

EPA-APPROVED REGULATIONS, TECHNICAL MEMORANDA, AND STATUTES IN THE MARYLAND SIP—Continued

Code of Maryland Administrative Regulations (COMAR) citation	Title/subject	State effective date	EPA approval date	Additional explanation/citation at 40 CFR 52.1100
26.11.40 NO_x Ozone Season Emission Caps for Non-trading Large NO_x Units				
26.11.40.01	Definitions	04/23/18	10/11/18, [Insert Federal Register citation].	
26.11.40.02	Applicability	04/23/18	10/11/18, [Insert Federal Register citation].	
26.11.40.03	NO _x Ozone Season Emission Caps.	04/23/18	10/11/18, [Insert Federal Register citation].	
26.11.40.04	Monitoring and Reporting Requirements.	04/23/18	10/11/18, [Insert Federal Register citation].	

* * * * *

[FR Doc. 2018-21653 Filed 10-10-18; 8:45 am]
BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 102

RIN 0991-AC0

Annual Civil Monetary Penalties Inflation Adjustment

AGENCY: Office of the Assistant Secretary for Financial Resources, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services is updating its regulations to reflect required annual inflation-related increases to the civil monetary penalties in its regulations, pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.

DATES: This rule is effective October 11, 2018.

FOR FURTHER INFORMATION CONTACT: Shaunta Johnson, Office of Grants and Acquisition Policy and Accountability, Office of the Assistant Secretary for Financial Resources, Room 514-G, Hubert Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201; 202-690-6396; FAX 202-690-5405.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of Pub. L. 114-74) (the “2015 Act”), which is intended to improve the effectiveness of civil

monetary penalties (CMPs) and to maintain the deterrent effect of such penalties, requires agencies to adjust the civil monetary penalties for inflation annually.

The Department of Health and Human Services (HHS) lists the civil monetary penalty authorities and the penalty amounts administered by all of its agencies in tabular form in 45 CFR 102.3.

II. Calculation of Adjustment

The annual inflation adjustment for each applicable civil monetary penalty is determined using the percent increase in the Consumer Price Index for all Urban Consumers (CPI-U) for the month of October of the year in which the amount of each civil penalty was most recently established or modified. In the December 15, 2017, Office of Management and Budget (OMB) Memorandum for the Heads of Executive Agencies and Departments, M-18-03, *Implementation of the Penalty Inflation Adjustments for 2018, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015*, OMB published the multiplier for the required annual adjustment. The cost-of-living adjustment multiplier for 2018, based on the CPI-U for the month of October 2017, not seasonally adjusted, is 1.02041.

Using the 2018 multiplier, HHS adjusted all its applicable monetary penalties in 45 CFR 102.3.

III. Statutory and Executive Order Reviews

The 2015 Act requires federal agencies to publish annual penalty inflation adjustments notwithstanding section 553 of the Administrative Procedure Act (APA).

Section 4(a) of the 2015 Act directs federal agencies to publish annual adjustments no later than January 15th of each year thereafter. In accordance with section 553 of the APA, most rules are subject to notice and comment and are effective no earlier than 30 days after publication in the **Federal Register**. However, section 4(b)(2) of the 2015 Act provides that each agency shall make the annual inflation adjustments “notwithstanding section 553” of the APA.

According to OMB’s Memorandum M-18-03, the phrase “notwithstanding section 553” means that “the public procedure the APA generally requires—notice, an opportunity for comment, and a delay in effective date—is not required for agencies to issue regulations implementing the annual adjustment.” Consistent with the language of the 2015 Act and OMB’s implementation guidance, this rule is not subject to notice and an opportunity for public comment and will be effective immediately upon publication.

Pursuant to OMB Memorandum M-18-03, HHS has determined that the annual inflation adjustment to the civil monetary penalties in its regulations does not trigger any requirements under procedural statutes and Executive Orders that govern rulemaking procedures.

IV. Effective Date

This rule is effective October 11 2018. The adjusted civil monetary penalty amounts apply to penalties assessed on or after October 11, 2018, if the violation occurred on or after November 2, 2015. If the violation occurred prior to November 2, 2015, or a penalty was assessed prior to September 6, 2016, the pre-adjustment civil penalty amounts in

effect prior to September 6, 2016, will apply.

List of Subjects in 45 CFR Part 102

Administrative practice and procedure, Penalties.

For reasons discussed in the preamble, the Department of Health and Human Services amends subtitle A, title

45 of the Code of Federal Regulations as follows:

PART 102—ADJUSTMENT OF CIVIL MONETARY PENALTIES FOR INFLATION

■ 1. The authority citation for part 102 continues to read as follows:

Authority: Public Law 101–410, Sec. 701 of Public Law 114–74, 31 U.S.C. 3801–3812.

■ 2. Amend § 102.3 by revising the table to read as follows:

§ 102.3 Penalty adjustment and table.

* * * * *

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS
[Effective October 11, 2018]

Citation		HHS agency	Description ²	Date of last statutorily established penalty figure ³	2016 Maximum adjusted penalty (\$)	2017 Maximum adjusted penalty (\$) ⁴	2018 Maximum adjusted penalty (\$)
U.S.C.	CFR ¹						
21 U.S.C.							
333(b)(2)(A)		FDA	Penalty for violations related to drug samples resulting in a conviction of any representative of manufacturer or distributor in any 10-year period.	2016	98,935	100,554	102,606
333(b)(2)(B)		FDA	Penalty for violation related to drug samples resulting in a conviction of any representative of manufacturer or distributor after the second conviction in any 10-yr period.	2016	1,978,690	2,011,061	2,052,107
333(b)(3)		FDA	Penalty for failure to make a report required by 21 U.S.C. 353(d)(3)(E) relating to drug samples.	2016	197,869	201,106	205,211
333(f)(1)(A)		FDA	Penalty for any person who violates a requirement related to devices for each such violation.	2016	26,723	27,160	27,714
333(f)(2)(A)		FDA	Penalty for aggregate of all violations related to devices in a single proceeding.	2016	1,781,560	1,810,706	1,847,663
			Penalty for any individual who introduces or delivers for introduction into interstate commerce food that is adulterated per 21 U.S.C. 342(a)(2)(B) or any individual who does not comply with a recall order under 21 U.S.C. 350l.	2016	75,123	76,352	77,910
			Penalty in the case of any other person other than an individual) for such introduction or delivery of adulterated food.	2016	375,613	381,758	389,550
333(f)(3)(A)		FDA	Penalty for aggregate of all such violations related to adulterated food adjudicated in a single proceeding.	2016	751,225	763,515	779,098
			Penalty for all violations adjudicated in a single proceeding for any person who violates 21 U.S.C. 331(j)(1) by failing to submit the certification required by 42 U.S.C. 282(j)(5)(B) or knowingly submitting a false certification; by failing to submit clinical trial information under 42 U.S.C. 282(j); or by submitting clinical trial information under 42 U.S.C. 282(j) that is false or misleading in any particular under 42 U.S.C. 282(j)(5)(D).	2016	11,383	11,569	11,805
333(f)(3)(B)		FDA	Penalty for each day any above violation is not corrected after a 30-day period following notification until the violation is corrected.	2016	11,383	11,569	11,805
333(f)(4)(A)(i)		FDA	Penalty for any responsible person that violates a requirement of 21 U.S.C. 355(o) (post-marketing studies, clinical trials, labeling), 21 U.S.C. 355(p) (risk evaluation and mitigation (REMS)), or 21 U.S.C. 355–1 (REMS).	2016	284,583	289,239	295,142

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
 [Effective October 11, 2018]

