiscal year. However, before the end of its fiscal year, the institution must—

(A) Request funds under the advanced payment method in § 668.162(b)(2) or the heightened cash monitoring method in § 668.162(d)(1) that the students are eligible to receive and make any disbursements to those students by the end of the fiscal year; or

(B) For institutions under the reimbursement or heightened cash monitoring methods in § 668.162(c) or (d)(2), make disbursements to those students by the end of the fiscal year and report as Federal funds in the revenue calculations the funds that the students are eligible to receive before requesting funds.

(3) *Revenue generated from programs and activities.* The institution must consider as revenue only those funds it generates from—

(i) Tuition, fees, and other institutional charges for students enrolled in eligible programs as defined in § 668.8;

(ii) Activities conducted by the institution that are necessary for the education and training of its students provided those activities are—

(A) Conducted on campus or at a facility under the institution's control;

(B) Performed under the supervision of a member of the institution's faculty;

(C) Required to be performed by all students in a specific educational program at the institution; and

(D) Related directly to services performed by students; and

(iii) Funds paid by a student, or on behalf of a student by a party unrelated to the institution, its owners, or affiliates, for an education or training program that is not eligible under § 668.8 and that does not include any courses offered in an eligible program. The non-eligible education or training program must be provided by the institution, and taught by one of its instructors, at its main campus or one of its approved additional locations, at another school facility approved by the appropriate State agency or accrediting agency, or at an employer facility. The institution may not count revenue from a non-eligible education or training program for which it merely provides facilities for test preparation courses, acts as a proctor, or oversees a course of self-study. The program must—

(A) Be approved or licensed by the appropriate State agency;

(B) Be accredited by an accrediting agency recognized by the Secretary under 34 CFR part 602;

(C) Provide an industry-recognized credential or certification;

(D) Provide training needed for students to maintain State licensing requirements; or

(E) Provide training needed for students to meet additional licensing requirements for specialized training for practitioners who already meet the general licensing requirements in that field.

(4) *Application of funds.* The institution must presume that any Federal funds it disburses, or delivers to a student, or determines was provided to a student by another Federal source, will be used to pay the student's tuition, fees, or institutional charges up to the amount of those Federal funds if a student makes a payment to the institution, except to the extent that the student's tuition, fees, or other charges are satisfied by—

(i) Grant funds provided by—

(A) Non-Federal public agencies that do not include Federal or institutional funds, unless the Federal portion of those grant funds can be determined, and that portion of Federal funds is included as Federal funds under this section. If the Federal funds cannot be determined no amount of the grant funds may be included under this section; or

(B) Private sources unrelated to the institution, its owners, or affiliates;

(ii) Funds provided under a contractual arrangement with the institution and a Federal, State, or local government agency for the purpose of providing job training to low-income individuals who need that training;

(iii) Funds used by a student from a savings plan for educational expenses established by or on behalf of the student if the savings plan qualifies for special tax treatment under the Internal Revenue Code of 1986; or

(iv) Institutional scholarships that meet the requirements in paragraph (a)(5)(iv) of this section.

(5) *Revenue generated from institutional aid.* The institution may include the following institutional aid as revenue:

(i) For loans made to students and credited in full to the students' accounts at the institution and used to satisfy tuition, fees, and other institutional charges, the principal payments made on those loans by current or former students that the institution received during the fiscal year, if the loans are—

(A) Bona fide as evidenced by standalone repayment agreements between the students and the institution that are enforceable promissory notes;

(B) Issued at intervals related to the institution's enrollment periods;

(C) Subject to regular loan repayments and collections by the institution; and

(D) Separate from the enrollment contracts signed by the students.

(ii) Funds from an income share agreement or any other alternative financing agreement in which the agreement is with the institution only or with any entity or individual in the institution's ownership tree, or with any common ownership of the institution and the entity providing the funds, or if the entity or another entity with common ownership has any other relationships or agreements with the institution, provided that—

(A) The institution clearly identifies the student's institutional charges, and those charges are the same or less than the stated rate for institutional charges;

(B) The agreement clearly identifies the maximum time and maximum amount a student would be required to pay, including the implied or imputed interest rate and any fees and revenue generated for a related third-party, the institution, or any entity described in paragraph (a)(5)(ii) introductory text, for that maximum time period; and

(C) All payments are applied with a portion allocated to the return of capital and a portion allocated to profit. Revenue, interest, and fees are not included in the calculation.

(iii) For scholarships provided by the institution in the form of monetary aid and based on the academic achievement or financial need of its students, the amount disbursed to students during the fiscal year. The scholarships must be disbursed from an established restricted account and may be included as revenue only to the extent that the funds in that account represent—

(A) Designated funds from an outside source that is unrelated to the institution, its owners, or its affiliates; or

(B) Income earned on those funds.

(6) *Funds excluded from revenues.* For the fiscal year, the institution does not include—

(i) The amount of Federal Work Study (FWS) wages paid directly to the student. However, if the institution credits the student's account with FWS funds, those funds are included as revenue;

(ii) The amount of funds received by the institution from a State under the LEAP, Special Leveraging Educational Assistance Partnership (SLEAP), or Grants for Access and Persistence (GAP) program;

(iii) The amount of institutional funds used to match Federal education assistance funds;

(iv) The amount of Federal education assistance funds refunded to students or returned to the Secretary under § 668.22 or required to be returned under the applicable program;

(v) The amount the student is charged for books, supplies, and equipment unless the institution includes that amount as tuition, fees, or other institutional charges;

(vi) Any amount from the proceeds of the factoring or sale of accounts receivable or institutional loans, regardless of whether the loans were sold with or without recourse;

(vii) Any amount from the sale of an income share agreement or other financing agreement; or

(viii) Any funds, including loans, provided by a third party related to the institution, its owners, or affiliates to a student in any form.

(b) [Reserved]

(c) *Sanctions.* If an institution does not derive at least 10 percent of its revenue from sources other than Federal funds—

(1) For two consecutive fiscal years, it loses its eligibility to participate in the title IV, HEA programs for at least two fiscal years. To regain eligibility, the institution must demonstrate that it complied with the State licensure and accreditation requirements under 34 CFR 600.5(a)(4) and (6), and the financial responsibility requirements under subpart L of this part, for a minimum of two fiscal years after the fiscal year it became ineligible;

(2) For any fiscal year, it becomes provisionally certified under § 668.13(c)(1)(ii) for the two fiscal years after the fiscal year it failed to satisfy the revenue requirement in this section. However, the institution's provisional certification terminates on—

(i) The expiration date of the institution's program participation agreement that was in effect on the date the Secretary determined the institution failed the requirement of this section; or

(ii) The date the institution loses its eligibility to participate under paragraph (c)(1) of this section;

(3) For any fiscal year, it must notify students of the possibility of loss of title IV eligibility;

(4) For any fiscal year, it must report the failure no later than 45 days after the end of its fiscal year, or immediately thereafter if subsequent information is obtained that shows an institution incorrectly determined that it passed the revenue requirement in this section for the prior fiscal year; and

(5) It is liable for any title IV, HEA program funds it disburses after the last day of the fiscal year it becomes ineligible to participate in the title IV, HEA program under paragraph (c)(1) of this section, excluding any funds the institution was entitled to disburse under § 668.26.

■ 17. Appendix C to subpart B of part 668 is revised to read as follows:

## Appendix C to Subpart B of Part 668—90/10 Revenue Calculation

### Section 1: Sample Student Account at the Institution/Funds Applied in Priority Order

SAMPLE STUDENT ACCOUNT LEDGER

| Line | Date | Charge/Payment | Memo | Debit | Credit | Balance |
|---|---|---|---|---|---|---|
| 1 | 12/31/2021 | Federal Direct Loan | | | 1,000.00 | (1,000.00) |
| 2 | 1/1/2022 | Tuition and Fees | | 17,000.00 | | 16,000.00 |
| 3 | 2/1/2022 | Cash Payment | | | 175.00 | 15,825.00 |
| 4 | 2/1/2022 | Federal Funds 1 | | | 2,000.00 | 13,825.00 |
| 5 | 2/1/2022 | FSEOG | (Fed. 375/Inst. 125) | | 500.00 | 13,325.00 |
| 6 | 5/1/2022 | Cash Payment | (Federal funds 3) | | 500.00 | 12,825.00 |
| 7 | 7/1/2022 | Federal Pell Grant | | | 1,700.00 | 11,125.00 |
| 8 | 7/1/2022 | Institutional Scholarship. | | | 500.00 | 10,625.00 |
| 9 | 7/1/2022 | Federal Direct Loan | | | 1,500.00 | 9,125.00 |
| 10 | 7/1/2022 | Cash Payment | (Federal funds 4) | | 3,700.00 | 5,425.00 |
| 11 | 8/1/2022 | Federal Funds 2 | | | 3,725.00 | 1,700.00 |
| 12 | 9/1/2022 | City Grant | | | 2,200.00 | (500.00) |
| 13 | 9/1/2022 | Refund Check | | 500.00 | | |

| Line item in the sample | | Amount in the sample |
|---|---|---|
| | **Funds Applied First** | |
| 12 | Grant funds for the student from non-Federal public agencies or private sources independent of the institution.<br>Funds provided for the student under a contractual arrangement with a Federal, State, or local government agency for the purpose of providing job training to low-income individuals.<br>Funds used by a student from savings plans for educational expenses established by or on behalf of the student that qualify for special tax treatment under the Internal Revenue Code. | 2,200.00 |
| 8 | Qualified institutional scholarships disbursed to the student<br>Adjustment: If the amount of Total Funds Applied First is more than Tuition and Fees, then Adjusted Total Funds Applied First is reduced by the amount over Tuition and Fees. | 500.00 |
| | Total Funds Applied First | 2,700.00 |
| | **Title IV Aid** | |
| 1 | Prior Year Title IV Carried Over Credit Balance | 1,000.00 |
| 9 | Federal Direct Loan | 1,500.00 |
| 7 | Federal Pell Grant | 1,700.00 |
| 5 | FSEOG (subject to matching reduction) ($500 − $375 FSEOG and $125 Institutional Match)<br>Federal Work Study Applied to Tuition and Fees (subject to matching reduction). | 500.00 |
| 5 | Adjustment: The amount of FSEOG funds disbursed to a student and the amount of FWS funds credited to the student's account are reduced by the amount of the institutional matching funds.<br>Adjustment: If the amount of Adjusted Total Funds Applied First + Total Student Title IV Revenue is more than Tuition and Fees, then Adjusted Total Student Title IV Revenue is reduced by the amount over Tuition and Fees.<br>Adjustment: If Title IV funds are returned for a student under § 668.22, then Student Title IV Revenue is reduced by the amount returned. | −125.00 |
| | Adjusted Total Title IV Aid | 4,575.00 |
| | **Other Federal Funds Paid Directly to the Institution** | |
| 4 | Federal Funds 1 | 2,000.00 |
| 11 | Federal Funds 2 | 3,725.00 |
| | Adjustment: If the amount of Adjusted Total Funds Applied First + Adjusted Total Student Title IV Revenue + Total Other Federal Funds Paid Directly to the Institution is more than Tuition and Fees, then Adjusted Total Other Federal Funds Paid Directly to the Institution is reduced by the amount over Tuition and Fees. | |
| | Adjusted Total Other Federal Funds Paid Directly to the Institution | 5,725.00 |
| | **Other Federal Funds Paid to Student** | |
| 6 | Federal Funds 3 | 500.00 |
| 10 | Federal Funds 4 | 3,700.00 |

| Line item in the sample | | Amount in the sample |
|---|---|---|
| | Adjustment: If the amount of Adjusted Funds Applied First + Adjusted Student Title IV Revenue + Adjusted Total Other Federal Funds Paid Directly to the Institution + Total Other Federal Funds Paid Directly to Student is more than Tuition and Fees, then Adjusted Federal Funds Paid Directly to Student is reduced by the amount over Tuition and Fees. | −200.00 |
| Adjusted Total Other Federal Funds Paid Directly to Student | | 4,000.00 |
| | **Cash Payments** | |
| 3 | Student payments | 175.00 |
| 5 | Adjustment: The amount of FSEOG funds disbursed to a student and the amount of FWS funds credited to the student's account are added to cash for the institutional matching funds. | 125.00 |
| | Adjustment: If the amount of Adjusted Total Funds Applied First + Adjusted Total Student Title IV Revenue + Adjusted Total Other Federal Funds Paid Directly to the Institution + Adjusted Total Other Federal Funds Paid to Student + Total Cash and Other Non- Title Payments are more than Tuition and Fees, then Adjusted Total Cash and Other Non-Title Payments is reduced by the amount over. | −300.00 |
| | Tuition and Fees | |
| Adjusted Total Cash and Other Non-Title IV Aid | | 0 |
| Adjusted Total All Federal and Cash Payments. | 17,000.00. | |

SECTION 2—REVENUE BY SOURCE—ONE STUDENT EXAMPLE

| Line item in the sample | | Amount disbursed | Adjusted amount |
|---|---|---|---|
| | **Student Title IV Revenue** | | |
| 1 | Title IV Credit Balance Carried Over from Prior Year | 1,000.00 | 1,000.00 |
| 9 | Federal Direct Loan | 1,500.00 | 1,500.00 |
| 7 | Federal Pell Grant | 1,700.00 | 1,700.00 |
| 5 | FSEOG (federal portion only) | 375.00 | 375.00 |
| Total Student Title IV Revenue | | 4,575.00 | 4,575.00 |
| | **Federal Funds Paid Directly to the Institution** | | |
| 6 | Federal Funds 1 | 2,000.00 | 2,000.00 |
| 10 | Federal Funds 2 | 3,725.00 | 3,725.00 |
| Total Student Federal Funds Paid Directly to the Institution | | 5,725.00 | 5,725.00 |
| | **Student Federal Funds Paid Directly to the Student** | | |
| 4 | Federal Funds 3 | 500.00 | 500.00 |
| 11 | Federal Funds 4 | 3,700.00 | 3,700.00 |
| 13 | Refunds Paid to Student | | −200.00 |
| Adjusted Student Federal Funds Paid Directly to Student | | 4,200.00 | 4,000.00 |
| Adjusted Student Federal Revenue | | 14,500.00 | 14,300.00 |
| | **Student Non-Federal Revenue** | | |
| 12 | Grant funds for the student from non-Federal public agencies or private sources independent of the institution. | 2,200.00 | 2,200.00 |
| 8 | Institutional scholarships disbursed to the student | 500.00 | 500.00 |
| 3,5,13 | Student payments | 300.00 | 0 |
| Student Non-Title IV Revenue | | 3,000.00 | 2,700.00 |
| Total Federal and Non-Federal Revenue | | 17,500.00 | 17,000.00 |

