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§ 101.93 Communications.

All communications concerning this part, including requests for copies of the part and explanatory information, requests for guidance or clarification, and requests for adjustment or exception shall be addressed to the Secretary, U.S. Department of Health and Human Services, and Washington, DC.

PART 102—ADJUSTMENT OF CIVIL MONETARY PENALTIES FOR INFLATION

Sec.

102.1 Applicability.

102.2 Applicability date.

102.3 Penalty adjustment and table.

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

SOURCE: 81 FR 61565, Sept. 6, 2016, unless otherwise noted.

§ 102.1 Applicability.

This part applies to each statutory provision under the laws administered by the Department of Health and Human Services concerning the civil monetary penalties which may be assessed or enforced by an agency pursuant to Federal law or is assessed or en-

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forced pursuant to civil judicial actions in the Federal courts or administrative proceedings. The regulations cited in this part supersede existing HHS regulations setting forth civil monetary penalty amounts. If applicable, the HHS agencies responsible for specific civil monetary penalties will amend their regulations to reflect the adjusted amounts and/or a cross-reference to 45 CFR part 102 in separate actions as soon as practicable.

§ 102.2 Applicability date.

The increased penalty amounts set forth in the right-most column of the table in Section 102.3, “Maximum Adjusted Penalty (\$),” apply to all civil monetary penalties which are assessed after August 1, 2016, including those penalties whose associated violations occurred after November 2, 2015.

§ 102.3 Penalty adjustment and table.

The adjusted statutory penalty provisions and their applicable amounts are set out in the following table. The right-most column in the table, “Maximum Adjusted Penalty (\$),” provides the maximum adjusted civil penalty amounts. The civil monetary penalty amounts are adjusted annually.

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TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS
January 17, 2020

21 U.S.C.: 333(b)(2)(A)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2019 Maximum adjusted penalty (\$)	2020 Maximum adjusted penalty (\$) ⁴
333(b)(2)(B)		FDA	Penalty for violations related to drug samples resulting in a conviction of any representative of manufacturer or distributor in any 10-year period.	2019	105,194	107,050
333(b)(3)		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.	2019	2,146,800	2,184,670
333(f)(1)(A)		FDA	Penalty for failure to make a report required by 21 U.S.C. 353(d)(3)(E) relating to drug samples.	2019	210,386	214,097
333(f)(2)(A)		FDA	Penalty for any person who violates a requirement related to devices for each such violation.	2019	28,413	28,914
			Penalty for aggregate of all violations related to devices in a single proceeding.	2019	1,894,261	1,927,676
			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.	2019	79,875	81,284

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TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
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CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2019 Maximum adjusted penalty (\$) ⁴	2020 Maximum adjusted penalty (\$) ⁴
333(f)(3)(A)	FDA	Penalty in the case of any other person other than an individual for such introduction or delivery of adulterated food. Penalty for aggregate of all such violations related to adulterated food adjudicated in a single proceeding. Penalty for all violations adjudicated in a single proceeding for any person who violates 21 U.S.C. 331(l) 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(l); or by submitting a clinical trial information under 42 U.S.C. 282(l) that is false or misleading in any particular under 42 U.S.C. 282(l)(5)(D).	2019 2019	399,374 798,747 12,103	406,419 812,837 12,316
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.	2019	12,103	12,316

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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). Penalty for aggregate of all such above violations in a single proceeding.	2019	302,585	307,923
333(f)(4)(A)(ii)	FDA	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. 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. Penalty for aggregate of all such above violations adjudicated in a single proceeding.	2019	1,210,340	1,231,690
333(f)(9)(A)	FDA	Penalty for any person who violates a requirement which relates to tobacco products for each such violation. Penalty for aggregate of all such violations of tobacco product requirement adjudicated in a single proceeding.	2019	17,547	17,857
			2019	1,169,798	1,190,433

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	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2019 Maximum adjusted penalty (\$) ⁴	2020 Maximum adjusted penalty (\$) ⁴
333(f)(9)(B)(i)(I)	FDA	Penalty per violation related to violations of tobacco requirements. Penalty for aggregate of all such violations of tobacco product requirements adjudicated in a single proceeding.	2019	292,450	297,609
333(f)(9)(B)(i)(II)	FDA	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. 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. Penalty for aggregate of all such violations related to tobacco product requirements adjudicated in a single proceeding.	2019	1,169,798	1,190,433

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<p>333(f)(9)(B)(ii)(I)</p> <p>333(f)(9)(B)(ii)(II)</p>	<p>FDA</p> <p>FDA</p>	<p>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 any 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.</p> <p>Penalty for aggregate of for all such above violations adjudicated in a single proceeding.</p> <p>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.</p> <p>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.</p> <p>Penalty for aggregate above tobacco product requirement violations adjudicated in a single proceeding.</p>	<p>2019 292,450 297,609</p> <p>2019 1,169,798 1,190,433</p> <p>2019 292,450 297,609</p> <p>2019 1,169,798 1,190,433</p> <p>2019 11,697,983 11,904,335</p>
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TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
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	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2019 Maximum adjusted penalty (\$) ⁴	2020 Maximum adjusted penalty (\$) ⁴
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. Penalty for each subsequent above violation in any 3-year period.	2019	302,585	307,923
333 note	FDA		Penalty to be applied for violations of 21 U.S.C. 387(f)(5) or of violations of restrictions on the sale or distribution of tobacco products promulgated under 21 U.S.C. 387(f)(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. Penalty in the case of a third violation of 21 U.S.C. 387(f)(5) or of the tobacco product regulations within a 24-month period.	2019	292	297