Citation		HHS agency	Description ²	Date of last statutorily established penalty figure ³	2016 Maximum adjusted penalty (\$)	2017 Maximum adjusted penalty (\$) ⁴	2018 Maximum adjusted penalty (\$)
U.S.C.	CFR ¹						
333(f)(4)(A)(ii)		FDA	Penalty for aggregate of all such above violations in a single proceeding.	2016	1,138,330	1,156,953	1,180,566
			Penalty for REMS violation that continues after written notice to the responsible person for the first 30-day period (or any portion thereof) the responsible person continues to be in violation.	2016	284,583	289,239	295,142
			Penalty for REMS violation that continues after written notice to responsible person doubles for every 30-day period thereafter the violation continues, but may not exceed penalty amount for any 30-day period.	2016	1,138,330	1,156,953	1,180,566
333(f)(9)(A)		FDA	Penalty for aggregate of all such above violations adjudicated in a single proceeding.	2016	11,383,300	11,569,531	11,805,665
			Penalty for any person who violates a requirement which relates to tobacco products for each such violation.	2016	16,503	16,773	17,115
333(f)(9)(B)(i)(I)		FDA	Penalty for aggregate of all such violations of tobacco product requirement adjudicated in a single proceeding.	2016	1,100,200	1,118,199	1,141,021
			Penalty per violation related to violations of tobacco requirements.	2016	275,050	279,550	285,256
333(f)(9)(B)(i)(II)		FDA	Penalty for aggregate of all such violations of tobacco product requirements adjudicated in a single proceeding.	2016	1,100,200	1,118,199	1,141,021
			Penalty in the case of a violation of tobacco product requirements that continues after written notice to such person, for the first 30-day period (or any portion thereof) the person continues to be in violation.	2016	275,050	279,550	285,256
333(f)(9)(B)(ii)(I)		FDA	Penalty for violation of tobacco product requirements that continues after written notice to such person shall double for every 30-day period thereafter the violation continues, but may not exceed penalty amount for any 30-day period.	2016	1,100,200	1,118,199	1,141,021
			Penalty for aggregate of all such violations related to tobacco product requirements adjudicated in a single proceeding.	2016	11,002,000	11,181,993	11,410,218
333(f)(9)(B)(ii)(II)		FDA	Penalty for any person who either does not conduct post-market surveillance and studies to determine impact of a modified risk tobacco product for which the HHS Secretary has provided them an order to sell, or who does not submit a protocol to the HHS Secretary after being notified of a requirement to conduct post-market surveillance of such tobacco products.	2016	275,050	279,550	285,256
			Penalty for aggregate of for all such above violations adjudicated in a single proceeding.	2016	1,100,200	1,118,199	1,141,021
333(f)(9)(B)(ii)(II)		FDA	Penalty for violation of modified risk tobacco product post-market surveillance that continues after written notice to such person for the first 30-day period (or any portion thereof) that the person continues to be in violation.	2016	275,050	279,550	285,256

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
 [Effective October 11, 2018]

Citation		HHS agency	Description ²	Date of last statutorily established penalty figure ³	2016 Maximum adjusted penalty (\$)	2017 Maximum adjusted penalty (\$) ⁴	2018 Maximum adjusted penalty (\$)
U.S.C.	CFR ¹						
			Penalty for post-notice violation of modified risk tobacco product post-market surveillance shall double for every 30-day period thereafter that the tobacco product requirement violation continues for any 30-day period, but may not exceed penalty amount for any 30-day period.	2016	1,100,200	1,118,199	1,141,021
			Penalty for aggregate above tobacco product requirement violations adjudicated in a single proceeding.	2016	11,002,000	11,181,993	11,410,218
333(g)(1)	FDA	Penalty for any person who disseminates or causes another party to disseminate a direct-to-consumer advertisement that is false or misleading for the first such violation in any 3-year period.	2016	284,583	289,239	295,142
			Penalty for each subsequent above violation in any 3-year period.	2016	569,165	578,477	590,284
333 note	FDA	Penalty to be applied for violations of restrictions on the sale or distribution of tobacco products promulgated under 21 U.S.C. 387f(d) (e.g., violations of regulations in 21 CFR Part 1140) with respect to a retailer with an approved training program in the case of a second regulation violation within a 12-month period.	2016	275	279	285
			Penalty in the case of a third tobacco product regulation violation within a 24-month period.	2016	550	559	570
			Penalty in the case of a fourth tobacco product regulation violation within a 24-month period.	2016	2,200	2,236	2,282
			Penalty in the case of a fifth tobacco product regulation violation within a 36-month period.	2016	5,501	5,591	5,705
			Penalty in the case of a sixth or subsequent tobacco product regulation violation within a 48-month period as determined on a case-by-case basis.	2016	11,002	11,182	11,410
			Penalty to be applied for violations of restrictions on the sale or distribution of tobacco products promulgated under 21 U.S.C. 387f(d) (e.g., violations of regulations in 21 CFR Part 1140) with respect to a retailer that does not have an approved training program in the case of the first regulation violation.	2016	275	279	285
			Penalty in the case of a second tobacco product regulation violation within a 12-month period.	2016	550	559	570
			Penalty in the case of a third tobacco product regulation violation within a 24-month period.	2016	1,100	1,118	1,141
			Penalty in the case of a fourth tobacco product regulation violation within a 24-month period.	2016	2,200	2,236	2,282
			Penalty in the case of a fifth tobacco product regulation violation within a 36-month period.	2016	5,501	5,591	5,705
			Penalty in the case of a sixth or subsequent tobacco product regulation violation within a 48-month period as determined on a case-by-case basis.	2016	11,002	11,182	11,410

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
 [Effective October 11, 2018]

Citation		HHS agency	Description ²	Date of last statutorily established penalty figure ³	2016 Maximum adjusted penalty (\$)	2017 Maximum adjusted penalty (\$) ⁴	2018 Maximum adjusted penalty (\$)
U.S.C.	CFR ¹						
335b(a)	FDA	Penalty for each violation for any individual who made a false statement or misrepresentation of a material fact, bribed, destroyed, altered, removed, or secreted, or procured the destruction, alteration, removal, or secretion of, any material document, failed to disclose a material fact, obstructed an investigation, employed a consultant who was debarred, debarred individual provided consultant services.	2016	419,320	426,180	434,878
			Penalty in the case of any other person (other than an individual) per above violation.	2016	1,677,280	1,704,720	1,739,513
360pp(b)(1)	FDA	Penalty for any person who violates any such requirements for electronic products, with each unlawful act or omission constituting a separate violation.	2016	2,750	2,795	2,852
			Penalty imposed for any related series of violations of requirements relating to electronic products.	2016	937,500	952,838	972,285
42 U.S.C.							
262(d)	FDA	Penalty per day for violation of order of recall of biological product presenting imminent or substantial hazard.	2016	215,628	219,156	223,629
263b(h)(3)	FDA	Penalty for failure to obtain a mammography certificate as required.	2016	16,773	17,047	17,395
300aa–28(b)(1)	FDA	Penalty per occurrence for any vaccine manufacturer that intentionally destroys, alters, falsifies, or conceals any record or report required.	2016	215,628	219,156	223,629
256b(d)(1)(B)(vi)	HRSA	Penalty for each instance of overcharging a 340B covered entity.	2016	5,437	5,526	5,639
299c–3(d)	AHRQ	Penalty for an establishment or person supplying information obtained in the course of activities for any purpose other than the purpose for which it was supplied.	2016	14,140	14,371	14,664
653(l)(2)	45 CFR 303.21(f)	ACF	Penalty for Misuse of Information in the National Directory of New Hires.	2016	1,450	1,474	1,504
262a(i)(1)	42 CFR 1003.910	OIG	Penalty for each individual who violates safety and security procedures related to handling dangerous biological agents and toxins.	2016	327,962	333,327	340,130
			Penalty for any other person who violates safety and security procedures related to handling dangerous biological agents and toxins.	2016	655,925	666,656	680,262
300jj–51	OIG	Penalty per violation for committing information blocking.	2016	1,000,000	1,016,360	1,037,104
1320a–7a(a) ⁵	42 CFR 1003.210(a)(1)	OIG	Penalty for knowingly presenting or causing to be presented to an officer, employee, or agent of the United States a false claim.	2018	15,024	15,270	20,000
			Penalty for knowingly presenting or causing to be presented a request for payment which violates the terms of an assignment, agreement, or PPS agreement.	2018	15,024	15,270	20,000
	42 CFR 1003.210(a)(2)		Penalty for knowingly giving or causing to be presented to a participating provider or supplier false or misleading information that could reasonably be expected to influence a discharge decision.	2018	22,537	22,906	30,000

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
 [Effective October 11, 2018]

