

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Office of the Secretary****42 CFR Part 3****Centers for Medicare & Medicaid Services****42 CFR Parts 402, 403, 411, 412, 422, 423, 460, 483, 488, and 493****Office of the Inspector General****42 CFR Part 1003****Office of the Secretary****45 CFR Parts 79, 93, 102, 147, 150, 155, 156, 158, and 160****Administration for Children and Families****45 CFR Part 303****RIN 0991-AC0****Adjustment of Civil Monetary Penalties for Inflation**

**AGENCY:** Department of Health and Human Services, Office of the Assistant Secretary for Financial Resources, Centers for Medicare & Medicaid Services, Office of the Inspector General, Administration for Children and Families.

**ACTION:** Interim final rule.

**SUMMARY:** The Department of Health and Human Services (HHS) is issuing a new regulation to adjust for inflation the maximum civil monetary penalty amounts for the various civil monetary penalty authorities for all agencies within HHS. We are taking this action to comply with the Federal Civil Penalties Inflation Adjustment Act of 1990 (the Inflation Adjustment Act), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. In addition, this interim final rule includes updates to certain agency-specific regulations to identify their updated information, and note the location of HHS-wide regulations.

**DATES:** This rule is effective on September 6, 2016.

**FOR FURTHER INFORMATION CONTACT:** 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. Regulatory Information**

The Department of Health and Human Services (HHS) is promulgating this interim final rule to ensure that the amount of civil monetary penalties authorized to be assessed or enforced by HHS reflect the statutorily mandated amounts and ranges as adjusted for inflation. Pursuant to Section 4(b) of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act), HHS is required to promulgate a “catch-up adjustment” through an interim final rule. Pursuant to the 2015 Act and 5 U.S.C. 553(b)(3)(B), HHS finds that good cause exists for immediate implementation of this interim final rule without prior notice and comment because it would be impracticable to delay publication of this rule for notice and comment. The 2015 Act specifies that the adjustments shall take effect not later than August 1, 2016. Additionally, the 2015 Act provides a clear formula for adjustment of the civil monetary penalties, leaving agencies little room for discretion. For these reasons, HHS finds that notice and comment would be impracticable in this situation. Additionally, if applicable, HHS agencies will update their civil monetary penalty-specific regulations to include a cross-reference to the revised regulations located at 45 CFR part 102 reflecting the new adjusted penalty amounts set out by HHS.<sup>1</sup>

**II. Background and Requirements of the Law**

On November 2, 2015, the President signed into law the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act) (Sec. 701 of the Bipartisan Budget Act of 2015, Public Law 114-74, November 2, 2015), which amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (the Inflation Adjustment Act) (Pub. L. 101-410, 104 Stat. 890 (1990) (codified as amended at 28 U.S.C. 2461 note 2(a)), to improve the effectiveness of civil monetary penalties and to maintain their deterrent effect. The 2015 Act, which removed an inflation update exclusion that previously applied to the Social Security Act as well as the Occupational Safety and Health Act, requires agencies to: (1) Adjust the level of civil monetary penalties with an initial “catch-up” adjustment through an interim final rulemaking (IFR); and (2) make

<sup>1</sup> All applicable civil monetary penalty authorities within the jurisdiction of HHS must be adjusted in accordance with the 2015 Act. Where existing HHS agency regulations setting forth civil monetary penalty amounts are not updated by this interim final rule, they will be amended in a separate action as soon as practicable.

subsequent annual adjustments for inflation.

The method of calculating inflation adjustments in the 2015 Act differs substantially from the methods used in past inflation adjustment rulemakings conducted pursuant to the Inflation Adjustment Act. Previously, adjustments to civil monetary penalties were conducted under rules that required significant rounding of figures. While this allowed penalties to be kept at round numbers, it meant that penalties would often not be increased at all if the inflation factor was not large enough. Furthermore, increases to penalties were capped at 10 percent. Over time, this formula caused penalties to lose value relative to total inflation.

The 2015 Act has removed these rounding rules; now, penalties are simply rounded to the nearest dollar. While this creates penalty values that are no longer round numbers, it does ensure that penalties will be increased each year to a figure commensurate with the actual calculated inflation. Furthermore, the 2015 Act “resets” the inflation calculations by excluding prior inflationary adjustments under the Inflation Adjustment Act, which contributed to a decline in the real value of penalty levels. To do this, the 2015 Act requires agencies to identify, for each penalty, the year and corresponding amount(s) for which the maximum penalty level or range of minimum and maximum penalties was established (*i.e.*, originally enacted by Congress) or last adjusted other than pursuant to the Inflation Adjustment Act.

In this rule, the adjusted civil penalty amounts are applicable only to civil penalties assessed after August 1, 2016, whose associated violations occurred after November 2, 2015, the date of enactment of the 2015 Amendments. Therefore, violations occurring on or before November 2, 2015, and assessments made prior to August 1, 2016, whose associated violations occurred after November 2, 2015, will continue to be subject to the civil monetary penalty amounts set forth in the Department’s existing regulations or as set forth by statute if the amount has not yet been adjusted by regulation.

Pursuant to the 2015 Act, the Department of Health and Human Services (HHS) has undertaken a thorough review of civil monetary penalties administered by its various components. This IFR sets forth the initial “catch-up” adjustment for civil monetary penalties as well as any necessary technical conforming changes to the language of the various regulations affected by this IFR. For

each component, HHS has provided a table showing how the penalties are being increased pursuant to the 2015 Act. The first two columns ("Citation") identify the United States Code (U.S.C.) statutory citation, and the applicable regulatory citation in the Code of Federal Regulations (CFR), if any. The third column ("Description") provides a short description of the penalty. In the fourth column ("Pre-Inflation Penalty"), HHS has listed the penalty amount as it exists prior to the inflationary adjustments made by the effective date of this rule, and in the fifth column ("Date of Last Penalty Figure or Adjustment"), HHS has provided the

amount and year of the penalty as enacted by Congress or changed through a mechanism other than pursuant to the Inflation Adjustment Act. In column six ("Percentage Increase"), HHS has listed the percentage increase based on the multiplier used to adjust from the CPI-U<sup>2</sup> of the year of enactment of the monetary penalty to the CPI-U for the current year, or a percentage equal to 150 percent, whichever is less. Multiplying the current penalty amount in column four by the percentage increase provides the "Increase" listed in column seven. The "Maximum Adjusted Penalty" in column eight is the sum of the current penalty amount

and the "increase". Where applicable, some HHS agencies will make as soon as practicable conforming edits to regulatory text. Additionally, HHS is issuing new regulatory text including the table showing how the penalties are being increased under the 2015 Act, located at 45 CFR part 102, to implement the civil monetary penalty (CMP) amounts adjusted for inflation agency-wide. Additionally, the 2015 Act requires agencies to publish annual adjustments not later than January 15 of every year after publication of the initial adjustment.