SECTION 2—REVENUE BY SOURCE—CALCULATION

| | Amount disbursed | Adjusted amount |
|---|---|---|
| **Student Title IV Revenue** | | |
| Title IV Credit Balance Carried Over from Prior Year | 45,000.00 | 45,0000.00 |
| Federal Direct Loan | 1,500,000.00 | 1,500,000.00 |
| Federal Pell Grant | 400,700.00 | 400,700.00 |
| FSEOG (subject to matching reduction) | 11,500.00 | 8,625.00 |
| Total Student Title IV Revenue | 1,957,200.00 | 1,954,325.00 |
| Refunds Paid to Students | | −35,500.00 |
| **Student Federal Funds Paid Directly to Student** | | |
| Federal Funds 3 | 50,000.00 | 50,000.00 |
| Federal Funds 4 | 3,700.00 | 3,700.00 |
| Total Student Federal Funds Paid Directly to Student | 53,700.00 | 53,700.00 |
| Refunds Paid to Student | | −200.00 |
| Adjusted Student Federal Funds Paid Directly to Student | 53,700.00 | 53,500.00 |
| Adjusted Student Federal Revenue | 3,575,625.00 | 3,517,050.00 |
| Adjusted Student Title IV Revenue | 1,957,200.00 | 1,918,825.00 |
| **Federal Funds Paid Directly to the Institution** | | |
| Federal Funds 1 | 200,000.00 | 200,000.00 |
| Federal Funds 2 | 1,355,725.00 | 1,355,725.00 |
| Federal Portion of Other Funds | 9,000.00 | 9,000.00 |
| Total Student Federal Funds Paid Directly to the Institution | 1,564,725.00 | 1,564,725.00 |
| Refunds Paid to Students | | −20,000.00 |
| Adjusted Student Title IV Federal Funds Paid Directly to the Institution | 1,564,725.00 | 1,544,725.00 |
| **Revenue From Other Sources (Totals for the Fiscal Year)** | | |
| Activities conducted by the institution that are necessary for education and training | 25,000.00 | 25,000.00 |
| Funds paid to the institution by, or on behalf of, students for education and training in qualified non-Title IV eligible programs | 143,000.00 | 143,000.00 |
| Revenue from Other Sources | 168,000.00 | 168,000.00 |
| Adjusted Non-Federal Revenue and Revenue from Other Sources | 587,800.00 | 559,500.00 |
| Total Federal and Non-Federal Revenue | 4,163,425.00 | 4,076,550.00 |

| Student non-Federal revenue | Amount | Adjusted amount |
|---|---|---|
| Grant funds for the student from non-Federal public agencies or private sources independent of the institution. | | |
| —State Grant (9.0451 percent Federal Funds) | 99,500.00 | 90,500.00 |
| —ABC Scholarship | 500.00 | 500.00 |
| Funds provided for the student under a contractual arrangement with a Federal, State, or local government agency for the purpose of providing job training to low-income individuals. | | |
| Funds used by a student from savings plan for educational expenses established by or on behalf of the student that qualify for special tax treatment under the Internal Revenue Code. | | |
| Qualified institutional scholarships disbursed to the student | 500.00 | 500.00 |
| Student payments | | |
| —Third Party Loans | 50,000.00 | 50,000.00 |
| —Third Party Loans-related Party/Institutional Loans | 107,000.00 | 100,000.00 |
| —ISA Institutional or Related Party | 37,000.00 | 25,000.00 |
| —ISA | 75,000.00 | 75,000.00 |
| —Student Cash | 50,300.00 | 50,300.00 |
| Student Non-Title IV Revenue | 419,800.00 | 391,800.00 |
| Refunds Paid to Student | | −300.00 |
| Adjusted Non-Federal Revenue | 419,800.00 | 391,500.00 |

Numerator 3,517,050.
Denominator 4,076,550 = 86.27 percent.

SECTION 3—CALCULATING THE REVENUE PERCENTAGE

Σ Adjusted Student Federal Revenue * ÷ Σ Adjusted Student Federal Revenue + Σ Adjusted Non-Federal Revenue and Revenue from Other Sources = 90/10 Revenue Percentage.

* Adjusted Student Federal Revenue = Adjusted Student Title IV Revenue + Adjusted Other Federal Funds Paid Directly to the Institution + Adjusted Other Federal Funds Paid Directly to Student

Σ Adjusted Student Federal Revenue = The sum of the amounts of all Federal funds, as adjusted, for each student at the institution during the fiscal year to whom the institution disbursed Title IV Aid and Other Federal Funds and Federal funds that students directly receive.

Σ Adjusted Non-Federal Revenue = The sum of the amounts of items applied first and adjusted cash payments for each student at the institution during the fiscal year whose non-Federal funds were used to pay all or some of those student's Tuition and Fee charges.

■ 18. Section 668.32 is amended by:
■ a. Revising paragraph (c)(2)(ii); and
■ b. Removing the parenthetical authority citation at the end of the section.

The revision reads as follows:

**§ 668.32 Student eligibility—general.**

* * * * *

(c) * * *

(2) * * *

(ii) If the student is a confined or incarcerated individual as defined in 34 CFR 600.2, is enrolled in an eligible prison education program as defined in § 668.236;

* * * * *

■ 19. Section 668.43 is amended by:
■ a. In paragraph (a)(5)(iv), removing the word ''and'' at the end of the paragraph;
■ b. In paragraph (a)(5)(v)(C), adding the word ''and'' at the end of the paragraph;
■ c. Adding paragraph (a)(5)(vi); and
■ d. Removing the parenthetical authority citation at the end of the section.

The addition reads as follows:

**§ 668.43 Institutional information.**

(a) * * *

(5) * * *

(vi) If a prison education program, as defined in § 668.236, is designed to meet educational requirements for a specific professional license or certification that is required for employment in an occupation (as described in § 668.236(a)(7) and (8)), information regarding whether that occupation typically involves State or Federal prohibitions on the licensure or employment of formerly confined or incarcerated individuals in any other State for which the institution has made a determination about State prohibitions on the licensure or certification of formerly confined or incarcerated individuals;

* * * * *

■ 20. Section 668.171 is amended by revising paragraphs (d)(4) and (f)(1)(vii) to read as follows:

**§ 668.171 General.**

* * * * *

(d) * * *

(4) For its most recently completed fiscal year, a proprietary institution did not receive at least 10 percent of its revenue from sources other than Federal funds, as provided under § 668.28(c);

* * * * *

(f) * * *

(1) * * *

(vii) For the non-Federal revenue provision in paragraph (d)(4) of this section, no later than 45 days after the end of the institution's fiscal year, as provided in § 668.28(c)(4).

* * * * *

■ 21. Add subpart P to read as follows:

## Subpart P—Prison Education Programs

Sec.



**§ 668.23 Scope and purpose.**

This subpart establishes regulations that apply to an institution that offers prison education programs to confined or incarcerated individuals. A confined or incarcerated individual enrolled in an eligible prison education program is eligible for Federal financial assistance under the Federal Pell Grant program. Unless provided in this subpart, confined or incarcerated individuals and institutions that offer prison education programs are subject to the same regulations and procedures that otherwise apply to title IV, HEA program participants.

**§ 668.235 Definitions.**

The following definitions apply to this subpart:

*Additional location* has the meaning given in 34 CFR 600.2.

*Advisory committee* is a group established by the oversight entity that provides nonbinding feedback to the oversight entity regarding the approval and operation of a prison education program within the oversight entity's jurisdiction.

*Confined or incarcerated individual* has the meaning given in 34 CFR 600.2.

*Feedback process* is the process developed by the oversight entity to gather nonbinding input from relevant stakeholders regarding the approval and operation of a prison education program within the oversight entity's jurisdiction. A feedback process may include an advisory committee.

*Oversight entity* means—

(1) The appropriate State department of corrections or other entity that is responsible for overseeing correctional facilities; or

(2) The Federal Bureau of Prisons.

*Relevant stakeholders* are individuals and organizations that provide input as part of a feedback process to the oversight entity regarding the approval and operation of a prison education program within the oversight entity's jurisdiction. These stakeholders must include representatives of confined or incarcerated individuals, organizations representing confined or incarcerated individuals, State higher education executive offices, and accrediting agencies and may include additional stakeholders as determined by the oversight entity.

**§ 668.236 Eligible prison education program.**

(a) An *eligible prison education program* means an education or training program that—

(1) Is an eligible program under § 668.8 offered by an institution of higher education as defined in 34 CFR 600.4, or a postsecondary vocational institution as defined in 34 CFR 600.6;

(2) Is offered by an eligible institution that has been approved to operate in a correctional facility by the oversight entity;

(3) After an initial two-year approval, is determined by the oversight entity to be operating in the best interest of students as described in § 668.241;

(4) Offers transferability of credits to at least one institution of higher education (as defined in 34 CFR 600.4 and 600.6) in the State where the correctional facility is located, or, in the case of a Federal correctional facility, in the State where most of the individuals confined or incarcerated individuals in

such facility will reside upon release as determined by the institution based on information provided by the oversight entity;

(5) Is offered by an institution that has not been subject, during the five years preceding the date of the determination, to—

(i) Any suspension, emergency action, or termination of programs under this title;

(ii) Any final accrediting action that is an adverse action as defined in 34 CFR 602.3 by the institution's accrediting agency; or

(iii) Any action by the State to revoke a license or other authority to operate;

(6) Subject to paragraph (b) of this section, is offered by an institution that is not subject to a current initiated adverse action;

(7) Satisfies any applicable educational requirements for professional licensure or certification, including any requirements to sit for licensure or certification examinations needed to practice or obtain employment in the sectors or occupations for which the program prepares the individual, in the State where the correctional facility is located or, in the case of a Federal correctional facility, in the State where most of the individuals confined or incarcerated individuals in such facility will reside upon release, as determined by the institution not less than annually based on information provided by the oversight entity; and

(8) Does not offer education that is designed to lead to licensure or employment for a specific job or occupation in the State if such job or occupation typically involves prohibitions on the licensure or employment of formerly confined or incarcerated individuals in the State where the correctional facility is located, or, in the case of a Federal correctional facility, in the State where most of the individuals confined or incarcerated individuals in such facility will reside upon release, as determined by the institution not less than annually based on information provided by the oversight entity.

(b) With respect to the criterion in paragraph (a)(6) of this section—

(1) If an accrediting agency initiates an adverse action, the institution cannot begin its first or a subsequent prison education program unless and until the initiated adverse action has been rescinded; and

(2) If the institution currently offers one or more prison education programs and is subject to an initiated adverse action, the institution must submit a teach-out plan and if practicable, a teach-out agreement, as defined in 34 CFR 600.2, to the institution's accrediting agency.

(c) With respect to the criterion in paragraph (a)(8) of this section—

(1) In the case of State and local correctional facilities, the postsecondary institution may not enroll any student in a prison education program if the student is prohibited or barred by any Federal law, or law in the State in which the correctional facility is located, from licensure or employment in the sectors or occupations for which the program prepares the individual based on any criminal conviction or specific types of criminal convictions; or

(2) In the case of a Federal correctional facility, the postsecondary institution may not enroll any student in a prison education program if the student is prohibited or barred by any Federal law, or law in the State in which more than half of the confined or incarcerated individuals in such facility will reside upon release, from licensure or employment in the sectors or occupations for which the program prepares the individual based on any criminal conviction or specific types of criminal convictions.

(3) Prohibitions on licensure or employment do not include local laws, screening requirements for good moral character, or similar provisions; State or Federal laws that have been repealed, even if the repeal has not yet taken effect or if the repeal occurs between assessments of the postsecondary institution by the oversight entity; or other restrictions as determined by the Secretary.

**§ 668.237 Accreditation requirements.**

(a) To be an eligible program under § 668.236, a prison education program must meet the requirements of the institution's accrediting agency or State approval agency.

(b) In order for any prison education program to qualify as an eligible program, the accrediting agency must have—

(1) Evaluated at least the first prison education program at the first two additional locations to ensure the institution's ability to offer and implement the program and that the program meets the agency's accreditation standards, and included it in the institution's grant of accreditation or pre-accreditation;

(2) Evaluated the first additional prison education program offered by a new method of delivery to ensure the institution's ability to offer and implement the program and that the program meets the agency's standards, and included it in the institution's grant of accreditation or pre-accreditation;

(3) Performed a site visit as soon as practicable but no later than one year after initiating the prison education program at the first two additional locations; and

(4) Reviewed and approved the methodology for how the institution, in collaboration with the oversight entity, made the determination that the prison education program meets the same standards as substantially similar programs that are not prison education programs at the institution.

**§ 668.238 Application requirements.**

(a) An institution that seeks to offer a prison education program must apply to the Secretary to have its first prison education program at the first two additional locations determined to be eligible programs for title IV, HEA program purposes. Following the Secretary's initial approval of an institution's prison education program, additional prison education programs offered by the same postsecondary institution at the same location may be determined eligible without further approvals from the Secretary except as required by 34 CFR 600.7, 600.10, 600.20(c)(1), or 600.21(a), as applicable, if such programs are consistent with the institution's accreditation or its State approval agency requirements.

(b) The institution's prison education program application must provide information satisfactory to the Secretary that includes—

(1) A description of the educational program, including the educational credential offered (degree level or certificate) and the field of study;

(2) Documentation from the institution's accrediting agency or State approval agency indicating that the agency has evaluated the prison education program and has included the program in the institution's grant of accreditation and approval documentation from the accrediting agency or State approval agency;

(3) The name of the correctional facility and documentation from the oversight entity that the prison education program has been approved to operate in the correctional facility;

(4) Documentation detailing the methodology, including thresholds, benchmarks, standards, metrics, data, and other information, the oversight entity used in approving the prison education program and how all the information was collected;

(5) Information about the types of services offered to admitted students, including orientation, tutoring, and academic and reentry counseling. If

reentry counseling is provided by a community-based organization that has partnered with the eligible prison education program, institution, or correctional facility to provide reentry services, the application also must provide information about the types of services offered by that community-based organization;

(6) Affirmative acknowledgement that the Secretary can limit or terminate approval of an institution to provide a prison education program as described in § 668.237;

(7) Affirmative agreement to submit all required reports to the Secretary pursuant to § 668.239;

(8) Documentation that the institution has entered into an agreement with the oversight entity to obtain data about transfer and release dates of confined or incarcerated individuals, which will be reported to the Department of Education; and

(9) Such other information as the Secretary deems necessary.

(c) For the second or subsequent eligible prison education program at a location, to meet the requirements under 34 CFR 600.21, an institution must submit—

(1) Documentation from the institution's accrediting agency noting that the institution complies with § 668.236(a)(6) and was not subject in the last five years to any final accrediting action that is an adverse action by the institution's accrediting agency;

(2) Documentation from the institution confirming that it was not subject in the last five years to any State action to revoke a license or other authority to operate; and

(3) Documentation that the institution has entered into an agreement with the oversight entity to obtain data about transfer and release dates of confined or incarcerated individuals, which will be reported to the Department of Education pursuant to § 668.239.

**§ 668.239 Reporting requirements.**

(a) An institution must submit reports, in accordance with deadlines established and published by the Secretary in the **Federal Register**.

(b) The institution reports such information as the Secretary requires, in compliance with procedures the Secretary describes.

(c) The institution reports information about transfer and release dates of confined or incarcerated individuals, as required by the Secretary, through an agreement with the oversight entity.

**§ 668.240 Limitation or termination of approval.**

(a) The Secretary may limit or terminate or otherwise end the approval of an institution to provide an eligible prison education program if the Secretary determines that the institution violated any terms of this subpart or that the institution submitted materially inaccurate information to the Secretary, accrediting agency, State agency, or oversight entity.

(b) If the Secretary initiates action limiting or terminating an institution's approval to operate an eligible prison education program, the institution must submit a teach-out plan and, if practicable, a teach-out agreements (as defined in 34 CFR 600.2) to its accrediting agency upon occurrence of the event.

**§ 668.241 Best interest determination.**

(a) An oversight entity's determination that a prison education program is operating in the best interest of students—

(1) Must include an assessment of—

(i) Whether the experience, credentials, and rates of turnover or departure of instructors for the prison education program are substantially similar to other programs at the institution, accounting for the unique geographic and other constraints of prison education programs;

(ii) Whether the transferability of credits for courses available to confined or incarcerated individuals and the applicability of such credits toward related degree or certificate programs is substantially similar to those at other similar programs at the institution, accounting for the unique geographic and other constraints of prison education programs;

(iii) Whether the prison education program's offering of relevant academic and career advising services to participating confined or incarcerated individuals, while they are confined or incarcerated, in advance of reentry, and upon release, is substantially similar to offerings to a student who is not a confined or incarcerated individual and who is enrolled in, and may be preparing to transfer from, the same institution, accounting for the unique geographic and other constraints of prison education programs; and

(iv) Whether the institution ensures that all formerly confined or incarcerated individuals are able to fully transfer their credits and continue their programs at any location of the institution that offers a comparable program, including by the same mode of instruction; and

(2) May include an assessment of—

(i) Whether the rates of recidivism, which do not include any recidivism by the student after a reasonable number of years of release and which only include new felony convictions, defined as each sentence of imprisonment exceeding one year and one month (*see* United States Sentencing Guideline section 4A1.1(a)), meet thresholds set by the oversight entity;

(ii) Whether the rates of completion reported by the Department, which do not include any students who were transferred across facilities and which account for the status of part-time students, meet thresholds set by the oversight entity with input from relevant stakeholders;

(iii) Whether the rate of confined or incarcerated individuals continuing their education post-release, as determined by the percentage of students who reenroll in higher education reported by the Department, meets thresholds established by the oversight entity with input from relevant stakeholders;

(iv) Whether job placement rates in the relevant field for such individuals meet any applicable standards required by the accrediting agency for the institution or program or a State where the institution is authorized. If no job placement rate standard applies to prison education programs offered by the institution, the oversight entity may define, and the institution may report, a job placement rate, with input from relevant stakeholders;

(v) Earnings for such individuals, which could include measuring such earnings against a threshold established by the oversight entity; and

(vi) Other indicators pertinent to program success as determined by the oversight entity.