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Penalty in the case of a fourth violation of 21 U.S.C. 387(f)(5) or of the tobacco product regulations within a 24-month period.	2019	2,340	2,381
Penalty in the case of a fifth violation of 21 U.S.C. 387(f)(5) or of the tobacco product regulations within a 36-month period.	2019	5,849	5,952
Penalty in the case of a sixth or subsequent violation of 21 U.S.C. 387(f)(5) or of the tobacco product regulations within a 48-month period as determined on a case-by-case basis.	2019	11,698	11,904
Penalty to be applied for violations of 21 U.S.C. 387(f)(5) or of violations of restrictions on the sale or distribution of tobacco products promulgated under 21 U.S.C. 387(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.	2019	292	297
Penalty in the case of a second violation of 21 U.S.C. 387(f)(5) or of the tobacco product regulations within a 12-month period.	2019	584	594
Penalty in the case of a third violation of 21 U.S.C. 387(f)(5) or of the tobacco product regulations within a 24-month period.	2019	1,170	1,191

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January 17, 2020

CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2019 Maximum adjusted penalty (\$) ⁴	2020 Maximum adjusted penalty (\$) ⁴
		Penalty in the case of a fourth violation of 21 U.S.C. 387(d)(5) or of the tobacco product regulations within a 24-month period.	2019	2,340	2,381
		Penalty in the case of a fifth violation of 21 U.S.C. 387(d)(5) or of the tobacco product regulations within a 36-month period.	2019	5,849	5,952
		Penalty in the case of a sixth or subsequent violation of 21 U.S.C. 387(f)(5) or of the tobacco product regulations within a 48-month period as determined on a case-by-case basis.	2019	11,698	11,904
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.	2019	445,846	453,711

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360pp(b)(1)	FDA	<p>Penalty in the case of any other person (other than an individual) per above violation.</p> <p>Penalty for any person who violates any such requirements for electronic products, with each unlawful act or omission constituting a separate violation.</p> <p>Penalty imposed for any related series of violations of requirements relating to electronic products.</p> <p>.....</p>	2019 1,783,384	2019 2,924	1,814,843
42 U.S.C. 262(d)	FDA	<p>.....</p> <p>Penalty per day for violation of order of recall of biological product presenting imminent or substantial hazard.</p> <p>Penalty for failure to obtain a mammography certificate as required.</p>	2019 229,269	2019 229,269	233,313
263b(h)(3)	FDA	Penalty per occurrence for any vaccine manufacturer that intentionally destroys, alters, falsifies, or conceals any record or report required.	2019 17,834	2019 229,269	18,149
300aa-28(b)(1)	FDA	Penalty for each instance of overcharging a 340B covered entity.	2019 5,781	2019 15,034	5,883
256b(d)(1)(B)(vi)	HRSA	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.	2019 15,299	2019 15,299	15,299
299c-(3)(d)	AHRO	Penalty for Misuse of Information in the National Directory of New Hires.	2019 1,542	2019 1,569	1,569
653(l)(2)	ACF	45 CFR 303.21(f)			

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	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2019 Maximum adjusted penalty (\$) ⁴	2020 Maximum adjusted penalty (\$) ⁴
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. Penalty for any other person who violates safety and security procedures related to handling dangerous biological agents and toxins.	2019	348,708	354,859
300jj-51	42 CFR 1003.210(a)(1)	OIG	Penalty per violation for committing information blocking. Penalty for knowingly presenting or causing to be presented to an officer, employee, or agent of the United States a false claim.	2019	697,418	709,720
1320a-7a(a)	42 CFR 1003.210(a)(2)	OIG	Penalty for knowingly presenting or causing to be presented a request for payment which violates the terms of an assignment, agreement, or PPS agreement. 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.	2019	1,063,260	1,082,016

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42 CFR 1003.210(a)(3)		2019	20,504	20,866
42 CFR 1003.1010	Penalty for an excluded party retaining ownership or control interest in a participating entity.	2019	20,504	20,866
42 CFR 1003.210(a)(4)	Penalty for referring an individual to induce program beneficiaries to use particular providers, practitioners, or suppliers.	2019	20,504	20,866
42 CFR 1003.310(a)(3)	Penalty for employing or contracting with an excluded individual.	2019	102,522	104,330
42 CFR 1003.210(a)(1)	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.	2019	20,504	20,866
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.	2019	102,522	104,330
42 CFR 1003.210(a)(8)	Penalty for knowing of an overpayment and failing to report and return.	2019	20,504	20,866
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.	2019	57,812	58,832

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	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2019 Maximum adjusted penalty (\$)	2020 Maximum adjusted penalty (\$) ⁴
1320a–7a(b)	42 CFR 1003.210(a)(9)	OIG	Penalty for failure to grant timely access to HHS OIG for audits, investigations, evaluations, and other statutory functions of HHS 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. 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.	2019	30,757	31,300
	42 CFR 1003.210(a)(10)		Penalty for a physician who executes a document that falsely certifies home health needs for Medicare beneficiaries.	2019	10,252	10,433

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1320a-7a(o)							
OIG							
Penalty for knowingly presenting or causing to be presented a false or fraudulent specified claim under a grant, contract, or other agreement for which the Secretary provides funding.	2016	10,000	10,176				
Penalty for knowingly making, using, or causing to be made or used any false statement, omission, or misrepresentation of a material fact in any application, proposal, bid, progress report, or other document required to directly or indirectly receive or retain funds provided pursuant to grant, contract, or other agreement.	2016	50,000	50,882				
Penalty for knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent specified claim under grant, contract, or other agreement.	2016	50,000	50,882				
Penalty for knowingly making, using, or causing to be made or used a false record or statement material to an obligation to pay or transmit funds or property with respect to grant, contract, or other agreement, or knowingly conceals or improperly avoids or decreases any such obligation.	2016	50,000 for each false record or statement, 10,646 per day.	53,231 for each false record or statement, 10,000 per day.				