Citation		HHS agency	Description ²	Date of last statutorily established penalty figure ³	2016 Maximum adjusted penalty (\$)	2017 Maximum adjusted penalty (\$) ⁴	2018 Maximum adjusted penalty (\$)
U.S.C.	CFR ¹						
	42 CFR 1003.210(a)(3)		Penalty for an excluded party retaining ownership or control interest in a participating entity.	2018	15,024	15,270	20,000
	42 CFR 1003.1010		Penalty for remuneration offered to induce program beneficiaries to use particular providers, practitioners, or suppliers.	2018	15,024	15,270	20,000
	42 CFR 1003.210(a)(4)		Penalty for employing or contracting with an excluded individual.	2018	14,718	14,959	20,000
	42 CFR 1003.310(a)(3)		Penalty for knowing and willful solicitation, receipt, offer, or payment of remuneration for referring an individual for a service or for purchasing, leasing, or ordering an item to be paid for by a Federal health care program.	2018	73,588	74,792	100,000
	42 CFR 1003.210(a)(1)		Penalty for ordering or prescribing medical or other item or service during a period in which the person was excluded.	2018	10,874	11,052	20,000
	42 CFR 1003.210(a)(6)		Penalty for knowingly making or causing to be made a false statement, omission or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider or supplier.	2018	54,372	55,262	100,000
	42 CFR 1003.210(a)(8)		Penalty for knowing of an overpayment and failing to report and return.	2018	10,874	11,052	20,000
	42 CFR 1003.210(a)(7)		Penalty for making or using a false record or statement that is material to a false or fraudulent claim.	2018	54,372	55,262	100,000
	42 CFR 1003.210(a)(9)		Penalty for failure to grant timely access to HHS OIG for audits, investigations, evaluations, and other statutory functions of HHS OIG.	2018	16,312	16,579	30,000
1320a-7a(b) ⁵	OIG	Penalty for payments by a hospital or critical access hospital to induce a physician to reduce or limit services to individuals under direct care of physician or who are entitled to certain medical assistance benefits.	2018	4,313	4,384	5,000
		Penalty for physicians who knowingly receive payments from a hospital or critical access hospital to induce such physician to reduce or limit services to individuals under direct care of physician or who are entitled to certain medical assistance benefits.	2018	4,313	4,384	5,000
	42 CFR 1003.210(a)(10)		Penalty for a physician who executes a document that falsely certifies home health needs for Medicare beneficiaries.	2018	7,512	7,635	10,000
1320a-7e(b)(6)(A)	42 CFR 1003.810	OIG	Penalty for failure to report any final adverse action taken against a health care provider, supplier, or practitioner.	2016	36,794	37,396	38,159
1320b-10(b)(1)	42 CFR 1003.610(a)	OIG	Penalty for the misuse of words, symbols, or emblems in communications in a manner in which a person could falsely construe that such item is approved, endorsed, or authorized by HHS.	2016	9,893	10,055	10,260
1320b-10(b)(2)	42 CFR 1003.610(a)	OIG	Penalty for the misuse of words, symbols, or emblems in a broadcast or telecast in a manner in which a person could falsely construe that such item is approved, endorsed, or authorized by HHS.	2016	49,467	50,276	51,302

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
[Effective October 11, 2018]

Citation		HHS agency	Description ²	Date of last statutorily established penalty figure ³	2016 Maximum adjusted penalty (\$)	2017 Maximum adjusted penalty (\$) ⁴	2018 Maximum adjusted penalty (\$)
U.S.C.	CFR ¹						
1395i-3(b)(3)(B)(ii)(1)	42 CFR 1003.210(a)(11)	OIG	Penalty for certification of a false statement in assessment of functional capacity of a Skilled Nursing Facility resident assessment.	2016	2,063	2,097	2,140
1395i-3(b)(3)(B)(ii)(2)	42 CFR 1003.210(a)(11)	OIG	Penalty for causing another to certify or make a false statement in assessment of functional capacity of a Skilled Nursing Facility resident assessment.	2016	10,314	10,483	10,697
1395i-3(g)(2)(A)	42 CFR 1003.1310	OIG	Penalty for any individual who notifies or causes to be notified a Skilled Nursing Facility of the time or date on which a survey is to be conducted.	2016	4,126	4,194	4,280
1395w-27(g)(2)(A)	42 CFR 1003.410	OIG	Penalty for a Medicare Advantage organization that substantially fails to provide medically necessary, required items and services.	2016	37,561	38,175	38,954
			Penalty for a Medicare Advantage organization that charges excessive premiums.	2016	36,794	37,396	38,159
			Penalty for a Medicare Advantage organization that improperly expels or refuses to reenroll a beneficiary.	2016	36,794	37,396	38,159
			Penalty for a Medicare Advantage organization that engages in practice that would reasonably be expected to have the effect of denying or discouraging enrollment.	2016	147,177	149,585	152,638
			Penalty per individual who does not enroll as a result of a Medicare Advantage organization's practice that would reasonably be expected to have the effect of denying or discouraging enrollment.	2016	22,077	22,438	22,896
			Penalty for a Medicare Advantage organization misrepresenting or falsifying information to Secretary.	2016	147,177	149,585	152,638
			Penalty for a Medicare Advantage organization misrepresenting or falsifying information to individual or other entity.	2016	36,794	37,396	38,159
			Penalty for Medicare Advantage organization interfering with provider's advice to enrollee and non-MCO affiliated providers that balance bill enrollees.	2016	36,794	37,396	38,159
			Penalty for a Medicare Advantage organization that employs or contracts with excluded individual or entity.	2016	36,794	37,396	38,159
			Penalty for a Medicare Advantage organization enrolling an individual in without prior written consent.	2016	36,794	37,396	38,159
			Penalty for a Medicare Advantage organization transferring an enrollee to another plan without consent or solely for the purpose of earning a commission.	2016	36,794	37,396	38,159
			Penalty for a Medicare Advantage organization failing to comply with marketing restrictions or applicable implementing regulations or guidance.	2016	36,794	37,396	38,159
			Penalty for a Medicare Advantage organization employing or contracting with an individual or entity who violates 1395w-27(g)(1)(A)-(J).	2016	36,794	37,396	38,159

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
 [Effective October 11, 2018]

Citation		HHS agency	Description ²	Date of last statutorily established penalty figure ³	2016 Maximum adjusted penalty (\$)	2017 Maximum adjusted penalty (\$) ⁴	2018 Maximum adjusted penalty (\$)
U.S.C.	CFR ¹						
1395w-141(i)(3)		OIG	Penalty for a prescription drug card sponsor that falsifies or misrepresents marketing materials, overcharges program enrollees, or misuse transitional assistance funds.	2016	12,856	13,066	13,333
1395cc(g)		OIG	Penalty for improper billing by Hospitals, Critical Access Hospitals, or Skilled Nursing Facilities.	2016	5,000	5,082	5,186
1395dd(d)(1)	42 CFR 1003.510	OIG	Penalty for a hospital or responsible physician dumping patients needing emergency medical care, if the hospital has 100 beds or more.	2016	103,139	104,826	106,965
			Penalty for a hospital or responsible physician dumping patients needing emergency medical care, if the hospital has less than 100 beds.	2016	51,570	52,414	53,484
1395mm(i)(6)(B)(i)	42 CFR 1003.410	OIG	Penalty for a HMO or competitive plan is such plan substantially fails to provide medically necessary, required items or services.	2016	51,570	52,414	53,484
			Penalty for HMOs/competitive medical plans that charge premiums in excess of permitted amounts.	2016	51,570	52,414	53,484
			Penalty for a HMO or competitive medical plan that expels or refuses to reenroll an individual per prescribed conditions.	2016	51,570	52,414	53,484
			Penalty for a HMO or competitive medical plan that implements practices to discourage enrollment of individuals needing services in future.	2016	206,278	209,653	213,932
			Penalty per individual not enrolled in a plan as a result of a HMO or competitive medical plan that implements practices to discourage enrollment of individuals needing services in the future.	2016	29,680	30,166	30,782
			Penalty for a HMO or competitive medical plan that misrepresents or falsifies information to the Secretary.	2016	206,278	209,653	213,932
			Penalty for a HMO or competitive medical plan that misrepresents or falsifies information to an individual or any other entity.	2016	51,570	52,414	53,484
			Penalty for failure by HMO or competitive medical plan to assure prompt payment of Medicare risk sharing contracts or incentive plan provisions.	2016	51,570	52,414	53,484
			Penalty for HMO that employs or contracts with excluded individual or entity.	2016	47,340	48,114	49,096
1395nn(g)(3)	42 CFR 1003.310	OIG	Penalty for submitting or causing to be submitted claims in violation of the Stark Law's restrictions on physician self-referrals.	2016	23,863	24,253	24,748
1395nn(g)(4)	42 CFR 1003.310	OIG	Penalty for circumventing Stark Law's restrictions on physician self-referrals.	2016	159,089	161,692	164,992
1395ss(d)(1)	42 CFR 1003.1110	OIG	Penalty for a material misrepresentation regarding Medigap compliance policies.	2016	9,893	10,055	10,260
1395ss(d)(2)	42 CFR 1003.1110	OIG	Penalty for selling Medigap policy under false pretense.	2016	9,893	10,055	10,260
1395ss(d)(3)(A)(ii)	42 CFR 1003.1110	OIG	Penalty for an issuer that sells health insurance policy that duplicates benefits.	2016	44,539	45,268	46,192
			Penalty for someone other than issuer that sells health insurance that duplicates benefits.	2016	26,723	27,160	27,714

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
[Effective October 11, 2018]