(b) An oversight entity makes the best interest determination—

(1) Through a feedback process that considers input from relevant stakeholders; and

(2) In light of the totality of the circumstances.

(c) If the oversight entity does not find a program to be in the best interest of students, it must allow for programs to re-apply within a reasonable timeframe.

(d) After the two years of initial approval under § 668.236, the oversight entity must determine that the prison education program is operating in the best interest of students, under paragraph (a) of this section.

(e)(1) After its initial determination under paragraph (d) of this section that a program is operating in the best interest of confined or incarcerated individuals, the institution must obtain subsequent evaluations of each eligible

prison education program from the responsible oversight entity not less than 120 calendar days prior to the expiration of the institution's Program Participation Agreements. The oversight entity may also make a determination between subsequent evaluations based on the oversight entity's regular monitoring and evaluation of program outcomes.

(2) Each subsequent evaluation must—

(i) Include the entire period following the prior determination and be based on the applicable factors in paragraph (a) of this section for all students enrolled in the program since the prior determination;

(ii) Include input from relevant stakeholders through the oversight entity's feedback process; and

(iii) Be submitted to the Secretary no later than 30 days following completion of the evaluation.

(f)(1) The institution must obtain and maintain documentation of the methodology by which the oversight entity made each determination under this section and under § 668.236(a)(2) and (3) for review by the institution's accrediting agency, for submission to the Department for approval of the first program at the first two additional locations, to document input from relevant stakeholders through the oversight entity's feedback process in paragraphs (b)(1) and (e)(2)(ii) of this section, for reporting to the Department, and for public disclosure.

(2) The institution must maintain the documentation described in paragraph (f)(1) of this section for as long as the program is active or, if the program is discontinued, for three years following the date of discontinuance.

**§ 668.242 Transition to a prison education program.**

For institutions operating eligible prison education programs in a correctional facility that is not a Federal or State penal institution:

(a) A confined or incarcerated individual who otherwise meets the eligibility requirements to receive a Federal Pell Grant and is enrolled in an eligible program that does not meet the requirements under subpart P of this part may continue to receive a Federal Pell Grant until the earlier of—

(1) July 1, 2029;

(2) The student reaches the maximum timeframe for program completion under § 668.34; or

(3) The student has exhausted Pell Grant eligibility under 34 CFR 690.6(e).

(b) An institution is not permitted to enroll a confined or incarcerated individual on or after July 1, 2023, who was not enrolled in an eligible program prior to July 1, 2023, unless the institution first converts the eligible program into an eligible prison education program as defined in § 668.236.

## PART 690—FEDERAL PELL GRANT PROGRAM

■ 22. The authority citation for part 690 continues to read as follows:

**Authority:** 20 U.S.C. 1070a, 1070g, unless otherwise noted.

■ 23. Section 690.62 is revised to read as follows:

**§ 690.62 Calculation of a Federal Pell Grant.**

(a) The amount of a student's Pell Grant for an academic year is based upon the payment and disbursement schedules published by the Secretary for each award year.

(b)(1)(i) For a confined or incarcerated individual enrolled in an eligible prison education program, no Federal Pell Grant may exceed the cost of attendance (as defined in section 472 of the HEA) at the institution that student attends.

(ii) If an institution determines that the amount of a Federal Pell Grant for that student exceeds the cost of attendance for that year, the amount of the Federal Pell Grant must be reduced until the Federal Pell Grant does not exceed the cost of attendance at such institution and does not result in a title IV credit balance under 34 CFR 668.164(h).

(2)(i) If a confined or incarcerated individual's Pell Grant, combined with any other financial assistance, exceeds the student's cost of attendance, the financial assistance other than the Pell Grant must be reduced by the amount that the total financial assistance exceeds the student's cost of attendance.

(ii) If the confined or incarcerated individual's other financial assistance cannot be reduced, the student's Pell Grant must be reduced by the amount that the student's total financial assistance exceeds the student's cost of attendance.

■ 24. Add § 690.68 to read as follows:

**§ 690.68 Severability.**

If any provision of this subpart or its application to any person, act, or practice is held invalid, the remainder of the subpart or the application of its provisions to any person, act, or practice will not be affected thereby.

[FR Doc. 2022–23078 Filed 10–27–22; 8:45 am]

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# FEDERAL REGISTER

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Part IV

## Department of Defense

Defense Acquisition Regulations System
48 CFR Parts 212, 237, and 252
Defense Federal Acquisition Regulation Supplement: Requirement for Firms Used To Support Department of Defense Audits (DFARS Case 2019–D010); Final Rule; Quick-Closeout Procedures Threshold (DFARS Case 2021–D001); Undefinitized Contract Actions (DFARS Case 2021–D003): Proposed Rule

**DEPARTMENT OF DEFENSE**

**Defense Acquisition Regulations System**

**48 CFR Parts 212, 237, and 252**

**[Docket DARS–2021–0021]**

**RIN 0750–AK47**

## Defense Federal Acquisition Regulation Supplement: Requirement for Firms Used To Support Department of Defense Audits (DFARS Case 2019–D010)

**AGENCY:** Defense Acquisition Regulations System, Department of Defense (DoD).

**ACTION:** Final rule.

**SUMMARY:** DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2019, as amended by a section of the National Defense Authorization Act for Fiscal Year 2020, that requires accounting firms that provide financial statement auditing or audit remediation services in support of the Financial Improvement and Audit Remediation Plan to provide to DoD a statement setting forth the details of any disciplinary proceedings with respect to the accounting firm or its associated persons before any entity with the authority to enforce compliance with rules or laws applying to audit services offered by the accounting firm. DoD policy extends this requirement to firms other than accounting firms.

**DATES:** Effective October 28, 2022.

**FOR FURTHER INFORMATION CONTACT:** Mr. David E. Johnson, telephone 202–913–5764.

**SUPPLEMENTARY INFORMATION:**

### I. Background

DoD published a proposed rule in the **Federal Register** at 86 FR 59947 on October 29, 2021, to implement section 1006 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2019 (Pub. L. 115–232), as amended by section 1011 of the NDAA for FY 2020 (Pub. L. 116–92). Section 1006 applies to accounting firms that provide financial statement auditing to DoD in support of the audit under 31 U.S.C. 3521 or audit remediation services in support of the Financial Improvement and Audit Remediation Plan described in 10 U.S.C. 240b. Such firms, when responding to a solicitation or awarded a contract for the acquisition of covered services, must disclose to DoD before any contract action (including award, renewals, and amendments) the details of any disciplinary proceedings with respect to the accounting firm or its associated persons before any entity with the authority to enforce compliance with rules or laws applying to audit services offered by the accounting firm. DoD, as a matter of policy to provide a level playing field between firms that provide audit services to support certain DoD audits, is extending this requirement to firms other than accounting firms that provide such services. Section 1011 amended section 1006 to require any disclosures to be treated as confidential to the extent required by the court or agency in which the proceeding occurred and to be treated in a manner consistent with any protections or privileges established by any other provision of Federal Law.

There were no public comments submitted in response to the proposed rule. There are no changes made to the final rule.

### II. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT) and for Commercial Services and Commercial Products, Including Commercially Available Off-the-Shelf (COTS) Items

Consistent with the determinations that DoD made with regard to application of the requirements of section 1006 of the NDAA for FY 2019, as amended by section 1011 of the NDAA for FY 2020, DoD is not applying the requirements of section 1006 of the NDAA for FY 2019 to contracts at or below the SAT; however, DoD is applying the rule to contracts for the acquisition of commercial items, excluding COTS items.

### III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993.

### IV. Congressional Review Act

As required by the Congressional Review Act (5 U.S.C. 801–808) before an interim or final rule takes effect, DoD will submit a copy of the interim or final rule with the form, Submission of Federal Rules under the Congressional Review Act, to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. A major rule under the Congressional Review Act cannot take effect until 60 days after it is published in the **Federal Register**. The Office of Information and Regulatory Affairs has determined that this rule is not a major rule as defined by 5 U.S.C. 804.

### V. Regulatory Flexibility Act

A final regulatory flexibility analysis (FRFA) has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq*. The FRFA is summarized as follows:

This final rule is necessary to implement section 1006 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2019, as amended by section 1011 of the NDAA for FY 2020, and DoD policy. Section 1006 applies to accounting firms that provide financial statement auditing to DoD in support of the audit under 31 U.S.C. 3521 or audit remediation services in support of the Financial Improvement and Audit Remediation Plan described in 10 U.S.C. 240b. Such firms, when responding to a solicitation or awarded a contract for the acquisition of covered services, must disclose to DoD before any contract action (including award, renewals, and amendments) the details of any disciplinary proceedings with respect to the accounting firm or its associated persons before any entity with the authority to enforce compliance with rules or laws applying to audit services offered by the accounting firm. DoD policy extends this requirement to firms other than accounting firms, in order to provide a level playing field in competitive acquisitions.

DoD received no public comments in response to the initial regulatory flexibility analysis in the proposed rule.

DoD estimates there are 12 respondents that submit offers and 10 respondents that receive award of a contract covered by this rule. Of the estimated 12 respondents, DoD further estimates that only two of these respondents are small entities.

This rule adds a provision and a clause that require reporting details of any disciplinary proceedings with respect to the firm or its associated persons before any contract action on a covered contract in support of certain DoD audits. There are no other reporting or recordkeeping requirements.

There are no significant alternatives that would meet the intent of the

statutes. The rule could be applied to only accounting firms, but that would not be fair to accounting firms competing against other than accounting firms. Applying the rule to other than accounting firms does not create a significant burden for small entities.

**VI. Paperwork Reduction Act**

This rule contains information collection requirements that have been approved by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35). This information collection requirement has been assigned OMB Control Number 0750–0006, entitled Defense Federal Acquisition Regulation Supplement (DFARS) Part 237 Clauses 252.237–7025 and 252.237–7026.

**List of Subjects in 48 CFR Parts 212, 237, and 252**

Government procurement.

**Jennifer D. Johnson,**

*Editor/Publisher, Defense Acquisition Regulations System.*

Therefore, 48 CFR parts 212, 237, and 252 are amended as follows:

■ 1. The authority citation for parts 212, 237, and 252 continues to read as follows:

**Authority:** 41 U.S.C. 1303 and 48 CFR chapter 1.

## PART 212—ACQUISITION OF COMMERCIAL ITEMS

■ 2. Amend section 212.301 by adding paragraphs (f)(xiv)(C) and (D) to read as follows:

**212.301 Solicitation provisions and contract clauses for the acquisition of commercial items.**

* * * * *

(f) * * *

(xiv) * * *

(C) Use the provision at 252.237–7025, Preaward Transparency Requirements for Firms Offering to Support Department of Defense Audits—Representation and Disclosure, as prescribed in 237.270(e)(3), to comply with section 1006 of the National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115–232) and section 1011 of the National Defense Authorization Act for Fiscal Year 2020 (Pub. L. 116–92).

(D) Use the clause at 252.237–7026, Postaward Transparency Requirements for Firms that Support Department of Defense Audits, as prescribed in 237.270(e)(4), to comply with section 1006 of the National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115–232) and section 1011 of the National Defense Authorization Act for Fiscal Year 2020 (Pub. L. 116–92).

* * * * *

## PART 237—SERVICE CONTRACTING

■ 3. Amend section 237.270 by—

■ a. Redesignating paragraph (d) as paragraph (e);

■ b. Adding a new paragraph (d); and

■ c. Adding paragraphs (e)(3) and (4).

The additions read as follows:

**237.270 Acquisition of audit services.**

* * * * *

(d) *Transparency requirement for firms used to support DoD audits.*

(1) This paragraph (d) implements the requirements of section 1006 of the National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115–232) and section 1011 of the National Defense Authorization Act for Fiscal Year 2020 (Pub. L. 116–92) for transparency of accounting firms used to support DoD audits; and extends the statutory requirement, as a matter of DoD policy, to firms other than accounting firms in order to ensure consistent availability of data for contracting officer evaluation and appropriate use.

(2) This requirement applies to solicitations and contracts for—

(i) Financial statement auditing required under 31 U.S.C. 3521(e); or

(ii) Audit remediation services in support of the Financial Improvement and Audit Remediation Plan described in 10 U.S.C. 240b.

(3) Any firm responding to a solicitation or awarded a contract for the acquisition of the services described in paragraph (d)(2) of this section is required to represent with regard to whether it has been subject to disciplinary proceedings within the last 3 years and, if the offeror represents that it has, to disclose to DoD before any contract action (including award, renewals, and modifications)—

(i) The details of any disciplinary proceedings, with respect to the firm or its associated persons (including principals and employees), before an entity with the authority to enforce compliance with rules or laws applying to audit services or audit remediation services offered by accounting firms or firms other than accounting firms; and

(ii) For subsequent contract actions after contract award, whether there has been any change with regard to previously reported disciplinary proceedings since the last contract action.

(e) * * *

(3) Use the provision at 252.237–7025, Preaward Transparency Requirements for Firms Offering to Support Department of Defense Audits—Representation and Disclosure, in solicitations, including solicitations using FAR part 12 procedures for the acquisition of commercial items, that include the clause at 252.237–7026, Postaward Transparency Requirements for Firms that Support Department of Defense Audits.

(4) Use the clause at 252.237–7026, Postaward Transparency Requirements for Firms that Support Department of Defense Audits, in solicitations and contracts, including solicitations and contracts using FAR part 12 procedures for the acquisition of commercial items, that—

(i) Exceed the simplified acquisition threshold; and

(ii) Are for the acquisition of financial statement auditing or audit remediation services as described in paragraph (d)(2) of this section.

## PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

**252.237–7000 [Amended]**

■ 4. Amend section 252.237–7000 introductory text by removing ''237.270(d)(1)'' and adding ''237.270(e)(1)'' in its place.

**252.237–7001 [Amended]**

■ 5. Amend section 252.237–7001 introductory text by removing ''237.270(d)(2)'' and adding ''237.270(e)(2)'' in its place.

■ 6. Add section 252.237–7025 to read as follows:

**252.237–7025 Preaward Transparency Requirements for Firms Offering to Support Department of Defense Audits—Representation and Disclosure.**

As prescribed in 237.270(e)(3), use the following provision:

**Preaward Transparency Requirements For Firms Offering To Support Department of Defense Audits—Representation and Disclosure (OCT 2022)**

(a) *Representation.* The Offeror represents that within the 3-year period preceding this offer, the Offeror and/or any of its principals or employees have [ ] have not [ ] been the subject of disciplinary proceedings before an entity with the authority to enforce compliance with rules or laws applying to audit services or audit remediation services offered by the Offeror, that—

(1) Are not yet fully adjudicated or settled; or

(2) Were fully adjudicated or settled against the Offeror and/or its principals or employees.

(b) *Disclosure.* If the Offeror checked ''have'' in the representation in paragraph (a) of this provision, the Offeror shall, at a minimum, disclose for each such proceeding—

(1) The entity hearing the case;
(2) The case or file number; and
(3) The allegation or conduct at issue and, if fully adjudicated or settled, a brief description of the outcome.