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CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2019 Maximum adjusted penalty (\$) ⁴	2020 Maximum adjusted penalty (\$) ⁴
1320a–7e(b)(6)(A)	OIG	Penalty for failure to grant timely access, upon reasonable request, to the Inspector General (I.G.) for purposes of audits, investigations, evaluations, or other statutory functions of I.G. in matters involving grants, contracts, or other agreements.	2016	15,000	15,265
1320b–10(b)(1)	OIG	Penalty for failure to report any final adverse action taken against a health care provider, supplier, or practitioner.	2019	39,121	39,811
1320b–10(b)(2)	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.	2019	10,519	10,705

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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.	2019	2,194	2,233
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.	2019	10,967	11,160
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.	2019	4,388	4,465
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.	2019	39,936	40,640
			Penalty for a Medicare Advantage organization that charges excessive premiums.	2019	39,121	39,811
			Penalty for a Medicare Advantage organization that improperly expels or refuses to reenroll a beneficiary.	2019	156,488	159,248
			Penalty for a Medicare Advantage organization that engages in practice that would reasonably be expected to have the effect of denying or discouraging enrollment.			

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TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
January 17, 2020

CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2019 Maximum adjusted penalty (\$) ⁴	2020 Maximum adjusted penalty (\$) ⁴
		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.	2019	23,473	23,887
		Penalty for a Medicare Advantage organization misrepresenting or falsifying information to Secretary.	2019	156,488	159,248
		Penalty for a Medicare Advantage organization misrepresenting or falsifying information to individual or other entity.	2019	39,121	39,811
		Penalty for Medicare Advantage organization interfering with provider's advice to enrollee and non-managed care organization (MCO) affiliated providers that balance bill enrollees.	2019	39,121	39,811
		Penalty for a Medicare Advantage organization that employs or contracts with excluded individual or entity.	2019	39,121	39,811
		Penalty for a Medicare Advantage organization enrolling an individual in without prior written consent.	2019	39,121	39,811

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Penalty for a Medicare Advantage organization transferring an enrollee to another plan without consent or solely for the purpose of earning a commission.	2019	39,121	39,811	
Penalty for a Medicare Advantage organization failing to comply with marketing restrictions or applicable implementing regulations or guidance.	2019	39,121	39,811	
Penalty for a Medicare Advantage organization employing or contracting with an individual or entity who violates 1395w-27(g)(1)(A)-(J).	2019	39,121	39,811	
Penalty for a prescription drug card sponsor that falsifies or misrepresents marketing materials, overcharges program enrollees, or misuse transitional assistance funds.	2019	13,669	13,910	
OIG				
"1395w-141(i)(3)	OIG			
"1395cc(g)	OIG			
"1395dd(d)(1)	42 CFR 1003.510			

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January 17, 2020

	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2019 Maximum adjusted penalty (\$) ⁴	2020 Maximum adjusted penalty (\$) ⁴
•395mm(i)(6)(B)(i)	42 CFR 1003.410	OIG	Penalty for a health maintenance organization (HMO) or competitive plan is such plan substantially fails to provide medically necessary, required items or services. Penalty for HMOs/competitive medical plans that charge premiums in excess of permitted amounts. Penalty for a HMO or competitive medical plan that expels or refuses to reinroll an individual per prescribed conditions. Penalty for a HMO or competitive medical plan that implements practices to discourage enrollment of individuals needing services in future. 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. Penalty for a HMO or competitive medical plan that misrepresents or falsifies information to the Secretary.	2019 2019 2019 2019 2019	54,833 54,833 54,833 219,327 31,558	55,800 55,800 55,800 223,196 32,115

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				55,800	
		2019	54,833	55,800	
	Penalty for a HMO or competitive medical plan that misrepresents or falsifies information to an individual or any other entity.	2019	54,833	55,800	
	Penalty for failure by HMO or competitive medical plan to assure prompt payment of Medicare risk sharing contracts or incentive plan provisions.	2019	50,334	51,222	
	Penalty for HMO that employs or contracts with excluded individual or entity.	2019	25,372	25,820	
	Penalty for submitting or causing to be submitted claims in violation of the Stark Law's restrictions on physician self-referrals.	2019	169,153	172,137	
	Penalty for circumventing Stark Law's restrictions on physician self-referrals.	2019	10,519	10,705	
	Penalty for a material misrepresentation regarding Medigap compliance policies.	2019	10,519	10,705	
	Penalty for selling Medigap policy under false pretense.	2019	47,357	48,192	
	Penalty for an issuer that sells health insurance policy that duplicates benefits.	2019	28,413	28,914	
	Penalty for someone other than issuer that sells health insurance that duplicates benefits.	2019	10,519	10,705	
	Penalty for using mail to sell a non-approved Medigap insurance policy.	2019	52,596	53,524	
	Penalty for a Medicaid MCO that substantially fails to provide medically necessary, required items or services.	2019			
1395mn(g)(3)	42 CFR 1003.310	OIG			
1395mn(g)(4)	42 CFR 1003.310	OIG			
1395ss(d)(1)	42 CFR 1003.1110	OIG			
1395ss(d)(2)	42 CFR 1003.1110	OIG			
1395ss(d)(3)(A)(ii)	42 CFR 1003.1110	OIG			
1395ss(d)(4)(A)	42 CFR 1003.1110	OIG			
1396b(m)(5)(B)(i)	42 CFR 1003.410	OIG			