Citation		HHS agency	Description ²	Date of last statutorily established penalty figure ³	2016 Maximum adjusted penalty (\$)	2017 Maximum adjusted penalty (\$) ⁴	2018 Maximum adjusted penalty (\$)
U.S.C.	CFR ¹						
1395ss(d)(4)(A)	42 CFR 1003.1110	OIG	Penalty for using mail to sell a non-approved Medigap insurance policy.	2016	9,893	10,055	10,260
1396b(m)(5)(B)(i)	42 CFR 1003.410	OIG	Penalty for a Medicaid MCO that substantially fails to provide medically necessary, required items or services.	2016	49,467	50,276	51,302
			Penalty for a Medicaid MCO that charges excessive premiums.	2016	49,467	50,276	51,302
			Penalty for a Medicaid MCO that improperly expels or refuses to reenroll a beneficiary.	2016	197,869	201,106	205,211
			Penalty per individual who does not enroll as a result of a Medicaid MCO's practice that would reasonably be expected to have the effect of denying or discouraging enrollment.	2016	29,680	30,166	30,782
			Penalty for a Medicaid MCO misrepresenting or falsifying information to the Secretary.	2016	197,869	201,106	205,211
			Penalty for a Medicaid MCO misrepresenting or falsifying information to an individual or another entity.	2016	49,467	50,276	51,302
			Penalty for a Medicaid MCO that fails to comply with contract requirements with respect to physician incentive plans.	2016	44,539	45,268	46,192
1396r(b)(3)(B)(ii)(I)	42 CFR 1003.210(a)(11)	OIG	Penalty for willfully and knowingly certifying a material and false statement in a Skilled Nursing Facility resident assessment.	2016	2,063	2,097	2,140
1396r(b)(3)(B)(ii)(II)	42 CFR 1003.210(a)(11)	OIG	Penalty for willfully and knowingly causing another individual to certify a material and false statement in a Skilled Nursing Facility resident assessment.	2016	10,314	10,483	10,697
1396r(g)(2)(A)(i)	42 CFR 1003.1310	OIG	Penalty for notifying or causing to be notified a Skilled Nursing Facility of the time or date on which a survey is to be conducted.	2016	4,126	4,194	4,280
1396r-8(b)(3)(B)	42 CFR 1003.1210	OIG	Penalty for the knowing provision of false information or refusing to provide information about charges or prices of a covered outpatient drug.	2016	178,156	181,071	184,767
1396r-8(b)(3)(C)(i)	42 CFR 1003.1210	OIG	Penalty per day for failure to timely provide information by drug manufacturer with rebate agreement.	2016	17,816	18,107	18,477
1396r-8(b)(3)(C)(ii)	42 CFR 1003.1210	OIG	Penalty for knowing provision of false information by drug manufacturer with rebate agreement.	2016	178,156	181,071	184,767
1396t(i)(3)(A)	42 CFR 1003.1310	OIG	Penalty for notifying home and community-based providers or settings of survey.	2016	3,563	3,621	3,695
11131(c)	42 CFR 1003.810	OIG	Penalty for failing to report a medical malpractice claim to National Practitioner Data Bank.	2016	21,563	21,916	22,363
11137(b)(2)	42 CFR 1003.810	OIG	Penalty for breaching confidentiality of information reported to National Practitioner Data Bank.	2016	21,563	21,916	22,363
299b-22(f)(1)	42 CFR 3.404	OCR	Penalty for violation of confidentiality provision of the Patient Safety and Quality Improvement Act.	2016	11,940	12,135	12,383
1320(d)-5(a)	45 CFR 160.404(b)(1)(i), (ii).	OCR	Penalty for each pre-February 18, 2009 violation of the HIPAA administrative simplification provisions.	2016	150	152	155
			Calendar Year Cap	2016	37,561	38,175	38,954

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
 [Effective October 11, 2018]

Citation		HHS agency	Description ²	Date of last statutorily established penalty figure ³	2016 Maximum adjusted penalty (\$)	2017 Maximum adjusted penalty (\$) ⁴	2018 Maximum adjusted penalty (\$)
U.S.C.	CFR ¹						
	45 CFR 160.404(b)(2)(i)(A), (B).	OCR	Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the covered entity or business associate did not know and by exercising reasonable diligence, would not have known that the covered entity or business associate violated such a provision. Minimum 2016 110 Maximum 2016 55,010 Calendar Year Cap 2016 1,650,300				
	45 CFR 160.404(b)(2)(ii)(A), (B).	OCR	Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the violation was due to reasonable cause and not to willful neglect. Minimum 2016 1,100 Maximum 2016 55,010 Calendar Year Cap 2016 1,650,300				
	45 CFR 160.404(b)(2)(iii)(A), (B).	OCR	Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the violation was due to willful neglect and was corrected during the 30-day period beginning on the first date the covered entity or business associate knew, or, by exercising reasonable diligence, would have known that the violation occurred. Minimum 2016 11,002 Maximum 2016 55,010 Calendar Year Cap 2016 1,650,300				
	45 CFR 160.404(b)(2)(iv)(A), (B).	OCR	Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the violation was due to willful neglect and was not corrected during the 30-day period beginning on the first date the covered entity or business associate knew, or by exercising reasonable diligence, would have known that the violation occurred. Minimum 2016 55,010 Maximum 2016 1,650,300 Calendar Year Cap 2016 1,650,300				
263a(h)(2)(B) & 1395w-2(b)(2)(A)(ii).	42 CFR 493.1834(d)(2)(i).	CMS	Penalty for a clinical laboratory's failure to meet participation and certification requirements and poses immediate jeopardy. Minimum 2016 6,035 Maximum 2016 19,787				
	42 CFR 493.1834(d)(2)(ii).	CMS	Penalty for a clinical laboratory's failure to meet participation and certification requirements and the failure does not pose immediate jeopardy. Minimum 2016 99 Maximum 2016 5,936				
300gg-15(f)	45 CFR 147.200(e)	CMS	Failure to provide the Summary of Benefits and Coverage. 2016 1,087				
300gg-18	45 CFR 158.606	CMS	Penalty for violations of regulations related to the medical loss ratio reporting and rebating. 2016 109				

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
[Effective October 11, 2018]

Citation		HHS agency	Description ²	Date of last statutorily established penalty figure ³	2016 Maximum adjusted penalty (\$)	2017 Maximum adjusted penalty (\$) ⁴	2018 Maximum adjusted penalty (\$)
U.S.C.	CFR ¹						
1320a–7h(b)(1)	42 CFR 402.105(d)(5), 42 CFR 403.912(a) & (c).	CMS	Penalty for manufacturer or group purchasing organization failing to report information required under 42 U.S.C. 1320a–7h(a), relating to physician ownership or investment interests.				
			Minimum	2016	1,087	1,105	1,128
			Maximum	2016	10,874	11,052	11,278
			Calendar Year Cap	2016	163,117	165,786	169,170
1320a–7h(b)(2)	42 CFR 402.105(h), 42 CFR 403.912(b) & (c).	CMS	Penalty for manufacturer or group purchasing organization knowingly failing to report information required under 42 U.S.C. 1320a–7h(a), relating to physician ownership or investment interests.				
			Minimum	2016	10,874	11,052	11,278
			Maximum	2016	108,745	110,524	112,780
			Calendar Year Cap	2016	1,087,450	1,105,241	1,127,799
1320a–7j(h)(3)(A)		CMS	Penalty for an administrator of a facility that fails to comply with notice requirements for the closure of a facility.	2016	108,745	110,524	112,780
	42 CFR 488.446(a)(1),(2), & (3).	CMS	Minimum penalty for the first offense of an administrator who fails to provide notice of facility closure.	2016	544	553	564
			Minimum penalty for the second offense of an administrator who fails to provide notice of facility closure.	2016	1,631	1,658	1,692
			Minimum penalty for the third and subsequent offenses of an administrator who fails to provide notice of facility closure.	2016	3,262	3,315	3,383
1320a–8(a)(1)		CMS	Penalty for an entity knowingly making a false statement or representation of material fact in the determination of the amount of benefits or payments related to old-age, survivors, and disability insurance benefits, special benefits for certain World War II veterans, or supplemental security income for the aged, blind, and disabled.	2016	7,954	8,084	8,249
			Penalty for violation of 42 U.S.C. 1320a–8(a)(1) if the violator is a person who receives a fee or other income for services performed in connection with determination of the benefit amount or the person is a physician or other health care provider who submits evidence in connection with such a determination.	2016	7,500	7,623	7,779
			Penalty for a representative payee (under 42 U.S.C. 405(j), 1007, or 1383(a)(2)) converting any part of a received payment from the benefit programs described in the previous civil monetary penalty to a use other than for the benefit of the beneficiary.	2016	6,229	6,331	6,460
1320a–8(a)(3)		CMS					
1320b–25(c)(1)(A)		CMS	Penalty for failure of covered individuals to report to the Secretary and 1 or more law enforcement officials any reasonable suspicion of a crime against a resident, or individual receiving care, from a long-term care facility.	2016	217,490	221,048	225,560

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
 [Effective October 11, 2018]