(c) *Treatment of the statements.* The Government will safeguard and treat as confidential all statements provided pursuant to this provision where the statement has been marked ''confidential'' or ''proprietary'' by the Offeror. Statements so marked will not be released by the Government to the public pursuant to a request under the Freedom of Information Act, 5 U.S.C. 552, without prior notification to the Offeror and opportunity for the Offeror to claim an exemption from release. The Government will treat any statement provided pursuant to this provision as confidential to the extent required by any other applicable law.

(End of provision)

■ 7. Add section 252. 237–7026 to read as follows:

**252.237–7026 Postaward Transparency Requirements for Firms that Support Department of Defense Audits.**

As prescribed in 237.270(e)(4), use the following clause:

**Postaward Transparency Requirements for Firms That Support Department of Defense Audits (OCT 2022)**

(a) Prior to each contract action under this contract (including renewal or modification), the Contractor shall disclose the details of any disciplinary proceedings, with respect to the firm and/or its principals or employees, before an entity with the authority to enforce compliance with rules or laws applying to audit services or audit remediation services offered by the Contractor, and whether there has been any change with regard to previously reported proceedings since the last contract action.

(b) The disclosure shall, at a minimum, include—
(1) The entity hearing the case;
(2) The case or file number; and
(3) A brief description of the allegation or conduct at issue and, if fully adjudicated or settled, a brief description of the outcome.

(c) The Government will safeguard and treat as confidential all statements provided pursuant to this clause where the statement has been marked ''confidential'' or ''proprietary'' by the Contractor. Statements so marked will not be released by the Government to the public pursuant to a request under the Freedom of Information Act, 5 U.S.C. 552, without prior notification to the Contractor and opportunity for the Contractor to claim an exemption from release. The Government will treat any statement provided pursuant to this clause as confidential to the extent required by any other applicable law.

(End of clause)

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## DEPARTMENT OF DEFENSE

## Defense Acquisition Regulations System

## 48 CFR Parts 215 and 242

**[Docket DARS–2021–0015]**

**RIN 0750–AK95**

## Defense Federal Acquisition Regulation Supplement: Requiring Data Other Than Certified Cost or Pricing Data (DFARS Case 2020–D008)

**AGENCY:** Defense Acquisition Regulations System, Department of Defense (DoD).

**ACTION:** Final rule.

**SUMMARY:** DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2020 that provides additional requirements relating to the submission of data other than cost or pricing data.

**DATES:** Effective October 28, 2022.

**FOR FURTHER INFORMATION CONTACT:** David E. Johnson, telephone 202–913–5764.

**SUPPLEMENTARY INFORMATION:**

### I. Background

DoD published a proposed rule in the **Federal Register** at 86 FR 48368 on August 30, 2021, to implement section 803 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2020 (Pub. L. 116–92). Section 803 amends 10 U.S.C. 2306a(d) (redesignated as 10 U.S.C. 3705) to prohibit contracting officers from determining that the price of a contract or subcontract is fair and reasonable based solely on historical prices paid by the Government and to state that an offeror is ineligible for award if the contracting officer is unable to determine proposed prices are fair and reasonable by any other means, when an offeror fails to make a good faith effort to comply with a reasonable request to submit data other than certified cost or pricing data, unless the head of the contracting activity (HCA) determines that it is in the best interest of the Government to make the award to that offeror. Five respondents submitted public comments in response to the proposed rule.

### II. Discussion and Analysis

DoD reviewed the public comments in the development of the final rule. A discussion of the comments and the changes made to the rule as a result of those comments is provided, as follows:

*A. Summary of Significant Changes From the Proposed Rule*

DoD revised DFARS 215.403–3(a)(1) to include the word ''subcontract'' to clarify that, in accordance with section 803 of the NDAA for FY 2020, the rule applies to subcontractors. One respondent suggested this revision.

DoD revised DFARS 215.403–3(a)(4) to include, in accordance with section 803 of the NDAA for FY 2020, the requirement that offerors make a good faith effort to comply with the Government's reasonable requests to furnish data other than certified cost or pricing data. Two respondents suggested this revision.

*B. Analysis of Public Comments*

1. Clarification of the Requirement Not To Base Price-Reasonableness Solely on Historical Prices Paid by the Government

*Comment:* Three respondents expressed confusion with the requirement not to base price reasonableness solely on historical prices paid by the Government. Multiple respondents requested clarification on the restriction of use of previously performed cost and price analysis. Another respondent expressed concern with inclusion of the requirement in multiple sections and recommended that the requirement should be clearly connected to other relevant factors such as time elapsed since prior purchase, and any differences in quantities purchased as part of the price reasonableness determination.

*Response:* The rule does not prohibit contracting officers from utilizing prior cost or price analyses, nor does it absolutely prohibit contracting officers from utilizing historical prices paid by the Government to determine prices fair and reasonable. Rather, the rule prohibits contracting officers from determining the price of a contract to be fair and reasonable based solely on historical prices paid by the Government. Under this rule, historical prices paid by the Government cannot properly comprise the only factor when determining prices fair and reasonable, but rather may be used as one factor among several. Inclusion of the requirement in DFARS 215.403–3 was intentional to ensure the contracting officer is aware of the requirement in the event that prior prices paid by the Government are the only information available, and other than certified cost or pricing data will likely have to be

obtained. The respondents' recommendation to clearly connect the requirement to other relevant factors was not incorporated as it already exists in DFARS 215.404–1(b)(ii). Accordingly, no changes to the rule are necessary as a result of these comments.

2. Application of the Rule to Subcontracts and Flowdown Requirements

*Comment:* Four respondents questioned whether the requirement flowed down to subcontracts. One respondent questioned whether or not the contractor would need to develop a package for the contracting officer to submit to the HCA for a determination that the purchase is in the best interest of the Government, or if the determination that the purchase is in the best interest of the Government could be made by an official of the contractor. Another respondent inquired whether contracting officers would be required to provide previous prices paid to contractors, and if there would be a requirement that contractors be prohibited from making a price reasonableness determination based solely on historical prices paid by the contractor. Further, another respondent questioned whether the contractors would be required to track information about subcontractors providing cost data, similar to the Contractor Performance Assessment Reporting System (CPARS).

*Response:* The rule does apply to subcontracts, and DoD concurs with adding the word ''subcontract'' to 215.403–3(a)(4) to reflect the statutory language at section 803 of the NDAA for FY 2020. The contractor would not need to develop a package for the contracting officer to submit to the HCA. The HCA would be making that decision based upon the inputs from the Government team, whether it was at the prime or subcontract level, and any inputs from the contractor would be limited to providing supporting data to the contracting officer. The Government would not be able to disclose price information unless the contractors involved agreed to the release of the data. The contracting officer would be responsible to assess and evaluate the analysis performed by the prime on their subcontractors to ensure they considered additional data aside from the previous prices paid. Contractors will not be required to track information about subcontractors providing cost data similar to CPARS. The contracting officer would be responsible for tracking this information for prime contractors and subcontractors.

3. Further Changes To Effect the Intent of the Rule

*Comment:* One respondent recommended augmenting DFARS 252.215–7010 with additional requirements intended to maximize cooperation from offerors when contracting officers make data requests.

*Response:* The respondent's recommendation is outside the scope of this rule.

4. Further Changes To Maximize Consistency

*Comment:* One respondent recommended amending DFARS 215.404–1(b)(v)(C) to change the term ''customer,'' to ''type of customer.''

*Response:* DoD does not concur with this recommendation because it is not required to implement the statute.

5. Inclusion of the Requirement for ''Good Faith'' Efforts To Comply With a Reasonable Request To Furnish Data Other Than Certified Cost or Pricing Data

*Comment:* Two respondents recommended revising the final rule at DFARS 215.403–3(a)(4), to include, in accordance with section 803 of the NDAA for FY 2020, the requirement that offerors make good faith efforts when complying with the Government's reasonable requests to furnish data other than certified cost or pricing data.

*Response:* DoD concurs with this recommendation and has revised DFARS 215.403–3(a)(4) to include ''make a good faith effort to comply with a reasonable request''.

## III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT) and for Commercial Services or Commercial Products, Including Commercially Available Off-the-Shelf (COTS) Items

This rule does not create any new solicitation provisions or contract clauses. It does not impact any existing solicitation provisions or contract clauses or their applicability to contracts valued at or below the SAT, for commercial services, or for commercial products including COTS items.

## IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993.

## V. Congressional Review Act

As required by the Congressional Review Act (5 U.S.C. 801–808) before an interim or final rule takes effect, DoD will submit a copy of the interim or final rule with the form, Submission of Federal Rules under the Congressional Review Act, to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. A major rule under the Congressional Review Act cannot take effect until 60 days after it is published in the **Federal Register**. The Office of Information and Regulatory Affairs has determined that this rule is not a major rule as defined by 5 U.S.C. 804.

## VI. Regulatory Flexibility Act

A final regulatory flexibility analysis has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* and is summarized as follows:

The objective of this rule is to implement section 803 of the National Defense Authorization Act for Fiscal Year 2020. Section 803 provides additional requirements for contracting officers and the head of the contracting activity relating to obtaining data other than certified cost or pricing data.

DoD received no public comments in response to the initial regulatory flexibility analysis.

This rule does not directly impose requirements on small entities. The section 803 requirement making certain offerors ineligible for award is already in the Federal Acquisition Regulation. This rule impacts (1) the contracting officer's need for data other than historical prices paid by the Government, unless there is adequate price competition; and (2) the criteria for the head of the contracting activity's determination to make an award. In some cases, the contracting officer's need for data other than historical prices paid by the Government may result in a request for additional data from an offeror. Based on data from the Federal Procurement Data System for FY 2018 through FY 2020, DoD estimates that 1,672 small entities may receive a request for additional data.

This rule entails no new reporting, recordkeeping, or other compliance requirements on small entities. There are no known alternative approaches to

the rule that would meet the stated objectives of the statute.

**VII. Paperwork Reduction Act**

This rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

**List of Subjects in 48 CFR Parts 215 and 242**

Government procurement.

**Jennifer D. Johnson,**

*Editor/Publisher, Defense Acquisition Regulations System.*

Therefore, 48 CFR parts 215 and 242 are amended as follows:

■ 1. The authority citation for parts 215 and 242 continues to read as follows:

**Authority:** 41 U.S.C. 1303 and 48 CFR chapter 1.

## PART 215—CONTRACTING BY NEGOTIATION

■ 2. Amend section 215.403–3 by adding paragraph (a) to read as follows:

**215.403–3 Requiring data other than certified cost or pricing data.**

* * * * *

(a) In accordance with 10 U.S.C. 2306a(d)—

(1) Contracting officers shall not determine the price of a contract or subcontract to be fair and reasonable based solely on historical prices paid by the Government (see PGI 215.403–3(4)); and

(4) In lieu of the factors for consideration listed in FAR 15.403–3(a)(4), a determination by the head of the contracting activity (see PGI 215.403–3(7)) that it is in the best interest of the Government to make the award to an offeror that does not make a good faith effort to comply with a reasonable request to submit data other than certified cost or pricing data shall be based on consideration of pertinent factors, including the following:

(i) The effort to obtain the data.

(ii) Availability of other sources of supply of the item or service.

(iii) The urgency or criticality of the Government's need for the item or service.

(iv) Reasonableness of the price of the contract, subcontract, or modification of the contract or subcontract based on information available to the contracting officer.

(v) Rationale or justification made by the offeror for not providing the requested data.

(vi) Risk to the Government if award is not made.

* * * * *

■ 3. Amend section 215.404–1 by revising paragraph (b)(ii) and paragraph (b)(v) introductory text to read as follows:

**215.404–1 Proposal analysis techniques.**

* * * * *

(b) * * *

(ii) If the contracting officer determines that the information obtained through market research is insufficient to determine the reasonableness of price, the contracting officer shall consider information submitted by the offeror of recent purchase prices paid by the Government and commercial customers for the same or similar commercial items under comparable terms and conditions in establishing price reasonableness on a subsequent purchase if the contracting officer is satisfied that the prices previously paid remain a valid reference for comparison. Price reasonableness shall not be based solely on historical prices paid by the Government (see 215.403–3(a)(1)). The contracting officer shall consider the totality of other relevant factors such as the time elapsed since the prior purchase and any differences in the quantities purchased (10 U.S.C. 2306a(b)(5)).

* * * * *

(v) When evaluating pricing data, the contracting officer shall consider materially differing terms and conditions, quantities, and market and economic factors (see PGI 215.404–1(b)(v)). For similar items, the contracting officer shall also consider material differences between the similar item and the item being procured (see FAR 15.404–1(b)(2)(ii)(B)). Material differences are those that could reasonably be expected to influence the contracting officer's determination of price reasonableness. The contracting officer shall consider the following factors when evaluating the relevance of the information available:

* * * * *

## PART 242—CONTRACT ADMINISTRATION AND AUDIT SERVICES

■ 4. Revise section 242.1502 to read as follows:

**242.1502 Policy.**

(g) Past performance evaluations in the Contractor Performance Assessment Reporting System—

(i) Shall include an assessment of the contractor's performance against, and efforts to achieve, the goals identified in its comprehensive small business subcontracting plan when the contract contains the clause at 252.219–7004, Small Business Subcontracting Plan (Test Program); and

(ii) Shall, unless exempted by the head of the contracting activity, include a notation on contractors that have denied multiple requests for submission of data other than certified cost or pricing data over the preceding 3-year period, but nevertheless received an award (10 U.S.C. 2306a(d)(2)(B)(ii)).

[FR Doc. 2022–23276 Filed 10–27–22; 8:45 am]

**BILLING CODE 5001–06–P**

## DEPARTMENT OF DEFENSE

### Defense Acquisition Regulations System

### 48 CFR Part 242

**[Docket DARS–2022–0025]**

**RIN 0750–AL20**

## Defense Federal Acquisition Regulation Supplement: Quick-Closeout Procedures Threshold (DFARS Case 2021–D001)

**AGENCY:** Defense Acquisition Regulations System, Department of Defense (DoD).

**ACTION:** Proposed rule.

**SUMMARY:** DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a recommendation from the Government Accountability Office regarding quick-closeout procedures.

**DATES:** Comments on the proposed rule should be submitted in writing to the address shown below on or before December 27, 2022, to be considered in the formation of a final rule.

**ADDRESSES:** Submit comments identified by DFARS Case 2021–D001, using any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Search for ''DFARS Case 2021–D001.'' Select ''Comment'' and follow the instructions to submit a comment. Please include your name, company name (if any), and ''DFARS Case 2021–D001'' on any attached documents.
- *Email: osd.dfars@mail.mil.* Include DFARS Case 2021–D001 in the subject line of the message.

Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *https://www.regulations.gov,* approximately two to three days after submission to verify posting.

**FOR FURTHER INFORMATION CONTACT:** David E. Johnson, telephone 202–913–5764.

**SUPPLEMENTARY INFORMATION:**

### I. Background

DoD is proposing to amend the DFARS to implement a recommendation made by the Government Accountability Office (GAO) in GAO Report 17–738, Federal Contracting: Additional Management Attention and Action Needed to Close Contracts and Reduce Audit Backlog, published in September 2017. In this report, GAO recommended that DoD develop a means for DoD-wide oversight into both components' progress in meeting goals on closing contracts and the status of contracts eligible for closeout. Additionally, the Advisory Panel on Streamlining and Codifying Acquisition Regulations (Section 809 Panel) recommended authorizing the settlement of final overhead rates when it is in the best interest of the Government and closing complete contracts regardless of dollar value or the percentage of unsettled direct and indirect costs allocable to the contracts (recommendation 58). The Section 809 Panel was established pursuant to section 809 of the National Defense Authorization Act for Fiscal Year 2016 (Pub. L. 114–92) to deliver recommendations that could transform the defense acquisition system to meet the threats and demands of the 21st century.

As a result of the GAO and Section 809 Panel recommendations, DoD proposes to update the quick-closeout procedures and expand contracts eligible for quick closeout. In lieu of the thresholds at Federal Acquisition Regulation (FAR) 42.708(a)(2)(i) and (ii), this proposed rule provides that cost amounts are insignificant when unsettled direct and indirect costs are less than $2 million on a contract, task order, or delivery order, regardless of the total contract, task order, or delivery order amount. Additionally, Defense Contract Management Agency (DCMA) administrative contracting officers may negotiate the settlement of direct and indirect costs for a specific contract, task order, or delivery order to be closed in advance of the determination of final direct costs and indirect rates set forth in FAR 42.705 regardless of the dollar value or percentage of unsettled direct or indirect costs allocable to the contract.