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CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2019 Maximum adjusted penalty (\$) ⁴	2020 Maximum adjusted penalty (\$) ⁴
		Penalty for a Medicaid MCO that charges excessive premiums. Penalty for a Medicaid MCO that improperly expels or refuses to reinroll a beneficiary. 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.	2019	52,596	53,524
		Penalty for a Medicaid MCO misrepresenting or falsifying information to the Secretary. Penalty for a Medicaid MCO misrepresenting or falsifying information to an individual or another entity.	2019	210,386	214,097
		Penalty for a Medicaid MCO that fails to comply with contract requirements with respect to physician incentive plans.	2019	47,357	48,192
1396(b)(3)(B)(ii)(I)	OIG	Penalty for willfully and knowingly certifying a material and false statement in a Skilled Nursing Facility resident assessment.	2019	2,194	2,233
42 CFR 1003.210(a)(11)					

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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.	2019	10,967	11,160
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.	2019	4,388	4,465
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.	2019	189,427	192,768
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.	2019	18,943	19,277
1396r-8(b)(3)(C)(ii)	42 CFR 1003.1210	OIG	Penalty for knowing provision of false information by drug manufacturer with rebate agreement.	2019	189,427	192,768
1396r(i)(3)(A)	42 CFR 1003.1310	OIG	Penalty for notifying home and community-based providers or settings of survey.	2019	3,788	3,855
11131(c)	42 CFR 1003.810	OIG	Penalty for failing to report a medical malpractice claim to National Practitioner Data Bank.	2019	22,927	23,331
11137(b)(2)	42 CFR 1003.810	OIG	Penalty for breaching confidentiality of information reported to National Practitioner Data Bank.	2019	22,927	23,331
299b-22(f)(1)	42 CFR 3.404	OCR	Penalty for violation of confidentiality provision of the Patient Safety and Quality Improvement Act.	2019	12,695	12,919

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TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
January 17, 2020

	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2019 Maximum adjusted penalty (\$) ⁴	2020 Maximum adjusted penalty (\$) ⁴
	45 CFR 160.404(b)(1)(i), (ii).	OCR	Penalty for each pre-February 18, 2009 violation of the Health Insurance Portability and Accountability Act (HIPAA) administrative simplification provisions.	2019	159	162
1320(d)–5(a)	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.	2019	39,936	40,640
	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.	2019	117	119
			Minimum	2019	58,490	59,522
			Maximum	2019	1,754,698	1,785,651
			Calendar Year Cap	2019	1,754,698	1,785,651

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<p>45 CFR 160.404(b)(2)(iv)(A), (B).</p> <p>OCR</p>	<p>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:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;">Minimum</td><td style="width: 10%;">2019</td><td style="width: 10%;">11,698</td><td style="width: 10%;">2019</td><td style="width: 10%;">11,698</td></tr> <tr> <td>Maximum</td><td>2019</td><td>58,490</td><td>2019</td><td>58,490</td></tr> <tr> <td>Calendar Year Cap</td><td>2019</td><td>1,754,698</td><td>2019</td><td>1,754,698</td></tr> </table> <p>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:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;">Minimum</td><td style="width: 10%;">2019</td><td style="width: 10%;">59,522</td><td style="width: 10%;">2019</td><td style="width: 10%;">59,522</td></tr> <tr> <td>Maximum</td><td>2019</td><td>1,785,651</td><td>2019</td><td>1,785,651</td></tr> <tr> <td>Calendar Year Cap</td><td>2019</td><td>1,785,651</td><td>2019</td><td>1,785,651</td></tr> </table>	Minimum	2019	11,698	2019	11,698	Maximum	2019	58,490	2019	58,490	Calendar Year Cap	2019	1,754,698	2019	1,754,698	Minimum	2019	59,522	2019	59,522	Maximum	2019	1,785,651	2019	1,785,651	Calendar Year Cap	2019	1,785,651	2019	1,785,651
Minimum	2019	11,698	2019	11,698																											
Maximum	2019	58,490	2019	58,490																											
Calendar Year Cap	2019	1,754,698	2019	1,754,698																											
Minimum	2019	59,522	2019	59,522																											
Maximum	2019	1,785,651	2019	1,785,651																											
Calendar Year Cap	2019	1,785,651	2019	1,785,651																											
<p>45 CFR 160.404(b)(2)(iv)(A), (B).</p> <p>OCR</p>	<p>Penalty for a clinical laboratory's failure to meet participation and certification requirements and poses immediate jeopardy:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;">Minimum</td><td style="width: 10%;">2019</td><td style="width: 10%;">6,417</td><td style="width: 10%;">2019</td><td style="width: 10%;">6,417</td></tr> <tr> <td>Maximum</td><td>2019</td><td>21,039</td><td>2019</td><td>21,039</td></tr> </table>	Minimum	2019	6,417	2019	6,417	Maximum	2019	21,039	2019	21,039																				
Minimum	2019	6,417	2019	6,417																											
Maximum	2019	21,039	2019	21,039																											
<p>42 CFR 493.1834(d)(2)(i) ..</p> <p>CMS</p>																															
<p>263a(h)(2)(B) & 1395w-2(b)(2)(A)(ii).</p>																															