#### CALCULATION OF CMP ADJUSTMENTS

Citation		Description <sup>2</sup>	Pre-inflation penalty (\$)	Date of last penalty figure or adjustment <sup>3</sup>	Percentage increase <sup>4</sup>	Increase (\$) <sup>5</sup>	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>						
21 U.S.C. (FDA):							
333(b)(2)(A) .....	.....	Penalty for violations related to drug samples resulting in a conviction of any representative of manufacturer or distributor in any 10-year period.	50,000	1988	97.869	48,935	98,935
333(b)(2)(B) .....	.....	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.	1,000,000	1988	97.869	978,690	1,978,690
333(b)(3) .....	.....	Penalty for failure to make a report required by 21 U.S.C. 353(d)(3)(E) relating to drug samples.	100,000	1988	97.869	97,869	197,869
333(f)(1)(A) .....	.....	Penalty for any person who violates a requirement related to devices for each such violation.	15,000	1990	78.156	11,723	26,723
		Penalty for aggregate of all violations related to devices in a single proceeding.	1,000,000	1990	78.156	781,560	1,781,560
333(f)(2)(A) .....	.....	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. 350i.	50,000	1996	50.425	25,123	75,123
		Penalty in the case of any other person other than an individual for such introduction or delivery of adulterated food.	250,000	1996	50.425	125,613	375,613
		Penalty for aggregate of all such violations related to adulterated food adjudicated in a single proceeding.	500,000	1996	50.425	251,225	751,225
333(f)(3)(A) .....	.....	Penalty for all violations adjudicated in a single proceeding for any person who fails to submit certification required by 42 U.S.C. 282(j)(5)(B) or knowingly submitting a false certification.	10,000	2007	13.833	1,383	11,383
333(f)(3)(B) .....	.....	Penalty for each day the above violation is not corrected after a 30-day period following notification until the violation is corrected.	10,000	2007	13.833	1,383	11,383

<sup>2</sup> Based upon the Consumer Price Index (CPI-U) for the month of October 2015. The CPI-U is

published by the Department of Labor, Bureau of

Labor Statistics, and is available at its Web site: <http://www.bls.gov/cpi/>.

## CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description <sup>2</sup>	Pre-inflation penalty (\$)	Date of last penalty figure or adjustment <sup>3</sup>	Percentage increase <sup>4</sup>	Increase (\$) <sup>5</sup>	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>						
333(f)(4)(A)(i) .....	.....	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).	250,000	2007	13.833	34,583	284,583
		Penalty for aggregate of all such above violations in a single proceeding.	1,000,000	2007	13.833	138,330	1,138,330
333(f)(4)(A)(ii) .....	.....	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.	250,000	2007	13.833	34,583	284,583
		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.	1,000,000	2007	13.833	138,330	1,138,330
		Penalty for aggregate of all such above violations adjudicated in a single proceeding.	10,000,000	2007	13.833	1,383,300	11,383,300
333(f)(9)(A) .....	.....	Penalty for any person who violates a requirement which relates to tobacco products for each such violation.	15,000	2009	10.02	1,503	16,503
		Penalty for aggregate of all such violations of tobacco product requirement adjudicated in a single proceeding.	1,000,000	2009	10.02	100,200	1,100,200
333(f)(9)(B)(i)(I) .....	.....	Penalty per violation related to violations of tobacco requirements.	250,000	2009	10.02	25,050	275,050
		Penalty for aggregate of all such violations of tobacco product requirements adjudicated in a single proceeding.	1,000,000	2009	10.02	100,200	1,100,200
333(f)(9)(B)(i)(II) .....	.....	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.	250,000	2009	10.02	25,050	275,050
		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.	1,000,000	2009	10.02	100,200	1,100,200
		Penalty for aggregate of all such violations related to tobacco product requirements adjudicated in a single proceeding.	10,000,000	2009	10.02	1,002,000	11,002,000
333(f)(9)(B)(ii)(I) .....	.....	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.	250,000	2009	10.02	25,050	275,050
		Penalty for aggregate of for all such above violations adjudicated in a single proceeding.	1,000,000	2009	10.02	100,200	1,100,200

## CALCULATION OF CMP ADJUSTMENTS—Continued

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U.S.C.	CFR <sup>1</sup>						
333(f)(9)(B)(ii)(II) .....	.....	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.	250,000	2009	10.02	25,050	275,050
		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.	1,000,000	2009	10.02	100,200	1,100,200
		Penalty for aggregate above tobacco product requirement violations adjudicated in a single proceeding.	10,000,000	2009	10.02	1,002,000	11,002,000
333(g)(1) .....	.....	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.	250,000	2007	13.833	34,583	284,583
		Penalty for each subsequent above violation in any 3-year period.	500,000	2007	13.833	69,165	569,165
333 note .....	.....	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.	250	2009	10.02	25	275
		Penalty in the case of a third tobacco product regulation violation within a 24-month period.	500	2009	10.02	50	550
		Penalty in the case of a fourth tobacco product regulation violation within a 24-month period.	2,000	2009	10.02	200	2,200
		Penalty in the case of a fifth tobacco product regulation violation within a 36-month period.	5,000	2009	10.02	501	5,501
		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.	10,000	2009	10.02	1,002	11,002
		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.	250	2009	10.02	25	275
		Penalty in the case of a second tobacco product regulation violation within a 12-month period.	500	2009	10.02	50	550
		Penalty in the case of a third tobacco product regulation violation within a 24-month period.	1,000	2009	10.02	100	1,100
		Penalty in the case of a fourth tobacco product regulation violation within a 24-month period.	2,000	2009	10.02	200	2,200
		Penalty in the case of a fifth tobacco product regulation violation within a 36-month period.	5,000	2009	10.02	501	5,501