### II. Discussion and Analysis

This proposed rule establishes a DoD-specific threshold for quick-closeout procedures. Instead of the threshold at FAR 42.708 of $1 million or 10 percent of the total value, DoD contracting officers will use a threshold of $2 million for contracts, task orders, and delivery orders. DCMA administrative contracting officers may negotiate the settlement of direct and indirect costs prior to the determination of final direct costs and indirect rates regardless of dollar value or percent of unsettled direct or indirect costs allocable to the contract. The proposed changes at DFARS 242.708 will increase the number of DoD contracts subject to quick-closeout procedures.

### III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT), for Commercial Products Including Commercially Available Off-the-Shelf (COTS) Items, and for Commercial Services

This rule does not create any new solicitation provisions or contract clauses. It does not impact any existing solicitation provisions or contract clauses or their applicability to contracts valued at or below the SAT, for commercial services, or for commercial products including COTS items.

### IV. Expected Impact of the Rule

Presently, at FAR 42.708(a)(2), cost amounts are considered relatively insignificant when the total unsettled direct costs and indirect costs to be allocated to any contract, task order, or delivery order does not exceed the lesser of $1 million or 10 percent of the total contract, task order, or delivery order. The proposed rule establishes a DoD-specific threshold of $2 million. The proposed rule also allows DCMA administrative contracting officers to negotiate the settlement of direct and indirect costs to be closed in advance of the determination of final direct costs and indirect rates regardless of the dollar value or percentage.

By establishing a higher threshold for DoD, this proposed rule expands the number of contracts subject to quick-closeout procedures. This rule will be beneficial to contractors and to the Government by promoting administrative efficiencies. DCMA administrative contracting officers' workflows will be expedited since settlement of costs may be negotiated prior to determination of final direct costs and indirect rates regardless of the dollar value or percent of unsettled direct or indirect costs allocable to the contract.

### V. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of

E.O. 12866, Regulatory Planning and Review, dated September 30, 1993.

**VI. Congressional Review Act**

As required by the Congressional Review Act (5 U.S.C. 801–808) before an interim or final rule takes effect, DoD will submit a copy of the interim or final rule with the form, Submission of Federal Rules under the Congressional Review Act, to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. A major rule under the Congressional Review Act cannot take effect until 60 days after it is published in the **Federal Register**. This rule is not anticipated to be a major rule under 5 U.S.C. 804.

**VII. Regulatory Flexibility Act**

DoD does not expect this proposed rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because no additional administrative burden will be placed on small entities. However, an initial regulatory flexibility analysis has been performed and is summarized as follows:

This rule proposes to revise the DFARS to implement changes to the indirect cost rate quick-closeout procedures. GAO Report 17–738, Federal Contracting: Additional Management Attention and Action Needed to Close Contracts and Reduce Audit Backlog, published September 2017 recommended that DoD develop a means for Department-wide oversight into both components' progress in meeting goals on closing contracts and the status of contracts eligible for closeout. The Advisory Panel on Streamlining and Codifying Acquisition Regulations (Section 809 Panel) was established pursuant to section 809 of the National Defense Authorization Act for Fiscal Year 2016 (Pub. L. 114–92) to deliver recommendations that could transform the defense acquisition system to meet the threats and demands of the 21st century. Additionally, the Section 809 Panel recommended authorizing the settlement of final overhead rates when it is in the best interest of the Government and closing complete contracts regardless of dollar value or the percentage of unsettled direct and indirect costs allocable to the contracts (recommendation 58).

This proposed rule states that the amount of unsettled direct costs and indirect costs to be allocated to the contract, task order, or delivery order will be considered relatively insignificant when the total unsettled direct costs or indirect costs to be allocated do not exceed $2 million. Additionally, DCMA administrative contracting officers may negotiate the settlement of direct and indirect costs for a specific contract, task order, or delivery order to be closed in advance of the determination of final direct costs and indirect rates set forth in FAR 42.705 regardless of the dollar value or percentage of unsettled direct or indirect costs allocable to the contract.

The objective of the proposed rule is to implement the GAO and Section 809 Panel recommendations described above. The legal basis for the rule is 41 U.S.C. 1303.

This proposed rule will likely affect small entities that have been or will be awarded contracts, task orders, and delivery orders valued over $2 million. Data was obtained from the Procurement Business Intelligence Service (PBIS) for contracts that were awarded in fiscal years 2019 through 2021 and eligible for quick-closeout procedures, were valued at more than $2 million, and contained one of the following FAR clauses:

- 52.216–7, Allowable Cost and Payment (including Alternates I, II, IV);
- 52.216–17, Incentive Price Revision—Successive Targets (including Alternate I);
- 52.242–3, Penalties for Unallowable Costs; and
- 52.242–4, Certification of Final Indirect Costs.

Data from PBIS revealed DoD awarded contracts to an average of 832 small businesses per year in fiscal years 2019 through 2021. Therefore, this proposed rule may apply to approximately 832 unique small entities.

The proposed rule does not impose any new reporting, recordkeeping, or compliance requirements.

The proposed rule does not duplicate, overlap, or conflict with any other Federal rules.

DoD did not identify any significant alternatives that would minimize or reduce the significant economic impact on small entities, because this proposed rule is not expected to have a significant impact on small entities.

DoD invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (DFARS Case 2021–D001), in correspondence.

**VIII. Paperwork Reduction Act**

This rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

**List of Subjects in 48 CFR Part 242**

Government procurement.

**Jennifer D. Johnson,**

*Editor/Publisher, Defense Acquisition Regulations System.*

Therefore, 48 CFR part 242 is proposed to be amended as follows:

## PART 242—CONTRACT ADMINISTRATION AND AUDIT SERVICES

■ 1. The authority citation for 48 CFR part 242 continues to read as follows:

**Authority:** 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 2. Add section 242.708 to read as follows:

**242.708 Quick-closeout procedure.**

(a) Defense Contract Management Agency administrative contracting officers are authorized to negotiate the settlement of direct and indirect costs for a specific contract, task order, or delivery order to be closed in advance of the determination of final direct costs and indirect rates set forth in FAR 42.705, regardless of the dollar value or percentage of unsettled direct or indirect costs allocable to the contract, task order, or delivery order.

(2) In lieu of the thresholds at FAR 42.708(a)(2)(i) and (ii), the amount of unsettled direct costs and indirect costs to be allocated to the contract, task order, or delivery order will be considered relatively insignificant when the total unsettled direct costs and indirect costs to be allocated to any one contract, task order, or delivery order do not exceed $2 million, regardless of the total contract, task order, or delivery order amount.

[FR Doc. 2022–23277 Filed 10–27–22; 8:45 am]

BILLING CODE 5001–06–P

## DEPARTMENT OF DEFENSE

### Defense Acquisition Regulations System

### 48 CFR Parts 215, 217, and 252

**[Docket DARS–2022–0026]**

**RIN 0750–AL22**

### Defense Federal Acquisition Regulation Supplement: Undefinitized Contract Actions (DFARS Case 2021–D003)

**AGENCY:** Defense Acquisition Regulations System, Department of Defense (DoD).

**ACTION:** Proposed rule.

**SUMMARY:** DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) as recommended by the DoD Inspector General to refine the management of undefinitized contract actions.

**DATES:** Comments on the proposed rule should be submitted in writing to the address shown below on or before December 27, 2022, to be considered in the formation of a final rule.

**ADDRESSES:** Submit comments identified by DFARS Case 2021–D003, using any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Search for ''DFARS Case 2021–D003.'' Select ''Comment'' and follow the instructions to submit a comment. Please include your name, company name (if any), and ''DFARS Case 2021–D003'' on any attached documents.
- *Email: osd.dfars@mail.mil.* Include DFARS Case 2021–D003 in the subject line of the message.

Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *https://www.regulations.gov,* approximately two to three days after submission to verify posting.

**FOR FURTHER INFORMATION CONTACT:** David E. Johnson, telephone 202–913–5764.

**SUPPLEMENTARY INFORMATION:**

## I. Background

DoD is proposing to revise the DFARS to implement recommendations to refine management of undefinitized contract actions (UCAs) as addressed in the DoD Inspector General Audit of Military Department Management of Undefinitized Contract Actions (Report No. DODIG–2020–084). This report recommends changes to the DFARS to encourage contractors to provide timely qualifying proposals, including the possibility of the Government withholding a percentage of payments yet to be paid under a UCA until it receives a qualifying proposal from the contractor.

This proposed rule reinforces the contracting officer's existing authority, notwithstanding FAR 52.216–26, Payments of Allowable Costs Before Definitization, to withhold up to 5 percent of all subsequent financing requests or take other appropriate actions when the contractor does not submit qualifying proposals in accordance with the contract definitization schedule. DoD contracting officers will appropriately document contract files and apply contract risk factors on DD Form 1547, Record of Weighted Guidelines, under this proposed rule.

## II. Discussion and Analysis

DFARS 215.404–71–3, Contract type risk and working capital adjustment, generally regards the contract type risk to be in the low end of the designated range when costs have been incurred prior to definitization. This proposed rule adds, at 215.404–71–3, paragraph (d)(2)(i), that when considering the reduced cost risks associated with allowable incurred costs on an undefinitized contract action, it is appropriate to apply separate contract risk factors for allowable incurred costs and estimated costs to complete when completing the contract risk factors section of DD Form 1547, Record of Weighted Guidelines.

DFARS subpart 217.74 prescribes policies and procedures for the management and oversight of undefinitized contract actions and related approval requirements. DFARS 217.7404–3(b) currently states that if the contractor does not submit a timely qualifying proposal, the contracting officer may suspend or reduce progress payments or take other appropriate action. This proposed rule revises the withholding guidance to specify ''an amount necessary to protect the interests of the Government, not to exceed 5 percent of all subsequent financing requests,'' if the qualifying proposal is not submitted in accordance with the contract definitization schedule. This proposed rule provides examples of other appropriate actions to include documenting the noncompliance in the contractor's past performance evaluation or terminating the contract for default. This proposed rule adds that contracting officers must ensure contract files are documented with justification for withholding or not withholding payments when the qualifying proposal was not submitted in accordance with the contract definitization schedule.

This proposed rule adds to the clause at DFARS 252.217–7027, Contract Definitization, that failure to meet the qualifying proposal date in the contract definitization schedule could result in the Government withholding an amount of up to 5 percent of all subsequent requests for financing until the contracting officer determines that a proposal is qualifying.

## III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT) and for Commercial Services and Commercial Products, Including Commercially Available Off-the-Shelf (COTS) Items

This rule amends the clause at DFARS 252.217–7027, Contract Definitization. However, this rule does not impose any new requirements on contracts at or below the SAT or for commercial services or commercial products, including COTS items. The clause will continue to not apply to acquisitions at or below the SAT and to acquisitions of commercial services and commercial products, including COTS items.

## IV. Expected Impact of the Rule

The proposed rule will incentivize contractors to submit qualifying proposals according to the contract definitization schedule to avoid the withholding of an amount of up to 5 percent of all subsequent financing requests. DoD contracting officers will be required to consider applying separate and differing contract risk factors to costs incurred and estimated costs to complete, when completing the DD Form 1547, Record of Weighted Guidelines. Contracting officers will also be required to document the contract file to show justification for withholding or not withholding a portion of financing payment when the qualifying proposal was not submitted according to the contract definitization schedule.

## V. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of

harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993.

**VI. Congressional Review Act**

As required by the Congressional Review Act (5 U.S.C. 801–808) before an interim or final rule takes effect, DoD will submit a copy of the interim or final rule with the form, Submission of Federal Rules under the Congressional Review Act, to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. A major rule under the Congressional Review Act cannot take effect until 60 days after it is published in the **Federal Register**. This rule is not anticipated to be a major rule under 5 U.S.C. 804.

**VII. Regulatory Flexibility Act**

DoD does not expect this proposed rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because no additional administrative burdens will be placed on small entities. However, an initial regulatory flexibility analysis has been performed and is summarized as follows:

DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) as recommended by the DoD Inspector General Audit of Military Department Management of Undefinitized Contract Actions (Report No. DODIG–2020–084) to refine the management of undefinitized contract actions. This report recommends changes to the DFARS to encourage contractors to provide timely qualifying proposals, including the possibility of the Government withholding a percentage of payments yet to be paid under an undefinitized contract action until it receives a qualifying proposal from the contractor.

This proposed rule incentivizes contractors to submit qualifying proposals in accordance with the contract definitization schedule; and, notwithstanding FAR 52.216–26, Payments of Allowable Costs Before Definitization, allows contracting officers to withhold an amount necessary to protect the interests of the Government, not to exceed 5 percent of all subsequent financing requests, or take other appropriate actions if a qualifying proposal is not submitted in accordance with the contract definitization schedule. Contracting officers will document in the contract file the justification for withholding or not withholding payments if the qualifying proposal was not submitted in accordance with the contract definitization schedule. This proposed rule clarifies that, when considering the reduced cost risks associated with allowable incurred costs on an undefinitized contract action, it is appropriate to apply separate and differing contract risk factors for allowable incurred costs and estimated costs to complete when documenting the contract risk sections of DD Form 1547, Record of Weighted Guidelines.

The objective of the proposed rule is to implement the recommendations of the DoD Inspector General. The legal basis for the rule is 41 U.S.C 1303.

This proposed rule will likely affect small entities that will be awarded undefinitized contract actions. Data was obtained from the Procurement Business Intelligence Service (PBIS) for all contracts and modifications containing DFARS clause 252.217–7027, Contract Definitization. Data from PBIS revealed DoD awarded a total of 2,162 contracts to 971 small businesses from fiscal year 2019 through fiscal year 2021, which averages out to 324 small businesses per year. Therefore, this proposed rule may apply to approximately 324 unique small entities.

The rule does not impose any new reporting, recordkeeping, or compliance requirements.

The rule does not duplicate, overlap, or conflict with any other Federal rules.

DoD did not identify any significant alternatives that would minimize or reduce the significant economic impact on small entities, because this proposed rule is not expected to have a significant impact on small entities.

DoD invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (DFARS Case 2021–D003), in correspondence.

**VIII. Paperwork Reduction Act**

This rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

**List of Subjects in 48 CFR Parts 215, 217, and 252**

Government procurement.

Jennifer D. Johnson,

*Editor/Publisher, Defense Acquisition Regulations System.*

Therefore, 48 CFR parts 215, 217, and 252 are proposed to be amended as follows:

■ 1. The authority citation for 48 CFR parts 215, 217, and 252 continues to read as follows:

**Authority:** 41 U.S.C. 1303 and 48 CFR chapter 1.

## PART 215—CONTRACTING BY NEGOTIATION

■ 2. Amend section 215.404–71–3 by revising paragraph (d)(2)(i) to read as follows:

**215.404–71–3 Contract type risk and working capital adjustment.**

* * * * *

(d) * * *

(2) * * *

(i) The contracting officer shall assess the extent to which costs have been incurred prior to definitization of the contract action (also see 217.7404–6(a) and 243.204–70–6). When considering the reduced cost risks associated with allowable incurred costs on an undefinitized contract action, it is appropriate to apply separate contract risk factors for allowable incurred costs and estimated costs to complete when completing the contract risk sections of DD Form 1547, Record of Weighted Guidelines. When costs have been incurred prior to definitization, generally regard the contract type risk to be in the low end of the designated range. If a substantial portion of the costs has been incurred prior to definitization, the contracting officer may assign a value as low as zero percent, regardless of contract type. However, if a contractor submits a qualifying proposal to definitize an undefinitized contract action and the contracting officer for such action definitizes the contract after the end of the 180-day period beginning on the date on which the contractor submitted the qualifying proposal as defined in 217.7401, the profit allowed on the contract shall accurately reflect the cost risk of the contractor as such risk existed on the date the contractor submitted the qualifying proposal.