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TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
January 17, 2020

	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2019 Maximum adjusted penalty (\$)	2020 Maximum adjusted penalty (\$) ⁴
	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:			
300gg–15(f)	45 CFR 147.200(e)	CMS	Minimum Maximum	2019 2019	108 6,311	108 6,422
300gg–18	45 CFR 158.606	CMS	Failure to provide the Summary of Benefits and Coverage.	2019	1,156	1,176
1320a–7h(b)(1)	42 CFR 402.105(d)(5), 42 CFR 403.912(a) & (c).	CMS	Penalty for violations of regulations related to the medical loss ratio reporting and rebating.	2019	116	118
1320a–7h(b)(2)	42 CFR 402.105(h), 42 CFR 403.912(b) & (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:	2019 2019 2019	1,176 11,562 173,496	1,156 11,766 176,495
			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:	2019	11,562	11,766

			Maximum Calendar Year Cap Penalty for an administrator of a facility that fails to comply with notice requirements for the closure of a facility.	1,115,624 1,156,242 1,115,624 117,664
			Minimum penalty for the first offense of an administrator who fails to provide notice of facility closure.	578
			Minimum penalty for the second offense of an administrator who fails to provide notice of facility closure.	588
			Minimum penalty for the third and subsequent offenses of an administrator who fails to provide notice of facility closure.	2019
			Minimum penalty for the third and subsequent offenses of an administrator who fails to provide notice of facility closure.	2019
			Penalty for an entity know- ingly making a false state- ment or representation of material fact in the deter- mination of the amount of benefits or payments re- lated to old-age, survivors, and disability insurance benefits, special benefits for certain World War II vet- erans, or supplemental se- curity income for the aged, blind, and disabled.	2019
1320a-7(h)(3)(A)	42 CFR 488.446(a)(1), (2), & (3).	CMS		
1320a-8(a)(1)		CMS		

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CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2019 Maximum adjusted penalty (\$) ⁴	2020 Maximum adjusted penalty (\$) ⁴
1320a–8(a)(3)	CMS	<p>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.</p> <p>Penalty for a representative payee under 42 U.S.C. 405(i), 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.</p>	2019	6,623	6,740
1320b–25(c)(1)(A)	CMS	<p>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.</p>	2019	231,249	235,328

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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.	2019 346,872	352,991
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.	2019 231,249	235,328
1395b-7(b)(2)(B)	42 CFR 402.105(g)	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.	2019 156	159
1395i-3(h)(2)(B)(ii)(I) ...	42 CFR 488.408(d)(1)(iii) ..	Penalty per day for a Skilled Nursing Facility that has a Category 2 violation of certification requirements:	2019 Maximum Category 2 noncompliance by a Skilled Nursing Facility: Minimum Maximum	110 6,579 6,695
1395i-3(h)(2)(B)(ii)(IV) ..	42 CFR 488.408(d)(1)(iv) ..	Penalty per instance of Category 2 noncompliance by a Skilled Nursing Facility:	2019 2,194 2,233 21,933 Maximum	22,320

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
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	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2019 Maximum adjusted penalty (\$)	2020 Maximum adjusted penalty (\$) ⁴
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 Maximum	2019 2019	6,690 21,933	6,808 22,320
42 CFR 488.408(e)(1)(iv) ..	CMS	Penalty per instance of Category 3 noncompliance by a Skilled Nursing Facility:	Minimum Maximum	2019 2019	2,194 21,933	2,233 22,320
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) Per Day (Maximum)	2019 2019	6,690 21,933	6,808 22,320
42 CFR 488.408(e)(2)(iii) ..	CMS	Penalty per instance of a Skilled Nursing Facility that fails to meet certification requirements. These amounts represent the upper range per day:	Per Instance (Minimum) Per Instance (Maximum)	2019 2019	2,194 21,933	2,233 22,320
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 lower range per day:	Minimum	2019 2019	6,690 21,933	6,808 22,320
42 CFR 488.438(a)(1)(ii) ...	CMS			2019	110	112

			6,579	6,695
42 CFR 488.438(a)(2)	CMS	MaximumPenalty per instance of a Skilled Nursing Facility that fails to meet certification requirements: MinimumMaximum	2019 2,194 21,933 15,975	2,233 22,320 16,257
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-7(a)).	2019 4,208	4,282
1395(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.	2019 4,027	4,098
1395(q)(2)(B)(i)	42 CFR 402.105(a)	Penalty for knowingly and willfully failing to provide information about a referring physician when seeking payment on an unassigned basis.	2019	4,027

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TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
January 17, 2020

	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2019 Maximum adjusted penalty (\$) ⁴	2020 Maximum adjusted penalty (\$) ⁴
-1395m(a)(11)(A)	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(i)(2)(B), which is assessed according to 1320a-7(a)).	2019	15,975	16,257
-1395m(a)(18)(B)	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(i)(2)(B), which is assessed according to 1320a-7(a)).	2019	15,975	16,257