Citation		HHS agency	Description ²	Date of last statutorily established penalty figure ³	2016 Maximum adjusted penalty (\$)	2017 Maximum adjusted penalty (\$) ⁴	2018 Maximum adjusted penalty (\$)
U.S.C.	CFR ¹						
1320b–25(c)(2)(A)		CMS	Penalty for failure of covered individuals to report to the Secretary and 1 or more law enforcement officials any reasonable suspicion of a crime against a resident, or individual receiving care, from a long-term care facility if such failure exacerbates the harm to the victim of the crime or results in the harm to another individual.	2016	326,235	331,572	338,339
1320b–25(d)(2)		CMS	Penalty for a long-term care facility that retaliates against any employee because of lawful acts done by the employee, or files a complaint or report with the State professional disciplinary agency against an employee or nurse for lawful acts done by the employee or nurse.	2016	217,490	221,048	225,560
1395b–7(b)(2)(B)	42 CFR 402.105(g)	CMS	Penalty for any person who knowingly and willfully fails to furnish a beneficiary with an itemized statement of items or services within 30 days of the beneficiary's request.	2016	147	149	152
1395i–3(h)(2)(B)(ii)(I)	42 CFR 488.408(d)(1)(iii)	CMS	Penalty per day for a Skilled Nursing Facility that has a Category 2 violation of certification requirements.
			Minimum	2016	103	105	107
			Maximum	2016	6,188	6,289	6,417
	42 CFR 488.408(d)(1)(iv).	CMS	Penalty per instance of Category 2 noncompliance by a Skilled Nursing Facility.
			Minimum	2016	2,063	2,097	2,140
			Maximum	2016	20,628	20,965	21,393
	42 CFR 488.408(e)(1)(iii)	CMS	Penalty per day for a Skilled Nursing Facility that has a Category 3 violation of certification requirements.
			Minimum	2016	6,291	6,394	6,525
			Maximum	2016	20,628	20,965	21,393
	42 CFR 488.408(e)(1)(iv).	CMS	Penalty per instance of Category 3 noncompliance by a Skilled Nursing Facility.
			Minimum	2016	2,063	2,097	2,140
			Maximum	2016	20,628	20,965	21,393
	42 CFR 488.408(e)(2)(ii).	CMS	Penalty per day and per instance for a Skilled Nursing Facility that has Category 3 noncompliance with Immediate Jeopardy.
			Per Day (Minimum)	2016	6,291	6,394	6,525
			Per Day (Maximum)	2016	20,628	20,965	21,393
			Per Instance (Minimum)	2016	2,063	2,097	2,140
			Per Instance (Maximum)	2016	20,628	20,965	21,393
	42 CFR 488.438(a)(1)(i)	CMS	Penalty per day of a Skilled Nursing Facility that fails to meet certification requirements. These amounts represent the upper range per day.
			Minimum	2016	6,291	6,394	6,524
			Maximum	2016	20,628	20,965	21,393
	42 CFR 488.438(a)(1)(ii)	CMS	Penalty per day of a Skilled Nursing Facility that fails to meet certification requirements. These amounts represent the lower range per day.
			Minimum	2016	103	105	107
			Maximum	2016	6,188	6,289	6,418
	42 CFR 488.438(a)(2) ...	CMS	Penalty per instance of a Skilled Nursing Facility that fails to meet certification requirements.
			Minimum	2016	2,063	2,097	2,140
			Maximum	2016	20,628	20,965	21,393

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
[Effective October 11, 2018]

Citation		HHS agency	Description ²	Date of last statutorily established penalty figure ³	2016 Maximum adjusted penalty (\$)	2017 Maximum adjusted penalty (\$) ⁴	2018 Maximum adjusted penalty (\$)
U.S.C.	CFR ¹						
1395l(h)(5)(D) ⁵	42 CFR 402.105(d)(2)(i)	CMS	Penalty for knowingly, willfully, and repeatedly billing for a clinical diagnostic laboratory test other than on an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	2018	15,024	15,270	30,000
1395l(i)(6)		CMS	Penalty for knowingly and willfully presenting or causing to be presented a bill or request for payment for an intraocular lens inserted during or after cataract surgery for which the Medicare payment rate includes the cost of acquiring the class of lens involved.	2016	3,957	4,022	4,104
1395l(q)(2)(B)(i)	42 CFR 402.105(a)	CMS	Penalty for knowingly and willfully failing to provide information about a referring physician when seeking payment on an unassigned basis.	2016	3,787	3,849	3,928
1395m(a)(11)(A) ⁵	42 CFR 402.1(c)(4), 402.105(d)(2)(ii).	CMS	Penalty for any durable medical equipment supplier that knowingly and willfully charges for a covered service that is furnished on a rental basis after the rental payments may no longer be made. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	2018	15,024	15,270	30,000
1395m(a)(18)(B) ⁵	42 CFR 402.1(c)(5), 402.105(d)(2)(iii).	CMS	Penalty for any nonparticipating durable medical equipment supplier that knowingly and willfully fails to make a refund to Medicare beneficiaries for a covered service for which payment is precluded due to an unsolicited telephone contact from the supplier. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	2018	15,024	15,270	30,000
1395m(b)(5)(C) ⁵	42 CFR 402.1(c)(6), 402.105(d)(2)(iv).	CMS	Penalty for any nonparticipating physician or supplier that knowingly and willfully charges a Medicare beneficiary more than the limiting charge for radiologist services. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	2018	15,024	15,270	30,000
1395m(h)(3) ⁵	42 CFR 402.1(c)(8), 402.105(d)(2)(vi).	CMS	Penalty for any supplier of prosthetic devices, orthotics, and prosthetics that knowingly and willfully charges for a covered prosthetic device, orthotic, or prosthetic that is furnished on a rental basis after the rental payment may no longer be made. (Penalties are assessed in the same manner as 42 U.S.C. 1395m(a)(11)(A), that is in the same manner as 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	2018	15,024	15,270	30,000

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
 [Effective October 11, 2018]

Citation		HHS agency	Description ²	Date of last statutorily established penalty figure ³	2016 Maximum adjusted penalty (\$)	2017 Maximum adjusted penalty (\$) ⁴	2018 Maximum adjusted penalty (\$)
U.S.C.	CFR ¹						
1395m(j)(2)(A)(iii)		CMS	Penalty for any supplier of durable medical equipment including a supplier of prosthetic devices, prosthetics, orthotics, or supplies that knowingly and willfully distributes a certificate of medical necessity in violation of Section 1834(j)(2)(A)(i) of the Act or fails to provide the information required under Section 1834(j)(2)(A)(ii) of the Act.	2016	1,591	1,617	1,650
1395m(j)(4) ⁵	42 CFR 402.1(c)(10), 402.105(d)(2)(vii).	CMS	Penalty for any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries for series billed other than on an assignment-related basis under certain conditions. (Penalties are assessed in the same manner as 42 U.S.C. 1395m(j)(4) and 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	2018	15,024	15,270	30,000
1395m(k)(6) ⁵	42 CFR 402.1(c)(31), 402.105(d)(3).	CMS	Penalty for any person or entity who knowingly and willfully bills or collects for any outpatient therapy services or comprehensive outpatient rehabilitation services on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395m(k)(6) and 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	2018	15,024	15,270	30,000
1395m(l)(6) ⁵	42 CFR 402.1(c)(32), 402.105(d)(4).	CMS	Penalty for any supplier of ambulance services who knowingly and willfully fills or collects for any services on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(b)(18)(B), which is assessed according to 1320a-7a(a)).	2018	15,024	15,270	30,000
1395u(b)(18)(B) ⁵	42 CFR 402.1(c)(11), 402.105(d)(2)(viii).	CMS	Penalty for any practitioner specified in Section 1842(b)(18)(C) of the Act or other person that knowingly and willfully bills or collects for any services by the practitioners on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	2018	15,024	15,270	30,000
1395u(j)(2)(B) ⁵	42 CFR 402.1(c)	CMS	Penalty for any physician who charges more than 125% for a non-participating referral. (Penalties are assessed in the same manner as 42 U.S.C. 1320a-7a(a)).	2018	15,024	15,270	30,000
1395u(k) ⁵	42 CFR 402.1(c)(12), 402.105(d)(2)(ix).	CMS	Penalty for any physician who knowingly and willfully presents or causes to be presented a claim for bill for an assistant at a cataract surgery performed on or after March 1, 1987, for which payment may not be made because of section 1862(a)(15). (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	2018	15,024	15,270	30,000

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
[Effective October 11, 2018]