* * * * *

## PART 217—SPECIAL CONTRACTING METHODS

■ 3. Amend section 217.7404–3 by revising paragraph (b) to read as follows:

**217.7404–3 Definitization schedule.**

* * * * *

(b)(1) Submission of a qualifying proposal in accordance with the definitization schedule is a material element of the contract. If the contractor does not submit a qualifying proposal in accordance with the contract definitization schedule, notwithstanding FAR 52.216–26, Payments of Allowable Costs Before Definitization, the contracting officer may withhold an amount necessary to protect the interests of the Government, not to exceed 5 percent of all subsequent financing requests, or take other appropriate actions (*e.g.,* documenting the noncompliance in the contractor's past performance evaluation or terminating the contract for default).

(2) Contracting officers shall document in the contract file the justification for withholding or not withholding payments if the qualifying proposal was not submitted in accordance with the contract definitization schedule.

## PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 4. Revise section 252.217–7027 to read as follows:

### 252.217–7027 Contract definitization.

As prescribed in 217.7406(b), use the following clause:

**Contract Definitization (Date)**

(a) A _____ *[insert specific type of contract action]* is contemplated. The Contractor agrees to begin promptly negotiating with the Contracting Officer the terms of a definitive contract that will include—

(1) All clauses required by the Federal Acquisition Regulation (FAR) on the date of execution of the undefinitized contract action;

(2) All clauses required by law on the date of execution of the definitive contract action; and

(3) Any other mutually agreeable clauses, terms, and conditions.

(b) The Contractor agrees to submit a _____ *[insert type of proposal; e.g., fixed-price or cost-and-fee]* proposal and certified cost or pricing data supporting its proposal. Notwithstanding FAR 52.216–26, Payments of Allowable Costs Before Definitization, failure to meet the qualifying proposal date in the contract definitization schedule could result in the Contracting Officer withholding an amount up to 5 percent of all subsequent requests for financing until the Contracting Officer determines that a proposal is qualifying.

(c) The schedule for definitizing this contract action is as follows *[insert target date for definitization of the contract action and dates for submission of proposal, beginning of negotiations, and, if appropriate, submission of the make-or-buy and subcontracting plans and certified cost or pricing data]:*

_____

_____

_____

_____

(d) If agreement on a definitive contract action to supersede this undefinitized contract action is not reached by the target date in paragraph (c) of this clause, or within any extension of it granted by the Contracting Officer, the Contracting Officer may, with the approval of the head of the contracting activity, determine a reasonable price or fee in accordance with FAR subpart 15.4 and part 31, subject to Contractor appeal as provided in the Disputes clause. In any event, the Contractor shall proceed with completion of the contract, subject only to the Limitation of Government Liability clause.

(1) After the Contracting Officer's determination of price or fee, the contract shall be governed by—

(i) All clauses required by the FAR on the date of execution of this undefinitized contract action for either fixed-price or cost-reimbursement contracts, as determined by the Contracting Officer under this paragraph (d);

(ii) All clauses required by law as of the date of the Contracting Officer's determination; and

(iii) Any other clauses, terms, and conditions mutually agreed upon.

(2) To the extent consistent with paragraph (d)(1) of this clause, all clauses, terms, and conditions included in this undefinitized contract action shall continue in effect, except those that by their nature apply only to an undefinitized contract action.

(e) The definitive contract resulting from this undefinitized contract action will include a negotiated _____ *[insert ''cost/price ceiling'' or ''firm-fixed price'']* in no event to exceed _____ *[insert the not-to-exceed amount].*

(End of clause)

[FR Doc. 2022–23280 Filed 10–27–22; 8:45 am]

BILLING CODE 5001–06–P

**DEPARTMENT OF DEFENSE**

**Defense Acquisition Regulations System**

**48 CFR Parts 203 and 212**

**[Docket DARS–2022–0013]**

**RIN 0750–AL36**

## Defense Federal Acquisition Regulation Supplement: Prohibition on Award to Contractors That Require Certain Nondisclosure Agreements (DFARS Case 2021–D018)

**AGENCY:** Defense Acquisition Regulations System, Department of Defense (DoD).

**ACTION:** Final rule.

**SUMMARY:** DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2021 that prohibits the award of any DoD contracts to an entity that requires its employees to sign internal confidentiality agreements or statements that would prohibit or otherwise restrict its employees from lawfully reporting waste, fraud, or abuse related to the performance of a DoD contract to a designated investigative or law enforcement representative of DoD authorized to receive such information.

**DATES:** Effective October 28, 2022.

**FOR FURTHER INFORMATION CONTACT:** Ms. Kimberly R. Ziegler, telephone 703–901–3176.

**SUPPLEMENTARY INFORMATION:**

### I. Background

DoD published a proposed rule in the **Federal Register** at 87 FR 37470 on June 23, 2022, to implement section 883 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2021 (Pub. L. 116–283). Section 883 prohibits the award of a DoD contract to an entity that requires its employees to sign internal confidentiality agreements or statements that would prohibit or otherwise restrict such employees from lawfully reporting waste, fraud, or abuse related to the performance of a DoD contract to a designated investigative or law enforcement representative within DoD authorized to receive such information. The statute also requires entities to inform its employees of the limitations on confidentiality agreements or other statements. Offerors are required to represent compliance with the statutory restrictions in the System for Award Management prior to submitting an offer or quote.

The requirements of section 883 closely resemble those provided in section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113–235), which was implemented at Federal Acquisition Regulation (FAR) 3.909, Prohibition on providing funds to an entity that requires certain internal confidentiality agreements or statements (82 FR 4717, dated January 13, 2017). Since the prohibition at section 743 applies Governmentwide, DoD is currently complying with section 883 based on the FAR application of section 743 to employees and contractors.

One respondent submitted a comment in response to the proposed rule.

### II. Discussion and Analysis

DoD reviewed the public comment in the development of the final rule. The respondent provided a comment about the definition of the term ''entity'' as it pertains to the application of the rule, which is outside of the scope of this rule. No changes were made in the final rule.

### III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT), for Commercial Products (Including Commercially Available Off-the-Shelf (COTS) Items), and for Commercial Services

This rule implements section 883 of the NDAA for FY 2021 (Pub. L. 116–283) but does not create any new solicitation provisions or contract clauses. The rule does apply DFARS clause 252.203–7002, Requirement to Inform Employees of Whistleblower Rights, to contracts valued at or below the SAT and for commercial services and products, including COTS items. The rule, at DFARS 203.909–3, also prescribes use of Federal Acquisition Regulation (FAR) provision 52.203–18, Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements-Representation, and FAR clause 52.203–19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements. The FAR clause and provision, except for personal services contracts, are already prescribed for use in acquisitions at or below the SAT; and the FAR clause 52.203–19 is also prescribed for use in commercial acquisitions.

*A. Applicability to Contracts at or Below the SAT*

41 U.S.C. 1905 governs the applicability of laws to contracts or subcontracts in amounts not greater than the SAT. It is intended to limit the applicability of laws to such contracts or subcontracts. 41 U.S.C. 1905 provides that if a provision of law contains criminal or civil penalties, or if the Federal Acquisition Regulatory Council (FAR Council) makes a determination that it is not in the best interest of the Federal Government to exempt contracts or subcontracts at or below the SAT, the law will apply to them. The Principal Director, Defense Pricing and Contracting (DPC), is the appropriate authority to make comparable determinations for regulations to be published in the DFARS, which is part of the FAR system of regulations.

*B. Applicability to Contracts for the Acquisition of Commercial Services and Commercial Products, Including COTS Items*

10 U.S.C. 2375 (redesignated as 10 U.S.C. 3452) governs the applicability of laws to DoD contracts and subcontracts for the acquisition of commercial services and commercial products, including COTS items, and is intended to limit the applicability of laws to contracts for the acquisition of commercial services and commercial products, including COTS items. 10 U.S.C. 2375 provides that if a provision of law contains criminal or civil penalties, or if the Under Secretary of Defense for Acquisition and Sustainment (USD(A&S)) makes a written determination that it is not in the best interest of the Federal Government to exempt commercial product and commercial service contracts, the provision of law will apply to contracts for the acquisition of commercial products and commercial services. Due to delegations of authority, the Principal Director, DPC is the appropriate authority to make this determination. DoD intends to apply this rule and the corresponding statutes (10 U.S.C. 2409 and section 883 of the NDAA for FY 2021) to acquisitions at or below the SAT and for commercial services and commercial products, including COTS items.

*C. Determination*

DoD intends to apply the requirements of 10 U.S.C. 2409 and section 883 of the NDAA for FY 2021 to contracts at or below the SAT and those awarded under FAR part 12 procedures because the statutory protections are intended to apply to any employee of a contractor or subcontractor who discloses or may be restricted from disclosing evidence of waste, fraud, and abuse. The statutes only exempt the application to elements of the intelligence community.

10 U.S.C. 2409 provides contractor employees protection from reprisal for disclosure of waste, fraud, and abuse to designated persons and bodies identified in the statute. An employee of a contractor or subcontractor may not be discharged, demoted, or otherwise discriminated against as a reprisal for such a disclosure. The statute does not apply to elements of the intelligence committee.

Section 883 prohibits the award of any DoD contract to an entity that requires its employees to sign internal confidentiality agreements or statements that would prohibit or otherwise restrict its employees from lawfully reporting waste, fraud, or abuse related to the performance of a DoD contract to a designated investigative or law enforcement representative of DoD authorized to receive such information.

It is not in the best interest of the Federal Government to exempt application of this rule to actions at or below the SAT or to commercial services and commercial products (including COTS items). An exception for contracts at or below the SAT and those for commercial services and commercial products (including COTS items) would exclude the majority of the contracts and individuals intended to be protected under the laws, thereby undermining the overarching public policy purpose of the laws.

**IV. Expected Impact of the Rule**

This proposed rule is not expected to have a significant impact on the public or Government agencies because the requirements of section 883 have already been implemented Governmentwide at FAR 3.909. DoD-specific implementation of section 883 would duplicate the previous implementation of section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113–235) as implemented Governmentwide in the FAR.

**V. Executive Orders 12866 and 13563**

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993.

**VI. Congressional Review Act**

As required by the Congressional Review Act (5 U.S.C. 801–808) before an interim or final rule takes effect, DoD will submit a copy of the interim or final rule with the form, Submission of Federal Rules Under the Congressional Review Act, to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. A major rule under the Congressional Review Act cannot take effect until 60 days after it is published in the **Federal Register**. The Office of Information and Regulatory Affairs has determined that this rule is not a major rule as defined by 5 U.S.C. 804.

**VII. Regulatory Flexibility Act**

A final regulatory flexibility analysis has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* and is summarized as follows:

This rule amends the DFARS to implement section 883 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2021 (Pub. L. 116–283). Section 883 prohibits the award of a DoD contract to an entity that requires its employees to sign internal confidentiality agreements or statements that would prohibit or otherwise restrict such employees from lawfully reporting waste, fraud, or abuse related to the performance of a DoD contract to a designated investigative or law enforcement representative within DoD authorized to receive such information.

The objective of the rule is to implement the DoD-specific statute that removes restrictions on the ability of employees to report waste, fraud, or abuse to the appropriate DoD authorities.

There were no significant issues raised by the public in response to the initial regulatory flexibility analysis.

This rule will apply to all small entities that are eligible to receive DoD contracts; however, the requirements of section 883 are already met through the Governmentwide implementation of a previously published prohibition at FAR 3.909 and in the System for Award Management (SAM) representations and certifications. As a result, the 361,000 unique small entities registered in SAM as of January 12, 2021, are already compliant with these requirements and will not be required to take any additional action to comply with the DoD-specific prohibition in section 883.

The rule does not impose any new reporting, recordkeeping, or compliance requirements.

There are no practical alternatives that will accomplish the objectives of the statute.

**VIII. Paperwork Reduction Act**

This rule does not contain any information collection requirements that require the approval of the Office of Management and Budget (OMB) under the Paperwork Reduction Act (44 U.S.C. chapter 35).

**List of Subjects in 48 CFR Parts 203 and 212**

Government procurement.

**Jennifer D. Johnson,**

*Editor/Publisher, Defense Acquisition Regulations System.*

Therefore, 48 CFR parts 203 and 212 are amended as follows:

■ 1. The authority citation for parts 203 and 212 continues to read as follows:

**Authority:** 41 U.S.C. 1303 and 48 CFR chapter 1.

## PART 203—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

■ 2. Revise section 203.900 to read as follows:

**203.900 Scope of subpart.**

This subpart implements 10 U.S.C. 2409 and section 883 of the National Defense Authorization Act for Fiscal Year 2021 (Pub. L. 116–283).

(a)(i) 10 U.S.C. 2409 provides DoD whistleblower protection policies and procedures for contractor employees. Use sections 203.901 through 203.906 of this subpart in lieu of FAR sections 3.901 through 3.906 to implement 10 U.S.C. 2409.

(ii) 10 U.S.C. 2409 does not apply to any element of the intelligence community, as defined in 50 U.S.C. 3003(4). Sections 203.901 through 203.906 do not apply to any disclosure made by an employee of a contractor or subcontractor of an element of the intelligence community if such disclosure—

(A) Relates to an activity or an element of the intelligence community; or

(B) Was discovered during contract or subcontract services provided to an element of the intelligence community.

(c) Section 883 of the National Defense Authorization Act for Fiscal Year 2021 (Pub. L. 116–283) prohibits the award of a DoD contract to contractors that require their employees to sign internal confidentiality agreements or statements that would prohibit or otherwise restrict such employees from lawfully reporting

waste, fraud, or abuse related to the performance of a DoD contract to a designated investigative or law enforcement representative within DoD authorized to receive such information.

■ 3. Add sections 203.909 and 203.909–3 to read as follows:

**203.909 Prohibition on providing funds to an entity that requires certain internal confidentiality agreements or statements.**

**203.909–3 Solicitation provision and contract clause.**

Use the provision at FAR 52.203–18, Prohibition on Contracting with Entities That Require Certain Internal Confidentiality Agreements or Statements—Representation, and the clause at FAR 52.203–19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements, prescribed at FAR 3.909–3 to implement section 883 of the National Defense Authorization Act for Fiscal Year 2021.

■ 4. Revise section 203.970 to read as follows:

**203.970 Contract clause.**

Use the clause at 252.203–7002, Requirement to Inform Employees of Whistleblower Rights, in all solicitations and contracts, including solicitations and contracts using FAR part 12 procedures for the acquisition of commercial items.

## PART 212—ACQUISITION OF COMMERCIAL ITEMS

■ 5. Amend section 212.301—

■ a. In paragraph (f)(i), by redesignating paragraphs (f)(i)(C) and (D) as paragraphs (f)(i)(D) and (E); and

■ b. By adding a new paragraph (f)(i)(C).

The addition reads as follows:

**212.301 Solicitation provisions and contract clauses for the acquisition of commercial items.**

* * * * *

(f) * * *

(i) * * *

(C) Use the clause at 252.203–7002, Requirement to Inform Employees of Whistleblower Rights, as prescribed in 203.970, to comply with 10 U.S.C. 2409.

* * * * *

[FR Doc. 2022–23281 Filed 10–27–22; 8:45 am]

**BILLING CODE 5001–06–P**

## DEPARTMENT OF DEFENSE

### Defense Acquisition Regulations System

### 48 CFR Parts 216 and 235

**[Docket DARS–2022–0023]**

**RIN 0750–AL58**

## Defense Federal Acquisition Regulation Supplement: Repeal of Preference for Fixed-Price Contracts (DFARS Case 2022–D007)

**AGENCY:** Defense Acquisition Regulations System, Department of Defense (DoD).

**ACTION:** Final rule.

**SUMMARY:** DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2022.

**DATES:** Effective October 28, 2022.

**FOR FURTHER INFORMATION CONTACT:** Ms. Kimberly R. Ziegler, telephone 703–901–3176.

**SUPPLEMENTARY INFORMATION:**

### I. Background

DoD is issuing a final rule amending the DFARS to implement section 817 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2022 (Pub. L. 117–81), which repeals section 829 of the NDAA for FY 2017 (Pub. L. 114–328). This rule removes text that was added to the DFARS associated with the implementation of section 829.