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1395m(b)(5)(C)	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(i)(2)(B), which is assessed according to 1320a-7(a)(a)).	2019	15,975	16,257
1395m(h)(3)	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(i)(2)(B), which is assessed according to 1320a-7(a)(a)).	2019	15,975	16,257
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(i)(2)(A)(i) of the Act or fails to provide the information required under Section 1834(i)(2)(A)(ii) of the Act.	2019	1,692	1,722

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TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
January 17, 2020

	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2019 Maximum adjusted penalty (\$) ⁴	2020 Maximum adjusted penalty (\$) ⁴
•395m(i)(4)	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 services billed other than on as assignment-related basis under certain conditions. (Penalties are assessed in the same manner as 42 U.S.C. 1395m(i)(4) and 1395u(i)(2)(B), which is assessed according to 1320a–7(a)(a)).	2019	15,975	16,257
•395m(k)(6)	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(i)(2)(B), which is assessed according to 1320a–7(a)(a)).	2019	15,975	16,257

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<p>1395m(l)(6)</p> <p>42 CFR 402.1(c)(32), 402.105(d)(4).</p>	<p>CMS</p> <p>Penalty for any supplier of ambulance services who knowingly and willfully bills 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-7(a)(a)).</p>	<p>2019</p> <p>15,975</p>	<p>16,257</p>
<p>1395u(b)(18)(B)</p> <p>42 CFR 402.1(c)(11), 402.105(d)(2)(viii).</p>	<p>CMS</p> <p>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-7(a)(a)).</p>	<p>2019</p> <p>15,975</p>	<p>16,257</p>
<p>1395u(j)(2)(B)</p> <p>42 CFR 402.1(c)</p>	<p>CMS</p> <p>Penalty for any physician who charges more than 125% for a nonparticipating referral. (Penalties are assessed in the same manner as 42 U.S.C. 1320a-7(a)(a)).</p>	<p>2019</p> <p>15,975</p>	<p>16,257</p>

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TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued
January 17, 2020

	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2019 Maximum adjusted penalty (\$) ⁴	2020 Maximum adjusted penalty (\$) ⁴
*1395u(k)	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(i)(2)(B), which is assessed according to 1320a–7(a)).	2019	15,975	16,257
*1395u(l)(3)	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(i)(2)(B), which is assessed according to 1320a–7(a)).	2019	15,975	16,257

1395u(m)(3)	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(l)(2)(B), which is assessed according to 1320a-7(a)).	15,975	16,257
1395u(n)(3)	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(l)(2)(B), which is assessed according to 1320a-7(a)).	15,975	16,257

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January 17, 2020

	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2019 Maximum adjusted penalty (\$) ⁴	2020 Maximum adjusted penalty (\$) ⁴
•395(u)(3)(B)	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–7(a).)	2019	15,975	16,257
•395u(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.	2019	4,208	4,282
•395w–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.	2019	13,669	13,910

1395w–4(g)(1)(B)	42 CFR 402.1(c)(17), 402.105(d)(2)(xiii).	CMS	<p>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–7(a)(a).)</p>	2019	15,975	16,257
1395w–4(g)(3)(B)	42 CFR 402.1(c)(18), 402.105(d)(2)(xiv).	CMS	<p>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–7(a)(a).)</p>	2019	15,975	16,257
1395w–27(g)(3)(A); 1857(g)(3).	42 CFR 422.760(b); 42 CFR 423.750(b).	CMS	<p>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.</p>	2019	39,811	39,121

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January 17, 2020

	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2019 Maximum adjusted penalty (\$) ⁴	2020 Maximum adjusted penalty (\$) ⁴
•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.	2019	15,649	15,925
•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.	2019	145,335	147,899
•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.	2019	9,472	9,639
•1395y(b)(5)(C)(i)	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.	2019	1,542	1,569

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<p>1395y(b)(6)(B)</p> <p>.....</p> <p>42 CFR 402.1(c)(21), 402.105(a).</p> <p>.....</p> <p>1395y(b)(7)(B)(I)</p> <p>.....</p> <p>1395y(b)(8)(E)</p> <p>.....</p> <p>1395nn(g)(5)</p> <p>.....</p> <p>42 CFR 411.361</p>	<p>CMS</p> <p>.....</p> <p>CMS</p> <p>.....</p> <p>CMS</p> <p>.....</p> <p>CMS</p> <p>.....</p> <p>CMS</p> <p>.....</p>	<p>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.</p> <p>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.</p> <p>Penalty for any non-group health plan that fails to identify claimants who are Medicare beneficiaries and provide information to the HHS Secretary to coordinate benefits and pursue any applicable recovery claim.</p> <p>Penalty for any person that fails to report information required by HHS under Section 1877(f) concerning ownership, investment, and compensation arrangements.</p>	<p>2019</p> <p>.....</p> <p>2019</p> <p>.....</p> <p>2019</p> <p>.....</p> <p>2019</p> <p>.....</p> <p>2019</p> <p>.....</p>	<p>3,383</p> <p>.....</p> <p>1,211</p> <p>.....</p> <p>1,211</p> <p>.....</p> <p>1,211</p> <p>.....</p> <p>20,134</p> <p>.....</p>	<p>3,443</p> <p>.....</p> <p>1,232</p> <p>.....</p> <p>1,232</p> <p>.....</p> <p>1,232</p> <p>.....</p> <p>20,489</p> <p>.....</p>
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	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2019 Maximum adjusted penalty (\$) ⁴	2020 Maximum adjusted penalty (\$) ⁴
•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 1395(l)(2) and 1320a–7(a)).	2019	15,975	16,257
•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.	2019	54,832	55,799
•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. Penalty for an issuer that sells or issues a Medicare supplemental policy without disclosure statement.	2019	28,413	28,914