Citation		HHS agency	Description ²	Date of last statutorily established penalty figure ³	2016 Maximum adjusted penalty (\$)	2017 Maximum adjusted penalty (\$) ⁴	2018 Maximum adjusted penalty (\$)
U.S.C.	CFR ¹						
1395u(l)(3) ⁵	42 CFR 402.1(c)(13), 402.105(d)(2)(x).	CMS	Penalty for any nonparticipating physician who does not accept payment on an assignment-related basis and who knowingly and willfully fails to refund on a timely basis any amounts collected for services that are not reasonable or medically necessary or are of poor quality under 1842(l)(1)(A). (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	2018	15,024	15,270	30,000
1395u(m)(3) ⁵	42 CFR 402.1(c)(14), 402.105(d)(2)(xi).	CMS	Penalty for any nonparticipating physician charging more than \$500 who does not accept payment for an elective surgical procedure on an assignment related basis and who knowingly and willfully fails to disclose the required information regarding charges and coinsurance amounts and fails to refund on a timely basis any amount collected for the procedure in excess of the charges recognized and approved by the Medicare program. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	2018	15,024	15,270	30,000
1395u(n)(3) ⁵	42 CFR 402.1(c)(15), 402.105(d)(2)(xii).	CMS	Penalty for any physician who knowingly, willfully, and repeatedly bills one or more beneficiaries for purchased diagnostic tests any amount other than the payment amount specified by the Act. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	2018	15,024	15,270	30,000
1395u(o)(3)(B) ⁵	42 CFR 414.707(b)	CMS	Penalty for any practitioner specified in Section 1842(b)(18)(C) of the Act or other person that knowingly and willfully bills or collects for any services pertaining to drugs or biologics by the practitioners on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(b)(18)(B) and 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	2018	15,024	15,270	30,000
1395u(p)(3)(A)	CMS	Penalty for any physician or practitioner who knowingly and willfully fails promptly to provide the appropriate diagnosis codes upon CMS or Medicare administrative contractor request for payment or bill not submitted on an assignment-related basis.	2016	3,957	4,022	4,104
1395w-3a(d)(4)(A)	42 CFR 414.806	CMS	Penalty for a pharmaceutical manufacturer's misrepresentation of average sales price of a drug, or biologic.	2016	12,856	13,066	13,333

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
 [Effective October 11, 2018]

Citation		HHS agency	Description ²	Date of last statutorily established penalty figure ³	2016 Maximum adjusted penalty (\$)	2017 Maximum adjusted penalty (\$) ⁴	2018 Maximum adjusted penalty (\$)
U.S.C.	CFR ¹						
1395w-4(g)(1)(B) ⁵	42 CFR 402.1(c)(17), 402.105(d)(2)(xiii).	CMS	Penalty for any nonparticipating physician, supplier, or other person that furnishes physician services not on an assignment-related basis who either knowingly and willfully bills or collects in excess of the statutorily-defined limiting charge or fails to make a timely refund or adjustment. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	2018	15,024	15,270	30,000
1395w-4(g)(3)(B) ⁵	42 CFR 402.1(c)(18), 402.105(d)(2)(xiv).	CMS	Penalty for any person that knowingly and willfully bills for statutorily defined State-plan approved physicians' services on any other basis than an assignment-related basis for a Medicare/Medicaid dual eligible beneficiary. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	2018	15,024	15,270	30,000
1395w-27(g)(3)(A); 1857(g)(3).	42 CFR 422.760(b); 42 CFR 423.760(b).	CMS	Penalty for each termination determination the Secretary makes that is the result of actions by a Medicare Advantage organization or Part D sponsor that has adversely affected an individual covered under the organization's contract.	2016	36,794	37,396	38,159
1395w-27(g)(3)(B); 1857(g)(3).	CMS	Penalty for each week beginning after the initiation of civil money penalty procedures by the Secretary because a Medicare Advantage organization or Part D sponsor has failed to carry out a contract, or has carried out a contract inconsistently with regulations.	2016	14,718	14,959	15,264
1395w-27(g)(3)(D); 1857(g)(3).	CMS	Penalty for a Medicare Advantage organization's or Part D sponsor's early termination of its contract.	2016	136,689	138,925	141,760
1395y(b)(3)(C)	42 CFR 411.103(b)	CMS	Penalty for an employer or other entity to offer any financial or other incentive for an individual entitled to benefits not to enroll under a group health plan or large group health plan which would be a primary plan.	2016	8,908	9,054	9,239
1395y(b)(5)(C)(ii)	42 CFR 402.1(c)(20), 42 CFR 402.105(b)(2).	CMS	Penalty for any non-governmental employer that, before October 1, 1998, willfully or repeatedly failed to provide timely and accurate information requested relating to an employee's group health insurance coverage.	2016	1,450	1,474	1,504
1395y(b)(6)(B)	42 CFR 402.1(c)(21), 402.105(a).	CMS	Penalty for any entity that knowingly, willfully, and repeatedly fails to complete a claim form relating to the availability of other health benefits in accordance with statute or provides inaccurate information relating to such on the claim form.	2016	3,182	3,234	3,300
1395y(b)(7)(B)(i)	CMS	Penalty for any entity serving as insurer, third party administrator, or fiduciary for a group health plan that fails to provide information that identifies situations where the group health plan is or was a primary plan to Medicare to the HHS Secretary.	2016	1,138	1,157	1,181

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
[Effective October 11, 2018]

Citation		HHS agency	Description ²	Date of last statutorily established penalty figure ³	2016 Maximum adjusted penalty (\$)	2017 Maximum adjusted penalty (\$) ⁴	2018 Maximum adjusted penalty (\$)
U.S.C.	CFR ¹						
1395pp(h) ⁵	42 CFR 402.1(c)(23), 402.105(d)(2)(xv).	CMS	Penalty for any durable medical equipment supplier, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries under certain conditions. (42 U.S.C. 1395(m)(18) sanctions apply here in the same manner, which is under 1395u(j)(2) and 1320a-7a(a)).	2018	15,024	15,270	30,000
1395nn(g)(5)	42 CFR 411.361	CMS	Penalty for any person that fails to report information required by HHS under Section 1877(f) concerning ownership, investment, and compensation arrangements.	2016	18,936	19,246	19,639
1395pp(h)	42 CFR 402.1(c)(23), 402.105(d)(2)(xv).	CMS	Penalty for any durable medical equipment supplier, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries under certain conditions. (42 U.S.C. 1395(m)(18) sanctions apply here in the same manner, which is under 1395u(j)(2) and 1320a-7a(a)).	2016	15,024	15,270	15,582
1395ss(a)(2)	42 CFR 402.1(c)(24), 405.105(f)(1).	CMS	Penalty for any person that issues a Medicare supplemental policy that has not been approved by the State regulatory program or does not meet Federal standards after a statutorily defined effective date.	2016	51,569	52,413	53,483
1395ss(d)(3)(A)(vi)(II)	CMS	Penalty for someone other than issuer that sells or issues a Medicare supplemental policy to beneficiary without a disclosure statement.	2016	26,723	27,160	27,714
1395ss(d)(3)(B)(iv)	CMS	Penalty for an issuer that sells or issues a Medicare supplemental policy without disclosure statement.	2016	44,539	45,268	46,192
			Penalty for someone other than issuer that sells or issues a Medicare supplemental policy without acknowledgement form..	2016	26,723	27,160	27,714
1395ss(p)(8)	42 CFR 402.1(c)(25), 402.105(e).	CMS	Penalty for issuer that sells or issues a Medicare supplemental policy without an acknowledgement form.	2016	44,539	45,268	46,192
	42 CFR 402.1(c)(25), 405.105(f)(2).	CMS	Penalty for any person that sells or issues Medicare supplemental policies after a given date that fail to conform to the NAIC or Federal standards established by statute.	2016	26,723	27,160	27,714
1395ss(p)(9)(C)	42 CFR 402.1(c)(25), 405.105(f)(2).	CMS	Penalty for any person that sells or issues Medicare supplemental policies after a given date that fail to conform to the NAIC or Federal standards established by statute.	2016	44,539	45,268	46,192
			Penalty for any person that sells a Medicare supplemental policy and fails to make available for sale the core group of basic benefits when selling other Medicare supplemental policies with additional benefits or fails to provide the individual, before selling the policy, an outline of coverage describing benefits.	2016	26,723	27,160	27,714

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
 [Effective October 11, 2018]