DoD published a final rule in the **Federal Register** at 84 FR 65304 on November 27, 2019, to implement section 829. Section 829 required contracting officers to first consider fixed-price contracts, including fixed-price incentive contracts, when determining contract type and to obtain approval from the head of the contracting activity for certain cost-reimbursement contracts.

This final rule removes references, policies, and limitations related to section 829 at DFARS sections 216.102(1), 216.301–3(2), 216.401(d), and 235.006(b)(i). Conforming changes are made to revise two cross-references at 235.006(b)(ii). At DFARS 216.102(3) an obsolete reference to DFARS 225.7301–1 is removed, since the requirement at 225.7301–1 was repealed by section 888 of the NDAA for FY 2021 (Pub. L. 116–283); see the final rule for DFARS Case 2021–D019 published in the **Federal Register** at 86 FR 48339 on August 30, 2021.

### II. Publication of This Final Rule for Public Comment Is Not Required by Statute

The statute that applies to the publication of the Federal Acquisition Regulation (FAR) is 41 U.S.C. 1707, Publication of Proposed Regulations. Subsection (a)(1) of the statute requires that a procurement policy, regulation, procedure, or form (including an amendment or modification thereof) must be published for public comment if it relates to the expenditure of appropriated funds and has either a significant effect beyond the internal operating procedures of the agency issuing the policy, regulation, procedure, or form, or has a significant cost or administrative impact on contractors or offerors. This final rule is not required to be published for public comment, because this rule is updating internal DoD operating procedures.

### III. Applicability to Contracts at or Below the Simplified Acquisition Threshold, for Commercial Services, and for Commercial Products, Including Commercially Available Off-the-Shelf (COTS) Items

This rule does not create any new solicitation provisions or contract clauses. It does not impact any existing solicitation provisions or contract clauses or their applicability to contracts at or below the simplified acquisition threshold, for commercial services, or for commercial products including COTS items.

### IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993.

### V. Congressional Review Act

As required by the Congressional Review Act (5 U.S.C. 801–808) before an interim or final rule takes effect, DoD will submit a copy of the interim or final rule with the form, Submission of Federal Rules under the Congressional Review Act, to the U.S. Senate, the U.S. House of Representatives, and the

Comptroller General of the United States. A major rule under the Congressional Review Act cannot take effect until 60 days after it is published in the **Federal Register**. The Office of Information and Regulatory Affairs has determined that this rule is not a major rule as defined by 5 U.S.C. 804.

### VI. Regulatory Flexibility Act

The Regulatory Flexibility Act does not apply to this rule because this final rule does not constitute a significant DFARS revision within the meaning of FAR 1.501–1, and 41 U.S.C. 1707 does not require publication for public comment.

### VII. Paperwork Reduction Act

This rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

### List of Subjects in 48 CFR Parts 216 and 235

Government procurement.

**Jennifer D. Johnson,**

*Editor/Publisher, Defense Acquisition Regulations System.*

Therefore, 48 CFR parts 216 and 235 are amended as follows:

■ 1. The authority citation for 48 CFR parts 216 and 235 continues to read as follows:

**Authority:** 41 U.S.C. 1303 and 48 CFR chapter 1.

## PART 216—TYPES OF CONTRACTS

■ 2. Revise section 216.102 to read as follows:

#### 216.102 Policies.

In accordance with section 811 of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112–239), use of any cost-reimbursement line item for the acquisition of production of major defense acquisition programs is prohibited, unless the exception at 234.004(2)(ii) applies.

■ 3. Revise section 216.301–3 to read as follows:

#### 216.301–3 Limitations.

For contracts in connection with a military construction project or a military family housing project, contracting officers shall not use cost-plus-fixed-fee, cost-plus-award-fee, or cost-plus-incentive-fee contract types (10 U.S.C. 2306(c)). This applies notwithstanding a declaration of war or the declaration by the President of a national emergency under section 201 of the National Emergencies Act (50 U.S.C. 1621) that includes the use of the Armed Forces.

■ 4. Amend section 216.401 by revising paragraph (d) to read as follows:

#### 216.401 General.

* * * * *

(d) The determination and findings justifying that the use of an incentive- or award-fee contract is in the best interest of the Government, may be signed by the head of contracting activity or a designee—

(i) No lower than one level below the head of the contracting activity for award-fee contracts; or

(ii) One level above the contracting officer for incentive-fee contracts.

* * * * *

## PART 235—RESEARCH AND DEVELOPMENT CONTRACTING

#### 235.006 [Amended]

■ 5. Amend section 235.006 by—

■ a. Removing paragraph (b)(i);

■ b. Redesignating paragraphs (b)(ii) and (iii) as paragraphs (b)(i) and (ii), respectively;

■ c. In the newly redesignated paragraph (b)(ii)(A)(*3*), removing ''(b)(iii)(A)(*1*) and (*2*)'' and adding ''(b)(ii)(A)(*1*) and (*2*)'' in its place; and

■ d. In the newly redesignated paragraph (b)(ii)(A)(*3*)(*ii*), removing ''(b)(iii)(A)(*3*)(*i*)'' and adding ''(b)(ii)(A)(*3*)(*i*)'' in its place.

[FR Doc. 2022–23283 Filed 10–27–22; 8:45 am]

**BILLING CODE 5001–06–P**

## DEPARTMENT OF DEFENSE

### 48 CFR Parts 211, 212, and 252

**[Docket DARS–2022–0024]**

**RIN 0750–AL73**

## Defense Federal Acquisition Regulation Supplement: Removal of Passive Radio Frequency Requirements (DFARS Case 2022–D020)

**AGENCY:** Defense Acquisition Regulations System, Department of Defense (DoD).

**ACTION:** Final rule.

**SUMMARY:** DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to remove passive radio frequency identification requirements.

**DATES:** Effective October 28, 2022.

**FOR FURTHER INFORMATION CONTACT:** Ms. Kimberly R. Ziegler, telephone 703–901–3176.

**SUPPLEMENTARY INFORMATION:**

### I. Background

DoD is amending the DFARS to remove requirements for the use of passive radio frequency identification (RFID) tags for shipments that meet the criteria at DFARS 211.275–2. DoD no longer requires the use of passive RFID tags for shipments due to the use of more cost-effective technologies.

Accordingly, this rule removes and reserves the contract clause at DFARS 252.211–7006, Passive Radio Frequency Identification, which requires contractors to submit advance shipment notices to associate the passive RFID tag with the corresponding shipment, and removes and reserves section 211.275, Passive radio frequency identification. DFARS sections 211.275–1, Definitions; 211.275–2, Policy; and 211.275–3, Contract clause, are also removed. DFARS clause 252.211–7006 is removed from the list of solicitation provisions and contract clauses for the acquisition of commercial items at DFARS 212.301.

DoD issued the final rule for DFARS Case 2004–D011 (70 FR 53955) on September 13, 2005, to require that contractors affix passive RFID tags at the case and palletized unit load levels when shipping packaged operational rations, clothing, individual equipment, tools, personal demand items, or weapon system repair parts to two specific Defense Distribution Depots. The rule also required contractors to send an advance shipment notice to provide the association between the unique identification encoded on the passive tag(s) and the product information at the applicable case and palletized unit load level(s).

DoD later updated the passive RFID requirements and the associated contract clause at DFARS 252.211–7006 (76 FR 58142) on September 20, 2011, to expand the use of the tags to numerous sites and provide a new website that enabled contractors to find the RFID identifier for each specific DoD ship-to address that used RFID technology.

### II. Publication of This Final Rule for Public Comment Is Not Required by Statute

The statute that applies to the publication of the Federal Acquisition Regulation (FAR) is 41 U.S.C. 1707, Publication of Proposed Regulations. Subsection (a)(1) of the statute requires that a procurement policy, regulation, procedure, or form (including an amendment or modification thereof) must be published for public comment if it relates to the expenditure of appropriated funds, and has either a

significant effect beyond the internal operating procedures of the agency issuing the policy, regulation, procedure, or form, or has a significant cost or administrative impact on contractors or offerors. This final rule is not required to be published for public comment, because DoD is not issuing a new regulation; rather, this rule is removing an unneeded contract clause from the DFARS that will reduce the administrative burden on contractors or offerors.

### III. Applicability to Contracts at or Below the Simplified Acquisition Threshold, for Commercial Products Including Commercially Available Off-the-Shelf (COTS) Items, and for Commercial Services

This rule does not impose any new requirements on contracts at or below the simplified acquisition threshold, for commercial products including commercially available off-the-shelf items, or for commercial services. The rule removes and reserves DFARS clause 252.211–7006, Passive Radio Frequency Identification, and removes the clause from the list of solicitation provisions and contract clauses for the acquisition of commercial items at DFARS 212.301.

### IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993.

### V. Congressional Review Act

As required by the Congressional Review Act (5 U.S.C. 801–808) before an interim or final rule takes effect, DoD will submit a copy of the interim or final rule with the form, Submission of Federal Rules Under the Congressional Review Act, to the U.S. Senate, the U.S. House of Representatives, and to the Comptroller General of the United States. A major rule under the Congressional Review Act cannot take effect until 60 days after it is published in the **Federal Register**. The Office of Information and Regulatory Affairs has determined that this rule is not a major rule as defined by 5 U.S.C. 804.

### VII. Regulatory Flexibility Act

The Regulatory Flexibility Act does not apply to this rule because this final rule does not constitute a significant DFARS revision within the meaning of FAR 1.501–1, and 41 U.S.C. 1707 does not require publication for public comment.

### VIII. Paperwork Reduction Act

This rule removes the information collection requirements associated with the clause at DFARS 252.211.7006, Passive Radio Frequency Identification, currently approved under OMB Control Number 0704–0434, entitled ''Radio Frequency Identification Advance Shipment Notices''. Accordingly, DoD submitted, and OMB approved, the following reduction of the annual reporting burden and OMB inventory of hours under OMB Control Number 0704–0434 as follows:

*Respondents:* 5,217.

*Responses per respondent:* 3,782.

*Total annual responses:* 19,732,850.

*Hours per response:* Approximately 1.16 seconds.

*Total response burden hours:* 6,358.

### List of Subjects in 48 CFR Parts 211, 212, and 252

Government procurement.

**Jennifer D. Johnson,**

*Editor/Publisher, Defense Acquisition Regulations System.*

Therefore, 48 CFR parts 211, 212, and 252 are amended as follows:

■ 1. The authority citation for 48 CFR parts 211, 212, and 252 continues to read as follows:

**Authority:** 41 U.S.C. 1303 and 48 CFR chapter 1.

## PART 211—DESCRIBING AGENCY NEEDS

**211.275 [Removed and Reserved]**

■ 2. Remove and reserve section 211.275.

**211.275–1 through 211.275–3 [Removed]**

■ 3. Remove sections 211.275–1 through 211.275–3.

## PART 212—ACQUISITION OF COMMERCIAL ITEMS

**212.301 [Amended]**

■ 4. Amend section 212.301 by—

■ a. Removing paragraph (f)(iv)(B); and

■ b. Redesignating paragraphs (f)(iv)(C) and (D) as paragraphs (f)(iv)(B) and (C).

## PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

**252.211–7006 [Removed and Reserved]**

■ 5. Remove and reserve section 252.211–7006.

[FR Doc. 2022–23284 Filed 10–27–22; 8:45 am]

**BILLING CODE 5001–06–P**

## DEPARTMENT OF DEFENSE

## Defense Acquisition Regulations System

## 48 CFR Parts 212 and 252

**[Docket DARS–2022–0027]**

**RIN 0750–AL71**

## Defense Federal Acquisition Regulation Supplement: Removal of Pilot Program for Acquisition of Military-Purpose Nondevelopmental Items (DFARS Case 2022–D022)

**AGENCY:** Defense Acquisition Regulations System, Department of Defense (DoD).

**ACTION:** Final rule.

**SUMMARY:** DoD is issuing a final rule to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to remove the Pilot Program for Acquisition of Military-Purpose Nondevelopmental Items, since the statutory authority for the program has expired.

**DATES:** Effective October 28, 2022.

**FOR FURTHER INFORMATION CONTACT:** Ms. Jeanette Snyder, telephone 703–508–7524.

**SUPPLEMENTARY INFORMATION:**

### I. Background

DoD is issuing a final rule to remove DFARS subpart 212.71, Pilot Program for Acquisition of Military-Purpose Nondevelopmental Items, and the solicitation provision at DFARS 252.212–7002, Pilot Program for Acquisition of Military-Purpose Nondevelopmental Items. Section 866 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2011 (Pub. L. 111–383; 10 U.S.C. 2302 note) authorized the pilot program for a 5-year period through January 6, 2016, and the pilot program was implemented in the DFARS by publication of an interim rule at 76 FR 38048. Subsequently, section 814 of the NDAA for FY 2014 extended the pilot program through December 31, 2019, and this sunset date was implemented in the DFARS by publication of a final rule at 79 FR

17446 on March 28, 2014. Since the pilot program expired on December 31, 2019, the program is being removed from the DFARS. No contracts were awarded as a result of this pilot program.

**II. Publication of This Final Rule for Public Comment Is Not Required by Statute**

The statute that applies to the publication of the Federal Acquisition Regulation (FAR) is 41 U.S.C. 1707, Publication of Proposed Regulations. Subsection (a)(1) of the statute requires that a procurement policy, regulation, procedure, or form (including an amendment or modification thereof) must be published for public comment if it relates to the expenditure of appropriated funds and has either a significant effect beyond the internal operating procedures of the agency issuing the policy, regulation, procedure, or form, or has a significant cost or administrative impact on contractors or offerors. This final rule is not required to be published for public comment because it merely removes obsolete text from the DFARS for a pilot program that did not result in the award of any contracts by DoD; therefore, this final rule does not impact the Government, contractors, or offerors.

**III. Applicability to Contracts at or Below the Simplified Acquisition Threshold, for Commercial Products Including Commercially Available Off-the-Shelf Items, and for Commercial Services**

This rule does not create any new solicitation provisions or contract clauses. Although this rule removes the provision at DFARS 252.212–7002, Pilot Program for Acquisition of Military Purpose Nondevelopmental Items, it does not impact any other existing solicitation provisions, contract clauses, or prescriptions for the use of solicitation provisions or contract clauses.

**IV. Executive Orders 12866 and 13563**

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under Section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993.

**V. Congressional Review Act**

As required by the Congressional Review Act (5 U.S.C. 801–808) before an interim or final rule takes effect, DoD will submit a copy of the interim or final rule with the form, Submission of Federal Rules under the Congressional Review Act, to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. A major rule under the Congressional Review Act cannot take effect until 60 days after it is published in the **Federal Register**. The Office of Information and Regulatory Affairs has determined that this rule is not a major rule as defined by 5 U.S.C. 804.

**VI. Regulatory Flexibility Act**

The Regulatory Flexibility Act does not apply to this rule because this final rule does not constitute a significant DFARS revision within the meaning of FAR 1.501–1, and 41 U.S.C. 1707 does not require publication for public comment.

**VII. Paperwork Reduction Act**

This proposed rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

**List of Subjects in 48 CFR Parts 212 and 252**

Government procurement.

**Jennifer D. Johnson,**

*Editor/Publisher, Defense Acquisition Regulations System.*

Therefore, 48 CFR parts 212 and 252 are amended as follows:

■ 1. The authority citation for 48 CFR parts 212 and 252 continues to read as follows:

**Authority:** 41 U.S.C. 1303 and 48 CFR chapter 1.

## PART 212—ACQUISITION OF COMMERCIAL ITEMS

### Subpart 212.71 [Removed and Reserved]

■ 2. Remove and reserve subpart 212.71, consisting of sections 212.7100, 212.7101, 212.7102, 212.7102–1 through 212.7102–3, and 212.7103.

## PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

### 252.212–7002 [Removed and Reserved]

■ 3. Remove and reserve section 252.212–7002.