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1395ss(d)(3)(B)(iv)	CMS	Penalty for someone other than issuer that sells or issues a Medicare supplemental policy without acknowledgement form.	2019	28,413	28,914
1395ss(p)(8)	CMS	Penalty for issuer that sells or issues a Medicare supplemental policy without an acknowledgement form.	2019	47,357	48,192
42 CFR 402.1(c)(25), 402.105(e).	CMS	Penalty for any person that sells or issues Medicare supplemental policies after a given date that fail to conform to the National Association of Insurance Commissioners (NAIC) or Federal standards established by statute.	2019	28,413	28,914
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.	2019	47,357	48,192
1395ss(p)(9)(C)	CMS	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.	2019	28,413	28,914
42 CFR 402.1(c)(26), 402.105(e).					

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	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2019 Maximum adjusted penalty (\$) ⁴	2020 Maximum adjusted penalty (\$) ⁴
	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.	2019	47,357	48,192
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.	2019	47,357	48,192
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(n)(1)(B).	2019	47,357	48,192

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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.	2019 20,104	20,459
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.	2019 47,357	48,192
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.	2019 20,503	20,865
1395bbb(c)(1)	42 CFR 488.725(c)	CMS	Penalty for an issuer who sells, issues, or renews a Medigap Rx policy who is a Part D enrollee.	2019 34,174	34,777
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	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. Maximum daily penalty amount for each day a home health agency is not in compliance with statutory requirements. Penalty per day for home health agency's noncompliance (Upper Range): Minimum Maximum	2019 21,039	21,410
				2019 17,883	18,198
				2019 21,039	21,410

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CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2019 Maximum adjusted penalty (\$) ⁴	2020 Maximum adjusted penalty (\$) ⁴
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.	2019	21,039	21,410
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.	2019	18,934	19,288
42 CFR 488.845(b)(3)(iii)		Penalty for an isolated incident of noncompliance in violation of established home health agency (HHA) policy.	2019	17,883	18,198
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	2019	3,157	3,213
		Maximum	2019	17,883	18,198
42 CFR 488.845(b)(5)		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):			
		Minimum	2019	1,052	1,071
		Maximum	2019	8,415	8,563

<p>42 CFR 488.845(b)(6)</p> <p>42 CFR 488.845(d)(1)(ii) ...</p> <p>42 CFR 460.46</p> <p>*396b(m)(5)(B)</p>	<p>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:</p> <table border="0"> <tr><td>Minimum</td><td>2019</td><td>2,104</td></tr> <tr><td>Maximum</td><td>2019</td><td>21,410</td></tr> <tr><td>Penalty for each day of non-compliance (Maximum).</td><td>2019</td><td>21,039</td></tr> <tr><td>Penalty for each day of non-compliance (Maximum).</td><td>2019</td><td>21,039</td></tr> <tr><td>Penalty for Programs of All-Inclusive Care for the Elderly (PACE) organization's practice that would reasonably be expected to have the effect of denying or discouraging enrollment:</td><td>2019</td><td>23,473</td></tr> <tr><td>Minimum</td><td>2019</td><td>156,488</td></tr> <tr><td>Maximum</td><td>2019</td><td>39,121</td></tr> <tr><td>Penalty for a PACE organization that charges excessive premiums.</td><td>2019</td><td>156,488</td></tr> <tr><td>Penalty for a PACE organization misrepresenting or falsifying information to CMS, the State, or an individual or other entity.</td><td>2019</td><td>39,121</td></tr> <tr><td>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.</td><td>2019</td><td>39,811</td></tr> </table> <p>CMS</p>	Minimum	2019	2,104	Maximum	2019	21,410	Penalty for each day of non-compliance (Maximum).	2019	21,039	Penalty for each day of non-compliance (Maximum).	2019	21,039	Penalty for Programs of All-Inclusive Care for the Elderly (PACE) organization's practice that would reasonably be expected to have the effect of denying or discouraging enrollment:	2019	23,473	Minimum	2019	156,488	Maximum	2019	39,121	Penalty for a PACE organization that charges excessive premiums.	2019	156,488	Penalty for a PACE organization misrepresenting or falsifying information to CMS, the State, or an individual or other entity.	2019	39,121	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.	2019	39,811
Minimum	2019	2,104																													
Maximum	2019	21,410																													
Penalty for each day of non-compliance (Maximum).	2019	21,039																													
Penalty for each day of non-compliance (Maximum).	2019	21,039																													
Penalty for Programs of All-Inclusive Care for the Elderly (PACE) organization's practice that would reasonably be expected to have the effect of denying or discouraging enrollment:	2019	23,473																													
Minimum	2019	156,488																													
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Penalty for a PACE organization that charges excessive premiums.	2019	156,488																													
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	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2019 Maximum adjusted penalty (\$) ⁴	2020 Maximum adjusted penalty (\$) ⁴
·396(h)(3)(C)(ii)(I)	42 CFR 488.408(d)(1)(iii) ..	CMS	Penalty for involuntarily disenrolling a participant. 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. Penalty per day for a nursing facility's failure to meet a Category 2 Certification: Minimum Maximum Penalty per instance for a nursing facility's failure to meet Category 2 certification: Minimum Maximum Penalty per day for a nursing facility's failure to meet Category 3 certification: Minimum Maximum Penalty per instance for a nursing facility's failure to meet Category 3 certification: Minimum Maximum Penalty per instance for a nursing facility's failure to meet Category 3 certification, which results in immediate jeopardy:	2019 2019 2019 2019 2019 2019 2019 2019 2019 2019 2019 2019	39,121 39,121 39,121 6,579 6,579 2,194 2,194 6,898 6,898 2,194 2,194	39,811 39,811 39,811 6,695 6,695 2,233 2,233 22,320 22,320 22,320 22,320
	42 CFR 488.408(d)(1)(iv) ..	CMS				
	42 CFR 488.408(e)(1)(iii) ..	CMS				
	42 CFR 488.408(e)(1)(iv) ..	CMS				
	42 CFR 488.408(e)(2)(ii) ...	CMS				