Citation		HHS agency	Description ²	Date of last statutorily established penalty figure ³	2016 Maximum adjusted penalty (\$)	2017 Maximum adjusted penalty (\$) ⁴	2018 Maximum adjusted penalty (\$)
U.S.C.	CFR ¹						
	42 CFR 402.1(c)(26), 405.105(f)(3), (4).		Penalty for any person that sells a Medicare supplemental policy and fails to make available for sale the core group of basic benefits when selling other Medicare supplemental policies with additional benefits or fails to provide the individual, before selling the policy, an outline of coverage describing benefits.	2016	44,539	45,268	46,192
1395ss(q)(5)(C)	42 CFR 402.1(c)(27), 405.105(f)(5).	CMS	Penalty for any person that fails to suspend the policy of a policyholder made eligible for medical assistance or automatically reinstates the policy of a policyholder who has lost eligibility for medical assistance, under certain circumstances.	2016	44,539	45,268	46,192
1395ss(r)(6)(A)	42 CFR 402.1(c)(28), 405.105(f)(6).	CMS	Penalty for any person that fails to provide refunds or credits as required by section 1882(r)(1)(B).	2016	44,539	45,268	46,192
1395ss(s)(4)	42 CFR 402.1(c)(29), 405.105(c).	CMS	Penalty for any issuer of a Medicare supplemental policy that does not waive listed time periods if they were already satisfied under a proceeding Medicare supplemental policy, or denies a policy, or conditions the issuances or effectiveness of the policy, or discriminates in the pricing of the policy base on health status or other specified criteria.	2016	18,908	19,217	19,609
1395ss(t)(2)	42 CFR 402.1(c)(30), 405.105(f)(7).	CMS	Penalty for any issuer of a Medicare supplemental policy that fails to fulfill listed responsibilities.	2016	44,539	45,268	46,192
1395ss(v)(4)(A)	CMS	Penalty someone other than issuer who sells, issues, or renews a Medigap Rx policy to an individual who is a Part D enrollee.	2016	19,284	19,599	19,999
			Penalty for an issuer who sells, issues, or renews a Medigap Rx policy who is a Part D enrollee.	2016	32,140	32,666	33,333
1395bbb(c)(1)	42 CFR 488.725(c)	CMS	Penalty for any individual who notifies or causes to be notified a home health agency of the time or date on which a survey of such agency is to be conducted.	2016	4,126	4,194	4,280
1395bbb(f)(2)(A)(i)	42 CFR 488.845(b)(2)(iii); 42 CFR 488.845(b)(3)–(6); and 42 CFR 488.845(d)(1)(ii). 42 CFR 488.845(b)(3) ...	CMS	Maximum daily penalty amount for each day a home health agency is not in compliance with statutory requirements.	2016	19,787	20,111	20,521
			Penalty per day for home health agency's noncompliance (Upper Range).				
			Minimum	2016	16,819	17,094	17,443
			Maximum	2016	19,787	20,111	20,521
	42 CFR 488.845(b)(3)(i)		Penalty for a home health agency's deficiency or deficiencies that cause immediate jeopardy and result in actual harm.	2016	19,787	20,111	20,521
	42 CFR 488.845(b)(3)(ii)		Penalty for a home health agency's deficiency or deficiencies that cause immediate jeopardy and result in potential for harm.	2016	17,808	18,099	18,468
	42 CFR 488.845(b)(3)(iii)		Penalty for an isolated incident of noncompliance in violation of established HHA policy.	2016	16,819	17,094	17,443
	42 CFR 488.845(b)(4) ...		Penalty for a repeat and/or condition-level deficiency that does not constitute immediate jeopardy, but is directly related to poor quality patient care outcomes (Lower Range).				
			Minimum	2016	2,968	3,017	3,079

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
 [Effective October 11, 2018]

Citation		HHS agency	Description ²	Date of last statutorily established penalty figure ³	2016 Maximum adjusted penalty (\$)	2017 Maximum adjusted penalty (\$) ⁴	2018 Maximum adjusted penalty (\$)
U.S.C.	CFR ¹						
	42 CFR 488.845(b)(5) ...		Maximum Penalty for a repeat and/or condition-level deficiency that does not constitute immediate jeopardy and that is related predominately to structure or process-oriented conditions (Lower Range).	2016	16,819	17,094	17,443
	42 CFR 488.845(b)(6) ...		Minimum Maximum Penalty imposed for instance of noncompliance that may be assessed for one or more singular events of condition-level noncompliance that are identified and where the noncompliance was corrected during the onsite survey.	2016 2016	989 7,915	1,005 8,044	1,026 8,208
	42 CFR 488.845(d)(1)(ii)		Penalty for each day of noncompliance (Maximum).	2016	19,787	20,111	20,521
1396b(m)(5)(B)	42 CFR 460.46	CMS	Penalty for PACE organization's practice that would reasonably be expected to have the effect of denying or discouraging enrollment.				
			Minimum Maximum Penalty for a PACE organization that charges excessive premiums.	2016 2016 2016	22,077 147,177 36,794	22,438 149,585 37,396	22,896 152,638 38,159
			Penalty for a PACE organization misrepresenting or falsifying information to CMS, the State, or an individual or other entity.	2016	147,177	149,585	152,638
			Penalty for each determination the CMS makes that the PACE organization has failed to provide medically necessary items and services of the failure has adversely affected (or has the substantial likelihood of adversely affecting) a PACE participant.	2016	36,794	37,396	38,159
			Penalty for involuntarily disenrolling a participant.	2016	36,794	37,396	38,159
			Penalty for discriminating or discouraging enrollment or disenrollment of participants on the basis of an individual's health status or need for health care services.	2016	36,794	37,396	38,159
1396r(h)(3)(C)(ii)(I)	42 CFR 488.408(d)(1)(iii)	CMS	Penalty per day for a nursing facility's failure to meet a Category 2 Certification.				
			Minimum Maximum	2016 2016	103 6,188	105 6,289	107 6,417
	42 CFR 488.408(d)(1)(iv).	CMS	Penalty per instance for a nursing facility's failure to meet Category 2 certification.				
			Minimum Maximum	2016 2016	2,063 20,628	2,097 20,965	2,140 21,393
	42 CFR 488.408(e)(1)(iii)	CMS	Penalty per day for a nursing facility's failure to meet Category 3 certification.				
			Minimum Maximum	2016 2016	6,291 20,628	6,394 20,965	6,525 21,393
	42 CFR 488.408(e)(1)(iv).	CMS	Penalty per instance for a nursing facility's failure to meet Category 3 certification.				
			Minimum Maximum	2016 2016	2,063 20,628	2,097 20,965	2,140 21,393
	42 CFR 488.408(e)(2)(ii)	CMS	Penalty per instance for a nursing facility's failure to meet Category 3 certification, which results in immediate jeopardy.				

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
 [Effective October 11, 2018]

Citation		HHS agency	Description ²	Date of last statutorily established penalty figure ³	2016 Maximum adjusted penalty (\$)	2017 Maximum adjusted penalty (\$) ⁴	2018 Maximum adjusted penalty (\$)
U.S.C.	CFR ¹						
	42 CFR 488.438(a)(1)(i)	CMS	Minimum Maximum Penalty per day for nursing facility's failure to meet certification (Upper Range).	2016 2016	2,063 20,628	2,097 20,965	2,140 21,393
	42 CFR 488.438(a)(1)(ii)	CMS	Minimum Maximum Penalty per day for nursing facility's failure to meet certification (Lower Range).	2016 2016	6,291 20,628	6,394 20,965	6,525 21,393
	42 CFR 488.438(a)(2) ...	CMS	Minimum Maximum Penalty per instance for nursing facility's failure to meet certification.	2016 2016	103 6,188	105 6,289	107 6,417
1396r(f)(2)(B)(iii)(l)(c)	42 CFR 483.151(b)(2)(iv) and (b)(3)(iii).	CMS	Minimum Maximum Grounds to prohibit approval of Nurse Aide Training Program—if assessed a penalty in 1819(h)(2)(B)(i) or 1919(h)(2)(A)(ii) of "not less than \$5,000" [Not CMP authority, but a specific CMP amount (CMP at this level) that is the triggering condition for disapproval].	2016 2016 2016	2,063 20,628 10,314	2,097 20,965 10,483	2,140 21,393 10,697
1396r(h)(3)(C)(ii)(l)	42 CFR 483.151(c)(2) ...	CMS	Grounds to waive disapproval of nurse aide training program—reference to disapproval based on imposition of CMP "not less than \$5,000" [Not CMP authority but CMP imposition at this level determines eligibility to seek waiver of disapproval of nurse aide training program].	2016	10,314	10,483	10,697
1396t(j)(2)(C)	CMS	Penalty for each day of noncompliance for a home or community care provider that no longer meets the minimum requirements for home and community care. Minimum Maximum	2016 2016	2 17,816	2 18,107	2 18,477
1396u-2(e)(2)(A)(i)	42 CFR 438.704	CMS	Penalty for a Medicaid managed care organization that fails substantially to provide medically necessary items and services. Penalty for Medicaid managed care organization that imposes premiums or charges on enrollees in excess of the premiums or charges permitted. Penalty for a Medicaid managed care organization that misrepresents or falsifies information to another individual or entity.	2016 2016 2016	36,794 36,794 36,794	37,396 37,396 37,396	38,159 38,159 38,159
1396u-2(e)(2)(A)(ii)	42 CFR 438.704	CMS	Penalty for a Medicaid managed care organization that fails to comply with the applicable statutory requirements for such organizations. Penalty for a Medicaid managed care organization that misrepresents or falsifies information to the HHS Secretary.	2016 2016	147,177 147,177	149,585 149,585	152,638 152,638
1396u-2(e)(2)(A)(iv)	42 CFR 438.704	CMS	Penalty for Medicaid managed care organization that acts to discriminate among enrollees on the basis of their health status. Penalty for each individual that does not enroll as a result of a Medicaid managed care organization that acts to discriminate among enrollees on the basis of their health status.	2016	22,077	22,438	22,896

CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
 [Effective October 11, 2018]

Citation		HHS agency	Description ²	Date of last statutorily established penalty figure ³	2016 Maximum adjusted penalty (\$)	2017 Maximum adjusted penalty (\$) ⁴	2018 Maximum adjusted penalty (\$)
U.S.C.	CFR ¹						
1396u(h)(2)	42 CFR Part 441, Subpart I.	CMS	Penalty for a provider not meeting one of the requirements relating to the protection of the health, safety, and welfare of individuals receiving community supported living arrangements services.	2016	20,628	20,965	21,393
1396w-2(c)(1)		CMS	Penalty for disclosing information related to eligibility determinations for medical assistance programs.	2016	11,002	11,182	11,410
18041(c)(2)	45 CFR 150.315; 45 CFR 156.805(c).	CMS	Failure to comply with requirements of the Public Health Services Act; Penalty for violations of rules or standards of behavior associated with issuer participation in the Federally-facilitated Exchange. (42 U.S.C. 300gg-22(b)(2)(C)).	2016	150	152	155
18081(h)(1)(A)(i)(II)	42 CFR 155.285	CMS	Penalty for providing false information on Exchange application.	2016	27,186	27,631	28,195
18081(h)(1)(B)	42 CFR 155.285	CMS	Penalty for knowingly or willfully providing false information on Exchange application.	2016	271,862	276,310	281,949
18081(h)(2)	42 CFR 155.260	CMS	Penalty for knowingly or willfully disclosing protected information from Exchange.	2016	27,186	27,631	28,195
31 U.S.C.							
1352	45 CFR 93.400(e)	HHS	Penalty for the first time an individual makes an expenditure prohibited by regulations regarding lobbying disclosure, absent aggravating circumstances. Penalty for second and subsequent offenses by individuals who make an expenditure prohibited by regulations regarding lobbying disclosure. Minimum Maximum	2016 2016 2016	18,936 189,361 18,936	19,246 192,459 19,246	19,639 196,387 19,639
	45 CFR Part 93, Appendix A.	HHS	Penalty for failure to provide certification regarding lobbying in the award documents for all sub-awards of all tiers. Minimum Maximum	2016 2016	18,936 189,361	19,246 192,459	19,639 196,387
	45 CFR 79.3(a)(1)(iv)	HHS	Penalty for failure to provide statement regarding lobbying for loan guarantee and loan insurance transactions. Minimum Maximum	2016 2016	18,936 189,361	19,246 192,459	19,639 196,387
3801-3812	45 CFR 79.3(b)(1)(ii)	HHS	Penalty against any individual who—with knowledge or reason to know—makes, presents or submits a false, fictitious or fraudulent claim to the Department.	2016	9,894	10,056	10,261

¹ Some HHS components have not promulgated regulations regarding their civil monetary penalty-specific statutory authorities.

² The description is not intended to be a comprehensive explanation of the underlying violation; the statute and corresponding regulation, if applicable, should be consulted.

³ Statutory or Inflation Act Adjustment.

⁴ The cost of living multiplier for 2018, based on the CPI-U for the month of October 2017, not seasonally adjusted, is 1.02041, as indicated in OMB Memorandum M-18-03, "Implementation of Penalty Inflation Adjustments for 2018, Pursuant to the Federal Civil Penalties Adjustment Act Improvements Act of 2015" (December 15, 2017).

⁵ 2018 Maximum Adjusted Penalty column adjusted based on changes to the Bipartisan Budget Act of 2018 for 42 U.S.C.1320a-7a(a),1320a-7a(b), 1395l(h)(5)(D), 1395m(a)(11)(A), 1395m(a)(18)(B), 1395m(b)(5)(C), 1395m(h)(3), 1395m(j)(4), 1395m(k)(6), 1395m(l)(6), 1395u(b)(18)(B), 1395u(j)(2)(B), 1395u(k), 1395u(l)(3), 1395u(m)(3), 1395u(n)(3), 1395u(o)(3)(B), 1395w-4(g)(1)(B), 1395w-4(g)(3)(B), 1395pp(h).

Dated: October 3, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2018-22005 Filed 10-10-18; 8:45 am]

BILLING CODE 4150-24-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 121004518-3398-01]

RIN 0648-XG524

Reef Fish Fishery of the Gulf of Mexico; 2018 Commercial Accountability Measure and Closure for Gulf of Mexico Gray Triggerfish

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS implements accountability measures (AMs) for the gray triggerfish commercial sector in the exclusive economic zone (EEZ) of the Gulf of Mexico (Gulf) through this temporary rule. NMFS projects that 2018 commercial landings for gray triggerfish will reach the commercial annual catch target (ACT) (commercial quota) by October 7, 2018. Therefore, NMFS is closing the commercial sector for Gulf gray triggerfish on October 7, 2018, and it will remain closed through the end of the fishing year on December 31, 2018. This closure is necessary to protect the Gulf gray triggerfish resource.

DATES: This temporary rule is effective at 12:01 a.m., local time, on October 7, 2018, until 12:01 a.m., local time, on January 1, 2019.

FOR FURTHER INFORMATION CONTACT: Lauren Waters, NMFS Southeast Regional Office, telephone: 727-824-5305, email: lauren.waters@noaa.gov.

SUPPLEMENTARY INFORMATION: NMFS manages the Gulf reef fish fishery, which includes gray triggerfish, under the Fishery Management Plan for the Reef Fish Resources of the Gulf of

Mexico (FMP). The Gulf of Mexico Fishery Management Council (Council) prepared the FMP and NMFS implements the FMP under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622. All gray triggerfish weights discussed in this temporary rule are in round weight.

On August 4, 2008, NMFS established gray triggerfish AMs as well as commercial quotas for gray triggerfish through Amendment 30A to the FMP (73 FR 38139). On May 9, 2013, NMFS issued a final rule to implement Amendment 37 to the FMP (78 FR 27084). In part, Amendment 37 revised gray triggerfish commercial ACLs and ACTs. The 2018 commercial quota (*i.e.*, the commercial ACT) for Gulf gray triggerfish specified in 50 CFR 622.39(a)(1)(vi) is 60,900 lb (27,624 kg).

As specified by 50 CFR 622.41(b)(1), NMFS is required to close the commercial sector for gray triggerfish when the commercial quota is reached, or is projected to be reached, by filing a notification to that effect with the Office of the Federal Register. NMFS has determined the 2018 commercial quota for Gulf gray triggerfish will be reached by October 7, 2018. Accordingly, this temporary rule closes the commercial sector for Gulf gray triggerfish effective at 12:01 a.m., local time, October 7, 2018, and it will remain closed until the start of the next commercial fishing season on January 1, 2019.

During the commercial closure, the operator of a vessel with a valid commercial vessel permit for Gulf reef fish having gray triggerfish onboard must have landed and bartered, traded, or sold such gray triggerfish prior to 12:01 a.m., local time, October 7, 2018. During the closure, the sale or purchase of gray triggerfish taken from the Gulf EEZ is prohibited. The prohibition on the sale or purchase does not apply to gray triggerfish that were harvested, landed ashore, and sold prior to 12:01 a.m., local time, October 7, 2018, and were held in cold storage by a dealer or processor.

Classification

The Regional Administrator for the NMFS Southeast Region has determined this temporary rule is necessary for the conservation and management of Gulf

gray triggerfish and is consistent with the Magnuson-Stevens Act and other applicable laws.

This action is taken under 50 CFR 622.41(b)(1) and is exempt from review under Executive Order 12866.

These measures are exempt from the procedures of the Regulatory Flexibility Act because the temporary rule is issued without opportunity for prior notice and comment.

This action responds to the best scientific information available. The Assistant Administrator for NOAA Fisheries (AA) finds that the need to immediately implement this action to close the commercial sector for gray triggerfish constitutes good cause to waive the requirements to provide prior notice and opportunity for public comment on this temporary rule pursuant to the authority set forth in 5 U.S.C. 553(b)(B), because such procedures are unnecessary and contrary to the public interest. Such procedures are unnecessary because Amendment 37 to the FMP (78 FR 27084; May 9, 2013), which established the closure provisions, was subject to notice and comment, and all that remains is to notify the public of the closure. Such procedures are contrary to the public interest because of the need to immediately implement this action to protect gray triggerfish since the capacity of the fishing fleet allows for rapid harvest of the commercial quota. Prior notice and opportunity for public comment would require time and could potentially result in a harvest well in excess of the established commercial quota.

For the aforementioned reasons, the AA also finds good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

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

Margo B. Schulze-Haugen,
Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2018-22142 Filed 10-5-18; 4:15 pm]

BILLING CODE 3510-22-P