[FR Doc. 2022–23286 Filed 10–27–22; 8:45 am]

BILLING CODE 5001–06–P

## DEPARTMENT OF DEFENSE

### Defense Acquisition Regulations System

### 48 CFR Parts 212, 213, 229, 232, and 252

**[Docket DARS–2022–0014]**

**RIN 0750–AL51**

### Defense Federal Acquisition Regulation Supplement: Reporting Tax Information on Certain Foreign Procurements (DFARS Case 2021–D029)

**AGENCY:** Defense Acquisition Regulations System, Department of Defense (DoD).

**ACTION:** Final rule.

**SUMMARY:** DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to allow for the efficient and accurate identification of contracts subject to excise tax withholding. DoD is also amending the DFARS to prohibit use of the Governmentwide commercial purchase card as a method of payment when the tax on certain foreign procurements applies. These changes will promote the efficient administration of the excise tax.

**DATES:** Effective October 28, 2022.

**FOR FURTHER INFORMATION CONTACT:** David E. Johnson, telephone 202–913–5764.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

DoD published a proposed rule in the **Federal Register** at 87 FR 37473 on June 23, 2022, to amend the DFARS to promote the efficient administration of the two-percent excise tax on specified Federal procurement payments to certain foreign persons. Section 301 of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111–347), codified at 26 U.S.C. 5000C, imposes a two-percent excise tax on specified Federal procurement payments to certain foreign persons; it does not apply to payments to United States persons. With certain exceptions,

to administer this tax DoD must withhold an amount equal to two percent of the amount of specified Federal procurement payments.

One respondent submitted a public comment in response to the proposed rule.

**II. Discussion and Analysis**

DoD reviewed the public comment in the development of the final rule. A discussion of the comment is provided, as follows:

*A. Summary of Significant Changes From the Proposed Rule*

There are no significant changes made from the proposed rule.

*B. Analysis of Public Comments*

*Comment:* A respondent expressed support for the rule.

*Response:* DoD acknowledges the support.

*C. Other Changes*

The contract clause at DFARS 252.229–7014, Full Exemption from Two-Percent Excise Tax on Certain Foreign Procurements, is added to the list at DFARS 212.301(f) of clauses that are applicable to commercial items.

**III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT) and for Commercial Services and Commercial Products, Including Commercially Available Off-the-Shelf (COTS) Items**

This rule creates a new DFARS clause 252.229–7014, Full Exemption from Two-Percent Excise Tax on Certain Foreign Procurements, to implement section 301 of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111–347), codified at 26 U.S.C. 5000C. The clause at DFARS 252.229–7014 is prescribed at DFARS 229.402–70(k) for use in contracts that include the clause at Federal Acquisition Regulation (FAR) 52.229–12, Tax on Certain Foreign Procurements, for which the contractor represented in its offer that it is a foreign person and is fully exempt from the tax for reasons cited on their Internal Revenue Service (IRS) Form W–14. FAR 52.229–12 is used when FAR 52.229–11, Tax on Certain Foreign Procurements—Notice and Representation, is used; and FAR 52.229–11 does not apply to acquisitions that do not exceed the SAT. Accordingly, DoD is not applying the rule to acquisitions at or below the SAT but is applying the rule to the acquisition of commercial services and commercial products, including COTS items.

*A. Applicability to Contracts for the Acquisition of Commercial Services and Commercial Products Including COTS Items*

10 U.S.C. 2375 (redesignated as 10 U.S.C. 3452) exempts contracts and subcontracts for the acquisition of commercial products, including COTS items, and commercial services from provisions of law enacted after October 13, 1994, unless the Under Secretary of Defense for Acquisition and Sustainment (USD(A&S)) makes a written determination that it would not be in the best interest of DoD to exempt contracts for the procurement of commercial products and commercial services from the applicability of the provision or contract requirement, except for a provision of law that—

- Provides for criminal or civil penalties;
- Requires that certain articles be bought from American sources pursuant to 10 U.S.C. 2533c (redesignated as 10 U.S.C. 4862), or that strategic materials critical to national security be bought from American sources pursuant to 10 U.S.C. 2533b (redesignated as 10 U.S.C. 4863); or
- Specifically refers to 10 U.S.C. 2375 and states that it shall apply to contracts and subcontracts for the acquisition of commercial items (including COTS items) and commercial services; or
- USD (A&S) determines in writing that it would not be in the best interest of the Government to exempt contracts or subcontracts for the acquisition of commercial items from the applicability of the provision or contract clause requirement.

Section 301 of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111–347), codified at 26 U.S.C. 5000C and implemented by this rule, does not impose criminal or civil penalties; does not require purchase pursuant to 10 U.S.C. 2533b or 2533c; and does not refer to 10 U.S.C. 2375. Section 301 will not apply to the acquisition of commercial products including COTS items or to the acquisition of commercial services unless a written determination is made. Due to delegations of authority from USD(A&S), the Principal Director, DPC, is the appropriate authority to make the written determination. DoD has made that determination to apply this rule to the acquisition of commercial products including COTS items and to the acquisition of commercial services, if otherwise applicable.

*B. Determination*

The clause at 252.229–7014 is intended to provide a simple and efficient way for contracting officers to alert the DoD payment systems and networks that a contractor claimed a full exemption from the two-percent excise tax in its offer, thereby preventing erroneous withholding of the tax. Not applying the clause to contracts for the acquisition of commercial services and commercial products, including COTS items, would exclude contracts intended to be covered by this rule and undermine the overarching purpose of the rule. Consequently, DoD is applying the rule to contracts for the acquisition of commercial services and commercial products, including COTS items.

**IV. Executive Orders 12866 and 13563**

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993.

**V. Congressional Review Act**

As required by the Congressional Review Act (5 U.S.C. 801–808) before an interim or final rule takes effect, DoD will submit a copy of the interim or final rule with the form, Submission of Federal Rules under the Congressional Review Act, to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. A major rule under the Congressional Review Act cannot take effect until 60 days after it is published in the **Federal Register**. The Office of Information and Regulatory Affairs has determined that this rule is not a major rule as defined by 5 U.S.C. 804.

**VI. Regulatory Flexibility Act**

A final regulatory flexibility analysis has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* and is summarized as follows:

This rule is intended to promote efficient administration of the two-percent excise tax on specified Federal procurement payments to certain foreign persons. The rule prescribes inclusion of a new DFARS clause in contracts when the tax on certain foreign procurements applies and the contractor claimed a full exemption

from the tax. In addition, the rule prohibits use of the Governmentwide commercial purchase card as a method of payment when the tax on certain foreign procurements applies and the contractor did not claim a full exemption.

DoD received no comments in response to the initial regulatory flexibility analysis.

The rule applies to Federal Government contracts that include FAR 52.229–12, that are valued over $250,000, and that are awarded to foreign persons for goods or services, if the goods are manufactured or produced or the services are provided in any country that is not a party to an international procurement agreement with the United States (see FAR 25.003 for the definitions of ''World Trade Organization Government Procurement Agreement (WTO GPA) country'' and ''Free Trade Agreement country''). Data for fiscal year 2021 was obtained from the Federal Procurement Data System for contract awards reflecting these criteria. There were 123 total awards; 117 were awarded to 56 unique large foreign entities and 6 were awarded to 4 unique small foreign entities for a total of 50 unique foreign entities. Accordingly, the final rule is not expected to have a significant impact on small entities based in the United States.

This rule imposes no reporting, recordkeeping, and other compliance requirements.

There are no known available alternatives to accomplish the desired objective of the statute.

## VII. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) applies to this rule. However, these changes to the DFARS do not impose additional information collection requirements to the paperwork burden previously approved under OMB Control Number 1545–2263, titled Tax on Certain Foreign Procurement.

## List of Subjects in 48 CFR Parts 212, 213, 229, 232, and 252

Government procurement.

**Jennifer D. Johnson,**

*Editor/Publisher, Defense Acquisition Regulations System.*

Therefore, 48 CFR parts 212, 213, 229, 232, and 252 are amended as follows:

■ 1. The authority citation for 48 CFR parts 212, 213, 229, 232, and 252 continues to read as follows:

**Authority:** 41 U.S.C. 1303 and 48 CFR chapter 1.

## PART 212—ACQUISITION OF COMMERCIAL ITEMS

■ 2. Amend section 212.301 by—

■ a. Redesignating paragraphs (f)(xiii) through (f)(xix) as paragraphs (f)(xiv) through (f)(xx); and

■ b. Adding new paragraph (f)(xiii).

The addition reads as follows:

### 212.301 Solicitation provisions and contract clauses for the acquisition of commercial items.

* * * * *

(f) * * *

(xiii) *Part 229—Taxes.* Use the clause at 252.229–7014, Full Exemption from Two-Percent Excise Tax on Certain Foreign Procurements, as prescribed at 229.402–70, to comply with 26 U.S.C. 5000C.

* * * * *

## PART 213—SIMPLIFIED ACQUISITION PROCEDURES

■ 3. Amend section 213.301 by redesignating paragraph (4) as paragraph (5) and adding a new paragraph (4).

The addition reads as follows:

### 213.301 Governmentwide commercial purchase card.

* * * * *

(4) The contracting officer shall not authorize the Governmentwide commercial purchase card as a method of payment during any contract period of performance if the contract includes the clause at FAR 52.229–12, Tax on Certain Foreign Procurements, unless the contract also includes the clause at 252.229–7014, Full Exemption from Two-Percent Excise Tax on Certain Foreign Procurements, indicating that the contractor is fully exempt from the tax.

* * * * *

## PART 229—TAXES

■ 4. Add subpart 229.2, consisting of section 229.204, to read as follows:

## Subpart 229.2—Federal Excise Taxes

### 229.204 Federal excise tax on specific foreign contract payments.

The contracting officer shall not authorize the Governmentwide commercial purchase card as a method of payment during any contract period of performance if the contract includes the clause at FAR 52.229–12, Tax on Certain Foreign Procurements, unless the contract also includes the clause at 252.229–7014, Full Exemption from Two-Percent Excise Tax on Certain Foreign Procurements, indicating that the contractor is fully exempt from the tax.

■ 5. Amend section 229.402–70 by adding paragraph (k) to read as follows:

### 229.402–70 Additional provisions and clauses.

* * * * *

(k) Use the clause at 252.229–7014, Full Exemption from Two-Percent Excise Tax on Certain Foreign Procurements, in contracts that include the clause at FAR 52.229–12, Tax on Certain Foreign Procurements, when the contractor has—

(1) Represented that it is a foreign person in response to the provision at FAR 52.229–11, Tax on Certain Foreign Procurements—Notice and Representation; and

(2) Indicated that it is fully exempt from the tax for reasons cited on their IRS Form W–14, Certificate of Foreign Contracting Party Receiving Federal Procurement Payments.

## PART 232—CONTRACT FINANCING

■ 6. Add sections 232.1108 and 232.1108–70 to subpart 232.11 to read as follows:

### 232.1108 Payment by Governmentwide commercial purchase card.

### 232.1108–70 Prohibition of Governmentwide commercial purchase card as a method of payment when the tax on certain foreign procurements applies.

The contracting officer shall not authorize the Governmentwide commercial purchase card as a method of payment during any contract period of performance if the contract includes the clause at FAR 52.229–12, Tax on Certain Foreign Procurements, unless the contract also includes the clause at 252.229–7014, Full Exemption from Two-Percent Excise Tax on Certain Foreign Procurements, indicating that the contractor is fully exempt from the tax.

## PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 7. Add section 252.229–7014 to read as follows:

### 252.229–7014 Full Exemption from Two-Percent Excise Tax on Certain Foreign Procurements.

As prescribed in 229.402–70(k), use the following clause:

**Full Exemption From Two-Percent Excise Tax on Certain Foreign Procurements (OCT 2022)**

(a) As the Contractor represented in its offer, any item, including any item delivered under subcontract; any service; or any combination thereof delivered under this contract is fully exempt from the 2-percent

excise tax withholding imposed by 26 U.S.C. 5000C and implemented by Federal Acquisition Regulation (FAR) 52.229–12, Tax on Certain Foreign Procurements.

(b) If the full exemption no longer applies due to a change in circumstances during the performance of the contract, causing the Contractor to become subject to the withholding for the 2-percent excise tax as imposed by 26 U.S.C. 5000C, then the Contractor shall immediately comply with the notification and billing requirements of FAR clause 52.229–12.

*(End of clause)*

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**Federal Register**

Vol. 87, No. 208

Friday, October 28, 2022

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Executive orders and proclamations **741–6000**

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## FEDERAL REGISTER PAGES AND DATE, OCTOBER

59633–60056 ..... 3
60057–60240 ..... 4
60241–60540 ..... 5
60541–60866 ..... 6
60867–61216 ..... 7
61217–61440 ..... 11
61441–61948 ..... 12
61949–62282 ..... 13
62283–62720 ..... 14
62721–62976 ..... 17
62977–63380 ..... 18
63381–63660 ..... 19
63661–63932 ..... 20
63933–64148 ..... 21
64149–64364 ..... 24
64365–64682 ..... 25
64683–65010 ..... 26
65011–65157 ..... 27
65159–65518 ..... 28

## CFR PARTS AFFECTED DURING OCTOBER

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

### 2 CFR

700 ..... 60059

### 3 CFR

**Proclamations:**

10456 ..... 60241
10457 ..... 60243
10458 ..... 60245
10459 ..... 60249
10460 ..... 60251
10461 ..... 60253
10462 ..... 60257
10463 ..... 60259
10464 ..... 60261
10465 ..... 60263
10466 ..... 61215
10467 ..... 61441
10468 ..... 61443
10469 ..... 61949
10470 ..... 61951
10471 ..... 61953
10472 ..... 61955
10473 ..... 61957
10474 ..... 62299
10475 ..... 62301
10476 ..... 63381
10477 ..... 63393
10478 ..... 63395
10479 ..... 63397
10480 ..... 63661
10481 ..... 64683

**Executive Orders:**

8809 (amended by 14085) ..... 60541
9158 (amended by 14085) ..... 60541
10694 (amended by 14085) ..... 60541
11046 (amended by 14085) ..... 60541
11545 (amended by 14085) ..... 60541
13830 (amended by 14085) ..... 60541
13851 (amended and revised by 14088) ..... 64685
14084 ..... 60535
14085 ..... 60541
14086 ..... 62283
14087 ..... 63399
14088 ..... 64685

**Administrative Orders:**

Memorandums:
Memorandum of September 30, 2022 ..... 60539
Memorandum of October 3, 2022 ..... 60545
Memorandum of October 4, 2022 ..... 61947
Notices:
Notice of October 12, 2022 ..... 62279
Notice of October 12, 2022 ..... 62281
Presidential Determinations:
No. 2022–24 of September 23, 2022 ..... 60057
No. 2022–25 of September 27, 2022 ..... 60547
No. 2023–01 of October 3, 2022 ..... 61943

### 5 CFR

Ch. 18 ..... 63401

### 7 CFR

272 ..... 59633
273 ..... 59633
457 ..... 64365
1740 ..... 63419

**Proposed Rules:**

205 ..... 61268
905 ..... 63431
922 ..... 63433
984 ..... 64385

### 8 CFR

214 ..... 61959, 62721

### 9 CFR

327 ..... 63420
351 ..... 63420
354 ..... 63420
381 ..... 63420
500 ..... 63420
590 ..... 63420
592 ..... 63420

**Proposed Rules:**

130 ..... 59731
201 ..... 60010

### 10 CFR

50 ..... 65128
429 ..... 63588, 63860, 64550, 64689
430 ..... 60867, 64550
431 ..... 63588, 63860, 64689
626 ..... 64369

**Proposed Rules:**

71 ..... 65177
429 ..... 63324, 63356
430 ..... 60941, 63324, 63356
431 ..... 60555, 60942, 62038

### 11 CFR

**Proposed Rules:**

110 ..... 65178

### 12 CFR

34 ..... 63663

## LIST OF PUBLIC LAWS

**Note:** No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

**Last List October 20, 2022**

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