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42 CFR 488.438(a)(1)(i)	CMS	Minimum Maximum Penalty per day for nursing facility's failure to meet certification (Upper Range); Minimum Maximum Penalty per day for nursing facility's failure to meet certification (Lower Range); Minimum Maximum Penalty per instance for nursing facility's failure to meet certification:	2019 2,194 21,933 22,320
42 CFR 488.438(a)(1)(ii)	CMS	Minimum Maximum Penalty per instance for nursing facility's failure to meet certification:	2019 6,690 21,933 22,320
42 CFR 488.438(a)(2)	CMS	Minimum Maximum Penalty per instance for nursing facility's failure to meet certification:	2019 6,579 110 112 6,695
42 CFR 488.438(a)(3)(i). and (b)(3)(ii).	42 CFR 483.151(b)(2)(iv) and (b)(3)(iii).	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 civil monetary penalties (CMPs) authority, but a specific CMP amount (CMP at this level) that is the triggering condition for disapproval].	2019 2,194 21,933 22,320 10,967 11,160
1396(f)(2)(B)(iii)(i)(c)	42 CFR 483.151(c)(2)	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].	2019 10,967 11,160

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	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2019 Maximum adjusted penalty (\$) ⁴	2020 Maximum adjusted penalty (\$) ⁴
1396t(i)(2)(C)	CMS	Penalty for each day of non-compliance for a home or community care provider that no longer meets the minimum requirements for home and community care: Minimum Maximum	2019 2019	18,943 19,277	2 19,277
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. Penalty for a Medicaid managed care organization that fails to comply with the applicable statutory requirements for such organizations.	2019 2019 2019 2019	39,121 39,121 39,811 39,121	39,811 39,811 39,811 39,121

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1396u-2(e)(2)(A)(ii)	42 CFR 438.704	CMS	Penalty for a Medicaid managed care organization that misrepresents or falsifies information to the HHS Secretary.	2019	156,488	159,248
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.	2019	156,488	159,248
1396u(h)(2)	42 CFR Part 441, Subpart I.	CMS	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.	2019	23,473	23,887
1396w-2(c)(1)	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.	2019	21,933	22,320
18041(c)(2)	45 CFR 150.315; 45 CFR 156.805(c).	CMS	Penalty for disclosing information related to eligibility determinations for medical assistance programs.	2019	11,698	11,904
18081(h)(1)(A)(i)(II)	42 CFR 155.285	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)).	2019	159	162
			Penalty for providing false information on Exchange application.	2019	28,906	29,416

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	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2019 Maximum adjusted penalty (\$)	2020 Maximum adjusted penalty (\$) ⁴
·8081(h)(1)(B)	42 CFR 155.285	CMS	Penalty for knowingly or willfully providing false information on Exchange application.	2019	289,060	294,159
·8081(h)(2)	42 CFR 155.260	CMS	Penalty for knowingly or willfully disclosing protected information from Exchange.	2019	28,906	29,416
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	2019	20,134	20,489

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45 CFR Part 93, Appendix A.	HHS	Maximum Penalty for failure to provide certification regarding lobbying in the award documents for all sub-awards of all tiers: Minimum Maximum Penalty for failure to provide statement regarding lobbying for loan guarantee and loan insurance transactions: Minimum Maximum Penalty against any individual who—with knowledge or reason to know—makes, presents or submits a false, fictitious or fraudulent claim to the Department. Penalty against any individual who—with knowledge or reason to know—makes, presents or submits a false, fictitious or fraudulent claim to the Department.	2019 201,340 204,892	2019 201,340 204,892	2019 201,340 204,892
3801–3812 45 CFR 79.3(a)(1)(iv) 45 CFR 79.3(b)(1)(ii)	HHS				

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 2020, based on the Consumer Price Index for all Urban Consumers (CPI-U) for the month of October 2019, not seasonally adjusted, is 1.01764, as indicated in OMB Memorandum M-20-05, “Implementation of Penalty Inflation Adjustments for 2019, Pursuant to the Federal Civil Penalties Adjustment Act Improvements Act of 2015” (December 16, 2019).

[81 FR 61565, Sept. 6, 2016, as amended at 83 FR 51370, Oct. 11, 2018; 84 FR 59550, Nov. 5, 2019; 85 FR 2870, Jan. 17, 2020]