## CALCULATION OF CMP ADJUSTMENTS—Continued

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U.S.C.	CFR <sup>1</sup>						
		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.	10,000	2009	10.02	1002	11,002
335b(a) .....	.....	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.	250,000	1992	67.728	169,320	419,320
		Penalty in the case of any other person (other than an individual) per above violation.	1,000,000	1992	67.728	677,280	1,677,280
360pp(b)(1) .....	.....	Penalty for any person who violates any such requirements for electronic products, with each unlawful act or omission constituting a separate violation.	1,100	1968	150	1,500	2,750
		Penalty imposed for any related series of violations of requirements relating to electronic products.	375,000	1968	150	562,500	937,500
42 U.S.C. (FDA): 262(d) .....	.....	Penalty per day for violation of order of recall of biological product presenting imminent or substantial hazard.	100,000	1986	115.628	115,628	215,628
263b(h)(3) .....	.....	Penalty for failure to obtain a mammography certificate as required.	10,000	1992	67.728	6,773	16,773
300aa–28(b)(1) .....	.....	Penalty per occurrence for any vaccine manufacturer that intentionally destroys, alters, falsifies, or conceals any record or report required.	100,000	1986	115.628	115,628	215,628
42 U.S.C. (HRSA): 256b(d)(1)(B)(vi) .....	.....	Penalty for each instance of overcharging a 340B covered entity.	5,000	2010	8.745	437	5,437
42 U.S.C. (AHRQ): 299c–(3)(d) .....	.....	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.	10,000	1999	41.402	4,140	14,140
42 U.S.C. ACF: 653(l)(2) .....	45 CFR 303.21(f) .....	Penalty for Misuse of Information in the National Directory of New Hires.	1,000	1998	45.023	450	1,450
42 U.S.C. (OIG): 262a(l)(1) .....	42 CFR Part 1003 .....	Penalty for each individual who violates safety and security procedures related to handling dangerous biological agents and toxins.	250,000	2002	31.185	77,962	327,962
		Penalty for any other person who violates safety and security procedures related to handling dangerous biological agents and toxins.	500,000	2002	31.185	155,925	655,925
1320a–7a(a) .....	42 CFR Part 1003 .....	Penalty for knowingly presenting or causing to be presented to an officer, employee, or agent of the United States a false claim.	10,000	1996	50.245	5,024	15,024
		Penalty for knowingly presenting or causing to be presented a request for payment which violates the terms of an assignment, agreement, or PPS agreement.	10,000	1996	50.245	5,024	15,024

## CALCULATION OF CMP ADJUSTMENTS—Continued

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U.S.C.	CFR <sup>1</sup>						
		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.	15,000	1996	50.245	7,537	22,537
		Penalty for an excluded party retaining ownership or control interest in a participating entity.	10,000	1996	50.245	5,024	15,024
		Penalty for remuneration offered to induce program beneficiaries to use particular providers, practitioners, or suppliers.	10,000	1996	50.245	5,024	15,024
		Penalty for employing or contracting with an excluded individual.	10,000	1997	47.177	4,718	14,718
		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.	50,000	1997	47.177	23,588	73,588
		Penalty for ordering or prescribing medical or other item or service during a period in which the person was excluded.	10,000	2010	8.745	874	10,874
		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.	50,000	2010	8.745	4,372	54,372
		Penalty for knowing of an overpayment and failing to report and return.	10,000	2010	8.745	874	10,874
		Penalty for making or using a false record or statement that is material to a false or fraudulent claim.	50,000	2010	8.745	4,372	54,372
		Penalty for failure to grant timely access to HHS OIG for audits, investigations, evaluations, and other statutory functions of HHS OIG.	15,000	2010	8.745	1,312	16,312
1320a–7a(b) .....	42 CFR Part 1003 .....	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.	2,000	1986	115.628	2,313	4,313
		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.	2,000	1986	115.628	2,313	4,313
		Penalty for a physician who executes a document that falsely certifies home health needs for Medicare beneficiaries.	5,000	1996	50.245	2,512	7,512
1320a–7e(b)(6)(A) ....	42 CFR Part 1003 .....	Penalty for failure to report any final adverse action taken against a health care provider, supplier, or practitioner.	25,000	1997	47.177	11,794	36,794
1320b–10(b)(1) .....	42 CFR Part 1003 .....	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.	5,000	1988	97.869	4,893	9,893

## CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description <sup>2</sup>	Pre-inflation penalty (\$)	Date of last penalty figure or adjustment <sup>3</sup>	Percentage increase <sup>4</sup>	Increase (\$) <sup>5</sup>	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>						
1320b–10(b)(2) .....	42 CFR Part 1003 .....	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.	25,000	1988	97.869	24,467	49,467
1395i–3(b)(3)(B)(iii)(1) .....	.....	Penalty for certification of a false statement in assessment of functional capacity of a Skilled Nursing Facility resident assessment.	1,000	1987	106.278	1,063	2,063
1395i–3(b)(3)(B)(iii)(2) .....	.....	Penalty for causing another to certify or make a false statement in assessment of functional capacity of a Skilled Nursing Facility resident assessment.	5,000	1987	106.278	5,314	10,314
1395i–3(g)(2)(A) .....	.....	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.	2,000	1987	106.278	2,126	4,126
1395w–27(g)(2)(A) ...	42 CFR 422.752; 42 CFR Part 1003.	Penalty for a Medicare Advantage organization that substantially fails to provide medically necessary, required items and services.	25,000	1996	50.245	12,561	37,561
		Penalty for a Medicare Advantage organization that charges excessive premiums.	25,000	1997	47.177	11,794	36,794
		Penalty for a Medicare Advantage organization that improperly expels or refuses to reenroll a beneficiary.	25,000	1997	47.177	11,794	36,794
		Penalty for a Medicare Advantage organization that engages in practice that would reasonably be expected to have the effect of denying or discouraging enrollment.	100,000	1997	47.177	47,177	147,177
		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.	15,000	1997	47.177	7,077	22,077
		Penalty for a Medicare Advantage organization misrepresenting or falsifying information to Secretary.	100,000	1997	47.177	47,177	147,177
		Penalty for a Medicare Advantage organization misrepresenting or falsifying information to individual or other entity.	25,000	1997	47.177	11,794	36,794
		Penalty for Medicare Advantage organization interfering with provider's advice to enrollee and non-MCO affiliated providers that balance bill enrollees.	25,000	1997	47.177	11,794	36,794
		Penalty for a Medicare Advantage organization that employs or contracts with excluded individual or entity.	25,000	1997	47.177	11,794	36,794
		Penalty for a Medicare Advantage organization enrolling an individual in without prior written consent.	25,000	2010	47.177	11,794	36,794
		Penalty for a Medicare Advantage organization transferring an enrollee to another plan without consent or solely for the purpose of earning a commission.	25,000	2010	47.177	11,794	36,794
		Penalty for a Medicare Advantage organization failing to comply with marketing restrictions or applicable implementing regulations or guidance.	25,000	2010	47.177	11,794	36,794

## CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description <sup>2</sup>	Pre-inflation penalty (\$)	Date of last penalty figure or adjustment <sup>3</sup>	Percentage increase <sup>4</sup>	Increase (\$) <sup>5</sup>	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>						
		Penalty for a Medicare Advantage organization employing or contracting with an individual or entity who violates 1395w-27(g)(1)(A)–(J).	25,000	2010	47.177	11,794	36,794
1395w-141(i)(3) .....	42 CFR Part 1003 .....	Penalty for a prescription drug card sponsor that falsifies or misrepresents marketing materials, overcharges program enrollees, or misuse transitional assistance funds.	10,000	2003	28.561	2,856	12,856
1395cc(g) .....	42 CFR Part 1003 .....	Penalty for improper billing by Hospitals, Critical Access Hospitals, or Skilled Nursing Facilities.	2,000	1972	150	3,000	5,000
1395dd(d)(1) .....	42 CFR Part 1003 .....	Penalty for a hospital or responsible physician dumping patients needing emergency medical care, if the hospital has 100 beds or more.	50,000	1987	106.278	53,139	103,139
		Penalty for a hospital or responsible physician dumping patients needing emergency care, if the hospital has less than 100 beds.	25,000	1987	106.278	26,570	51,570
1395mm(i)(6)(B)(i) ....	42 CFR Part 1003 .....	Penalty for a HMO or competitive plan is such plan substantially fails to provide medically necessary, required items or services.	25,000	1987	106.278	26,570	51,570
		Penalty for HMOs/competitive medical plans that charge premiums in excess of permitted amounts.	25,000	1987	106.278	26,570	51,570
		Penalty for a HMO or competitive medical plan that expels or refuses to reenroll an individual per prescribed conditions.	25,000	1987	106.278	26,570	51,570
		Penalty for a HMO or competitive medical plan that implements practices to discourage enrollment of individuals needing services in future.	100,000	1987	106.278	106,278	206,278
		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.	15,000	1988	97.869	14,680	29,680
		Penalty for a HMO or competitive medical plan that misrepresents or falsifies information to the Secretary.	100,000	1987	106.278	106,278	206,278
		Penalty for a HMO or competitive medical plan that misrepresents or falsifies information to an individual or any other entity.	25,000	1987	106.278	26,570	51,570
		Penalty for failure by HMO or competitive medical plan to assure prompt payment of Medicare risk sharing contracts or incentive plan provisions.	25,000	1987	106.278	26,570	51,570
		Penalty for HMO that employs or contracts with excluded individual or entity.	25,000	1989	89.361	22,340	47,340
1395nn(g)(3) .....	42 CFR Part 1003 .....	Penalty for submitting or causing to be submitted claims in violation of the Stark Law's restrictions on physician self-referrals.	15,000	1994	59.089	8,863	23,863
1395nn(g)(4) .....	42 CFR Part 1003 .....	Penalty for circumventing Stark Law's restrictions on physician self-referrals.	100,000	1994	59.089	59,089	159,089
1395ss(d)(1) .....	42 CFR Part 1003 .....	Penalty for a material misrepresentation regarding Medigap compliance policies.	5,000	1988	97.869	4,893	9,893
1395ss(d)(2) .....	42 CFR Part 1003 .....	Penalty for selling Medigap policy under false pretense.	5,000	1988	97.869	4,893	9,893
1395ss(d)(3)(A)(ii) ....	42 CFR Part 1003 .....	Penalty for an issuer that sells health insurance policy that duplicates benefits.	25,000	1990	78.156	19,539	44,539



## CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description <sup>2</sup>	Pre-inflation penalty (\$)	Date of last penalty figure or adjustment <sup>3</sup>	Percentage increase <sup>4</sup>	Increase (\$) <sup>5</sup>	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>						
		Penalty for someone other than issuer that sells health insurance that duplicates benefits.	15,000	1990	78.156	11,723	26,723
1395ss(d)(4)(A) .....	42 CFR Part 1003 .....	Penalty for using mail to sell a non-approved Medigap insurance policy.	5,000	1988	97.869	4,893	9,893
1396b(m)(5)(B)(i) .....	42 CFR Part 1003 .....	Penalty for a Medicaid MCO that substantially fails to provide medically necessary, required items or services.	25,000	1988	97.869	24,467	49,467
		Penalty for a Medicaid MCO that charges excessive premiums.	25,000	1988	97.869	24,467	49,467
		Penalty for a Medicaid MCO that improperly expels or refuses to reenroll a beneficiary.	100,000	1988	97.869	97,869	197,869
		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.	15,000	1988	97.869	14,680	29,680
		Penalty for a Medicaid MCO misrepresenting or falsifying information to the Secretary.	100,000	1988	97.869	97,869	197,869
		Penalty for a Medicaid MCO misrepresenting or falsifying information to an individual or another entity.	25,000	1988	97.869	24,467	49,467
		Penalty for a Medicaid MCO that fails to comply with contract requirements with respect to physician incentive plans.	25,000	1990	78.156	19,539	44,539
1396r(b)(3)(B)(ii)(I) ...	42 CFR Part 1003 .....	Penalty for willfully and knowingly certifying a material and false statement in a Skilled Nursing Facility resident assessment.	1,000	1987	106.278	1,063	2,063
1396r(b)(3)(B)(ii)(II) ..	42 CFR Part 1003 .....	Penalty for willfully and knowingly causing another individual to certify a material and false statement in a Skilled Nursing Facility resident assessment.	5,000	1987	106.278	5,314	10,314
1396r(g)(2)(A)(i) .....	42 CFR Part 1003 .....	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.	2,000	1987	106.278	2,126	4,126
1396r-8(b)(3)(B) .....	42 CFR Part 1003 .....	Penalty for the knowing provision of false information or refusing to provide information about charges or prices of a covered outpatient drug.	100,000	1990	78.156	78,156	178,156
1396r-8(b)(3)(C)(i) ...	42 CFR Part 1003 .....	Penalty per day for failure to timely provide information by drug manufacturer with rebate agreement.	10,000	1990	78.156	7,816	17,816
1396r-8(b)(3)(C)(ii) ..	42 CFR Part 1003 .....	Penalty for knowing provision of false information by drug manufacturer with rebate agreement.	100,000	1990	78.156	78,156	178,156
1396t(i)(3)(A) .....	42 CFR Part 1003 .....	Penalty for notifying home and community-based providers or settings of survey.	2,000	1990	78.156	1,563	3,563
11131(c) .....	42 CFR Part 1003 .....	Penalty for failing to report a medical malpractice claim to National Practitioner Data Bank.	10,000	1986	115.628	11,563	21,563
11137(b)(2) .....	42 CFR Part 1003 .....	Penalty for breaching confidentiality of information reported to National Practitioner Data Bank.	10,000	1986	115.628	11,563	21,563
42 U.S.C. (OCR): 299b-22(f)(1) .....	42 CFR 3.404(b) .....	Penalty for violation of confidentiality provision of the Patient Safety and Quality Improvement Act.	10,000	2005	19.40	1,940	11,940
1320(d)-5(a) .....	45 CFR 160.404(b)(1)(i),(ii).	Penalty for each pre-February 18, 2009 violation of the HIPAA administrative simplification provisions.	100	1996	50.245	50	150
		Calendar Year Cap .....	25,000	1996	50.245	12,561	37,561

## CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description <sup>2</sup>	Pre-inflation penalty (\$)	Date of last penalty figure or adjustment <sup>3</sup>	Percentage increase <sup>4</sup>	Increase (\$) <sup>5</sup>	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>						
42 U.S.C. (CMS): 263a(h)(2)(B) & 1395w- 2(b)(2)(A)(ii).	45 CFR 160.404(b)(2)(i)(A),(B).	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 ..... 100 Maximum ..... 50,000 Calendar Year Cap ..... 1,500,000					
	45 CFR 160.404(b)(2)(ii)(A),(B).	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 ..... 1,000 Maximum ..... 50,000 Calendar Year Cap ..... 1,500,000					
	45 CFR 160.404(b)(2)(iii)(A),(B).	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 ..... 10,000 Maximum ..... 50,000 Calendar Year Cap ..... 1,500,000					
	45 CFR 160.404(b)(2)(iv)(A),(B).	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 ..... 50,000 Maximum ..... 1,500,000 Calendar Year Cap ..... 1,500,000					
	42 CFR 493.1834(d)(2)(i).	Penalty for a clinical laboratory's failure to meet participation and certification requirements and poses immediate jeopardy: Minimum ..... 3,050 Maximum ..... 10,000					
	42 CFR 493.1834(d)(2)(ii).	Penalty for a clinical laboratory's failure to meet participation and certification requirements and the failure does not pose immediate jeopardy: Minimum ..... 50 Maximum ..... 3,000					
	45 CFR 147.200(e) .....	Failure to provide the Summary of Benefits and Coverage (SBC).	1,000	2010	8.745	87	1,087
	45 CFR 158.606 .....	Penalty for violations of regulations related to the medical loss ratio reporting and rebating.	100	2010	8.745	9	109

## CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description <sup>2</sup>	Pre-inflation penalty (\$)	Date of last penalty figure or adjustment <sup>3</sup>	Percentage increase <sup>4</sup>	Increase (\$) <sup>5</sup>	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>						
1320a–7h(b)(1) .....	42 CFR 402.105(d)(5), 42 CFR 403.912(a) & (c).	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 .....	1,000	2010	8.745	87	1,087
		Maximum .....	10,000	2010	8.745	874	10,874
		Calendar Year Cap .....	150,000	2010	8.745	13,117	163,117
1320a–7h(b)(2) .....	42 CFR 402.105(h), 42 CFR 403.912(b) & (c).	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 .....	10,000	2010	8.745	874	10,874
		Maximum .....	100,000	2010	8.745	8,745	108,745
		Calendar Year Cap .....	1,000,000	2010	8.745	87,450	1,087,450
1320a–7j(h)(3)(A) .....	.....	Penalty for an administrator of a facility that fails to comply with notice requirements for the closure of a facility.	100,000	2010	8.745	8,745	108,745
	42 CFR 488.446(a)(1),(2), & (3).	Minimum penalty for the first offense of an administrator who fails to provide notice of facility closure.	500	2010	8.745	44	544
		Minimum penalty for the second offense of an administrator who fails to provide notice of facility closure.	1,500	2010	8.745	131	1,631
		Minimum penalty for the third and subsequent offenses of an administrator who fails to provide notice of facility closure.	3,000	2010	8.745	262	3,262
1320a–8(a)(1) .....	.....	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.	5,000	1994	59.089	2,954	7,954
		Penalty for the violation of 42 U.S.C. 1320a–8a(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.	7,500	2015	1	4,431	7,500
1320a–8(a)(3) .....	.....	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.	5,000	2004	24.588	1,229	6,229
1320b–25(c)(1)(A) ....	.....	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.	200,000	2010	8.745	17,490	217,490

## CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description <sup>2</sup>	Pre-inflation penalty (\$)	Date of last penalty figure or adjustment <sup>3</sup>	Percentage increase <sup>4</sup>	Increase (\$) <sup>5</sup>	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>						
1320b–25(c)(2)(A) ....	.....	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.	300,000	2010	8.745	26,235	326,235
1320b–25(d)(2) .....	.....	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.	200,000	2010	8.745	17,490	217,490
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.	100	1997	47.177	47	147
1395i–3(h)(2)(B)(iii)(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:					
		Minimum .....	50	1987	106.278	53	103
		Maximum .....	3,000	1987	106.278	3,188	6,188
	42 CFR 488.408(d)(1)(iv).	Penalty per instance of Category 2 noncompliance by a Skilled Nursing Facility:					
		Minimum .....	1,000	1987	106.278	1,063	2,063
		Maximum .....	10,000	1987	106.278	10,628	20,628
	42 CFR 488.408(e)(1)(iii)	Penalty per day for a Skilled Nursing Facility that has a Category 3 violation of certification requirements:					
		Minimum .....	3,050	1987	106.278	3,241	6,291
		Maximum .....	10,000	1987	106.278	10,628	20,628
	42 CFR 488.408(e)(1)(iv).	Penalty per instance of Category 3 noncompliance by a Skilled Nursing Facility:					
		Minimum .....	1,000	1987	106.278	1,063	2,063
		Maximum .....	10,000	1987	106.278	10,628	20,628
		Penalty per day and per instance for a Skilled Nursing Facility that has Category 3 noncompliance with Immediate Jeopardy.					
		Per Day (Minimum) .....	3,050	1987	106.278	3,241	6,291
		Per Day (Maximum) .....	10,000	1987	106.278	10,628	20,628
		Per Instance (Minimum) .....	1,000	1987	106.278	1,063	2,063
		Per Instance (Maximum) .....	10,000	1987	106.278	10,628	20,628
42 CFR 488.438(a)(1)(i)		Penalty per day of a Skilled Nursing Facility that fails to meet certification requirements. These amounts represent the upper range per day:					
		Minimum .....	3,050	1987	106.278	3,241	6,291
		Maximum .....	10,000	1987	106.278	10,628	20,628
	42 CFR 488.438(a)(1)(ii)	Penalty per day of a Skilled Nursing Facility that fails to meet certification requirements. These amounts represent the lower range per day:					
		Minimum .....	50	1987	106.278	53	103
		Maximum .....	3,000	1987	106.278	3,188	6,188
	42 CFR 488.438(a)(2) ...	Penalty per instance of a Skilled Nursing Facility that fails to meet certification requirements:					
		Minimum .....	1,000	1987	106.278	1,063	2,063
		Maximum .....	10,000	1987	106.278	10,628	20,628

## CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description <sup>2</sup>	Pre-inflation penalty (\$)	Date of last penalty figure or adjustment <sup>3</sup>	Percentage increase <sup>4</sup>	Increase (\$) <sup>5</sup>	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>						
1395l(h)(5)(D) .....	42 CFR 402.105(d)(2)(i)	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)).	10,000	1996	50.245	5,024	15,024
1395l(i)(6) .....	.....	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.	2,000	1988	197.869	1,957	3,957
1395l(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.	2,000	1989	89.361	1,787	3,787
1395m(a)(11)(A) .....	42 CFR 402.1(c)(4), 402.105(d)(2)(ii).	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)).	10,000	1996	50.245	5,024	15,024
1395m(a)(18)(B) .....	42 CFR 402.1(c)(5), 402.105(d)(2)(iii).	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)).	10,000	1996	50.245	5,024	15,024
1395m(b)(5)(C) .....	42 CFR 402.1(c)(6), 402.105(d)(2)(iv).	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)).	10,000	1996	50.245	5,024	15,024
1395m(h)(3) .....	42 CFR 402.1(c)(8), 402.105(d)(2)(vi).	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)).	10,000	1996	50.245	5,024	15,024

## CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description <sup>2</sup>	Pre-inflation penalty (\$)	Date of last penalty figure or adjustment <sup>3</sup>	Percentage increase <sup>4</sup>	Increase (\$) <sup>5</sup>	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>						
1395m(j)(2)(A)(iii) .....	.....	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.	1,000	1994	59.089	591	1,591
1395m(j)(4) .....	42 CFR 402.1(c)(10), 402.105(d)(2)(vii).	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)).	10,000	1996	50.245	5,024	15,024
1395m(k)(6) .....	42 CFR 402.1(c)(31), 402.105(d)(3).	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)).	10,000	1996	50.245	5,024	15,024
1395m(l)(6) .....	42 CFR 402.1(c)(32), 402.105(d)(4).	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)).	10,000	1996	50.245	5,024	15,024
1395u(b)(18)(B) .....	42 CFR 402.1(c)(11), 402.105(d)(2)(viii).	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)).	10,000	1996	50.245	5,024	15,024
1395u(j)(2)(B) .....	42 CFR 402.1(c) .....	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)).	10,000	1996	50.245	5,024	15,024
1395u(k) .....	42 CFR 402.1(c)(12), 402.105(d)(2)(ix).	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)).	10,000	1996	50.245	5,024	15,024

## CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description <sup>2</sup>	Pre-inflation penalty (\$)	Date of last penalty figure or adjustment <sup>3</sup>	Percentage increase <sup>4</sup>	Increase (\$) <sup>5</sup>	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>						
1395u(l)(3) .....	42 CFR 402.1(c)(13), 402.105(d)(2)(x).	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)).	10,000	1996	50.245	5,024	15,024
1395u(m)(3) .....	42 CFR 402.1(c)(14), 402.105(d)(2)(xi).	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)).	10,000	1996	50.245	5,024	15,024
1395u(n)(3) .....	42 CFR 402.1(c)(15), 402.105(d)(2)(xii).	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)).	10,000	1996	50.245	5,024	15,024
1395u(o)(3)(B) .....	42 CFR 414.707(b) .....	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)).	10,000	1996	50.245	5,024	15,024
1395u(p)(3)(A) .....	.....	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.	2,000	1988	97.869	1,957	3,957
1395w-3a(d)(4)(A) ...	42 CFR 414.806 .....	Penalty for a pharmaceutical manufacturer's misrepresentation of average sales price of a drug, or biologic.	10,000	2003	28.561	2,856	12,856

## CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description <sup>2</sup>	Pre-inflation penalty (\$)	Date of last penalty figure or adjustment <sup>3</sup>	Percentage increase <sup>4</sup>	Increase (\$) <sup>5</sup>	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>						
1395w-4(g)(1)(B) .....	42 CFR 402.1(c)(17), 402.105(d)(2)(xiii).	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)).	10,000	1996	50.245	5,024	15,024
1395w-4(g)(3)(B) .....	42 CFR 402.1(c)(18), 402.105(d)(2)(xiv).	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)).	10,000	1996	50.245	5,024	15,024
1395w-27(g)(3)(A); 1857(g)(3).	42 CFR 422.760(b); 42 CFR 423.760(b).	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.	25,000	1997	47.177	11,794	36,794
1395w-27(g)(3)(B); 1857(g)(3).	.....	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.	10,000	1997	47.177	4,718	14,718
1395w-27(g)(3)(D); 1857(g)(3).	.....	Penalty for a Medicare Advantage organization's or Part D sponsor's early termination of its contract.	100,000	2000	36.689	36,689	136,689
1395y(b)(3)(C) .....	42 CFR 411.103(b) .....	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.	5,000	1990	78.156	3,908	8,908
1395y(b)(5)(C)(ii) .....	42 CFR 402.1(c)(20), 402.105(b)(2).	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.	1,000	1998	89.361	450	1,450
1395y(b)(6)(B) .....	42 CFR 402.1(c)(21), 402.105(a).	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.	2,000	1994	59.089	1,182	3,182
1395y(b)(7)(B)(i) .....	.....	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.	1,000	2007	13.833	138	1,138



## CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description <sup>2</sup>	Pre-inflation penalty (\$)	Date of last penalty figure or adjustment <sup>3</sup>	Percentage increase <sup>4</sup>	Increase (\$) <sup>5</sup>	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>						
1395y(b)(8)(E) .....	.....	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.	1,000	2007	13.833	138	1,138
1395nn(g)(5) .....	42 CFR 411.361 .....	Penalty for any person that fails to report information required by HHS under Section 1877(f) concerning ownership, investment, and compensation arrangements.	10,000	1989	89.361	8,936	18,936
1395pp(h) .....	42 CFR 402.1(c)(23), 402.105(d)(2)(xv).	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)).	10,000	1996	50.245	5,024	15,024
1395ss(a)(2) .....	42 CFR 402.1(c)(24), 405.105(f)(1).	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.	25,000	1987	106.278	26,569	51,569
1395ss(d)(3)(A)(vi) (II).	.....	Penalty for someone other than issuer that sells or issues a Medicare supplemental policy to beneficiary without a disclosure statement.	15,000	1990	78.156	11,723	26,723
		Penalty for an issuer that sells or issues a Medicare supplemental policy without disclosure statement.	25,000	1990	78.156	19,539	44,539
1395ss(d)(3)(B)(iv) .....	.....	Penalty for someone other than issuer that sells or issues a Medicare supplemental policy without acknowledgement form.	15,000	1990	78.156	11,723	26,723
		Penalty for issuer that sells or issues a Medicare supplemental policy without an acknowledgement form.	25,000	1990	78.156	19,539	44,539
1395ss(p)(8) .....	42 CFR 402.1(c)(25), 402.105(e).	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.	15,000	1990	78.156	11,723	26,723
	42 CFR 402.1(c)(25), 405.105(f)(2).	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.	25,000	1990	78.156	19,539	44,539
1395ss(p)(9)(C) .....	42 CFR 402.1(c)(26), 402.105(e).	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.	15,000	1990	78.156	11,723	26,723

## CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description <sup>2</sup>	Pre-inflation penalty (\$)	Date of last penalty figure or adjustment <sup>3</sup>	Percentage increase <sup>4</sup>	Increase (\$) <sup>5</sup>	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>						
	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.	25,000	1990	78.156	19,539	44,539
1395ss(q)(5)(C) .....	42 CFR 402.1(c)(27), 405.105(f)(5).	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.	25,000	1990	78.156	19,539	44,539
1395ss(r)(6)(A) .....	42 CFR 402.1(c)(28), 405.105(f)(6).	Penalty for any person that fails to provide refunds or credits as required by section 1882(r)(1)(B).	25,000	1990	78.156	19,539	44,539
1395ss(s)(4) .....	42 CFR 402.1(c)(29), 405.105(c).	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.	5,000	1990	78.156	3,908	8,908
1395ss(t)(2) .....	42 CFR 402.1(c)(30), 405.105(f)(7).	Penalty for any issuer of a Medicare supplemental policy that fails to fulfill listed responsibilities.	25,000	1990	78.156	19,539	44,539
1395ss(v)(4)(A) .....	.....	Penalty someone other than issuer who sells, issues, or renews a medigap Rx policy to an individual who is a Part D enrollee.	15,000	2003	28.561	4,284	19,284
		Penalty for an issuer who sells, issues, or renews a Medigap Rx policy who is a Part D enrollee.	25,000	2003	28.561	7,140	32,140
1395bbb(c)(1) .....	42 CFR 488.725(c) .....	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.	2,000	1987	106.278	2,126	4,126
1395bbb(f)(2)(A)(i) ....	42 CFR 488.845(b)(2)(iii)	Maximum daily penalty amount for each day a home health agency is not in compliance with statutory requirements.	10,000	1988	97.869	9,787	19,787
	42 CFR 488.845(b)(3) ...	Penalty per day for home health agency's noncompliance (Upper Range):					
		Minimum .....	8,500	1988	97.869	8,319	16,819
		Maximum .....	10,000	1988	97.869	9,787	19,787
	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.	10,000	1988	97.869	9,787	19,787
	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.	9,000	1988	97.869	8,808	17,808
	42 CFR 488.845(b)(3)(iii)	Penalty for an isolated incident of noncompliance in violation of established HHA policy.	8,500	1988	97.869	8,319	16,819
	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 .....	1,500	1988	97.869	1,468	2,968
		Maximum .....	8,500	1988	97.869	8,319	16,819

## CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description <sup>2</sup>	Pre-inflation penalty (\$)	Date of last penalty figure or adjustment <sup>3</sup>	Percentage increase <sup>4</sup>	Increase (\$) <sup>5</sup>	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>						
	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 ..... Maximum .....	500 4,000	1988 1988	97.869 97.869	489 3,915	989 7,915
42 CFR 488.845(b)(6) .....	.....	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: Minimum ..... Maximum .....	1,000 10,000	1988 1988	97.869 97.869	979 9,787	1,979 19,787
	42 CFR 488.845(d)(1)(ii)	Penalty for each day of noncompliance (Maximum).	10,000	1988	97.869	9,787	19,787
1396b(m)(5)(B) .....	42 CFR 460.46 .....	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. Penalty for a PACE organization misrepresenting or falsifying information to CMS, the State, or an individual or other entity. 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. 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.	15,000 100,000 25,000 100,000 25,000 25,000	1997 1997 1997 1997 1997 1997	47.177 47.177 47.177 47.177 47.177 47.177	7,077 47,177 11,794 47,177 11,794 11,794	22,077 147,177 36,794 147,177 36,794 36,794
1396r(h)(3)(C)(ii)(I) ...	42 CFR 488.408(d)(1)(iii)	Penalty per day for a nursing facility's failure to meet a Category 2 Certification: Minimum ..... Maximum .....	50 3,000	1987 1987	106.278 106.278	53 3,188	103 6,188
	42 CFR 488.408(d)(1)(iv).	Penalty per instance for a nursing facility's failure to meet Category 2 certification: Minimum ..... Maximum .....	1,000 10,000	1987 1987	106.278 106.278	1,063 10,628	2,063 20,628
	42 CFR 488.408(e)(1)(iii)	Penalty per day for a nursing facility's failure to meet Category 3 certification: Minimum ..... Maximum .....	3,050 10,000	1987 1987	106.278 106.278	3,241 10,628	6,291 20,628
	42 CFR 488.408(e)(1)(iv).	Penalty per instance for a nursing facility's failure to meet Category 3 certification: Minimum ..... Maximum .....	1,000 10,000	1987 1987	106.278 106.278	1,063 10,628	2,063 20,628
	42 CFR 488.408(e)(2)(ii)	Penalty per instance for a nursing facility's failure to meet Category 3 certification, which results in immediate jeopardy: Minimum ..... Maximum .....	1,000 10,000	1987 1987	106.278 106.278	1,063 10,628	2,063 20,628

## CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description <sup>2</sup>	Pre-inflation penalty (\$)	Date of last penalty figure or adjustment <sup>3</sup>	Percentage increase <sup>4</sup>	Increase (\$) <sup>5</sup>	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>						
	42 CFR 488.438(a)(1)(i)	Penalty per day for nursing facility's failure to meet certification (Upper Range):					
		Minimum .....	3,050	1987	106.278	3,241	6,291
		Maximum .....	10,000	1987	106.278	10,628	20,628
	42 CFR 488.438(a)(1)(ii)	Penalty per day for nursing facility's failure to meet certification (Lower Range):					
		Minimum .....	50	1987	106.278	53	103
		Maximum .....	3,000	1987	106.278	3,188	6,188
	42 CFR 488.438(a)(2) ...	Penalty per instance for nursing facility's failure to meet certification:					
		Minimum .....	1,000	1987	106.278	1,063	2,063
		Maximum .....	10,000	1987	106.278	10,628	20,628
1396r(f)(2)(B)(iii)(I)(c)	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 CMP authority, but a specific CMP amount (CMP at this level) that is the triggering condition for disapproval].	5,000	1987	106.278	5,314	10,314
1396r(h)(3)(C)(iii)(I) ...	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].	5,000	1987	106.278	5,314	10,314
1396t(j)(2)(C) .....	.....	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 .....	1	1990	78.156	1	2
		Maximum .....	10,000	1990	78.156	7,816	17,816
1396u–2(e)(2)(A)(i) ...	42 CFR 438.704 .....	Penalty for a Medicaid managed care organization that fails substantially to provide medically necessary items and services.	25,000	1997	47.177	11,794	36,794
		Penalty for Medicaid managed care organization that imposes premiums or charges on enrollees in excess of the premiums or charges permitted.	25,000	1997	47.177	11,794	36,794
		Penalty for a Medicaid managed care organization that misrepresents or falsifies information to another individual or entity.	25,000	1997	47.177	11,794	36,794
		Penalty for a Medicaid managed care organization that fails to comply with the applicable statutory requirements for such organizations.	25,000	1997	47.177	11,794	36,794
1396u–2(e)(2)(A)(ii) ..	42 CFR 438.704 .....	Penalty for a Medicaid managed care organization that misrepresents or falsifies information to the HHS Secretary.	100,000	1997	47.177	47,177	147,177
		Penalty for Medicaid managed care organization that acts to discriminate among enrollees on the basis of their health status.	100,000	1997	47.177	47,177	147,177
1396u–2(e)(2)(A)(iv)	42 CFR 438.704 .....	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.	15,000	1997	47.177	7,077	22,077
1396u(h)(2) .....	42 CFR 441, Subpart I ..	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.	10,000	1990	106.278	10,628	20,628

## CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description <sup>2</sup>	Pre-inflation penalty (\$)	Date of last penalty figure or adjustment <sup>3</sup>	Percentage increase <sup>4</sup>	Increase (\$) <sup>5</sup>	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>						
1396w-2(c)(1) .....	.....	Penalty for disclosing information related to eligibility determinations for medical assistance programs.	10,000	2009	10.02	1,002	11,002
1903(m)(5)(B) .....	42 CFR 460.46 .....	Penalty for PACE organization's practice that would reasonably be expected to have the effect of denying or discouraging enrollment:					
		Minimum .....	15,000	1997	47.177	7,077	22,077
		Maximum .....	100,000	1997	47.177	47,177	147,177
		Penalty for a PACE organization that charges excessive premiums.	25,000	1997	47.177	11,794	36,794
		Penalty for a PACE organization misrepresenting or falsifying information to CMS, the State, or an individual or other entity.	100,000	1997	47.177	47,177	147,177
		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.	25,000	1997	47.177	11,794	36,794
		Penalty for involuntarily disenrolling a participant.	25,000	1997	47.177	11,794	36,794
		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.	25,000	1997	47.177	11,794	36,794
18041(c)(2) .....	45 CFR 150.315 and 45 CFR 156.805(c).	Failure to comply with requirements of 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)(C)).	100	1996	50.245	50	150
18081(h)(1)(A)(i)(II) ..	42 CFR 155.285 .....	Penalty for providing false information on Exchange application.	25,000	2010	8.745	2,186	27,186
18081(h)(1)(B) .....	42 CFR 155.285 .....	Penalty for knowingly or willfully providing false information on Exchange application.	250,000	2010	8.745	21,862	271,862
18081(h)(2) .....	42 CFR 155.260 .....	Penalty for knowingly or willfully disclosing protected information from Exchange.	25,000	2010	8.745	2,186	27,186
31 U.S.C. (HHS): 1352 .....	45 CFR 93.400(e) .....	Penalty for the first time an individual makes an expenditure prohibited by regulations regarding lobbying disclosure, absent aggravating circumstances.	10,000	1989	89.361	8,936	18,936
		Penalty for second and subsequent offenses by individuals who make an expenditure prohibited by regulations regarding lobbying disclosure:					
		Minimum .....	10,000	1989	89.361	8,936	18,936
		Maximum .....	100,000	1989	89.361	89,361	189,361
		Penalty for the first time an individual fails to file or amend a lobbying disclosure form, absent aggravating circumstances.	10,000	1989	89.361	8,936	18,936
		Penalty for second and subsequent offenses by individuals who fail to file or amend a lobbying disclosure form, absent aggravating circumstances:					
		Minimum .....	10,000	1989	89.361	8,936	18,936
		Maximum .....	100,000	1989	89.361	89,361	189,361
	45 CFR 93, Appendix A	Penalty for failure to provide certification regarding lobbying in the award documents for all sub-awards of all tiers:					
		Minimum .....	10,000	1989	89.361	8,936	18,936
		Maximum .....	100,000	1989	89.361	89,361	189,361

## CALCULATION OF CMP ADJUSTMENTS—Continued

Citation		Description <sup>2</sup>	Pre-inflation penalty (\$)	Date of last penalty figure or adjustment <sup>3</sup>	Percentage increase <sup>4</sup>	Increase (\$) <sup>5</sup>	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>						
3801–3812 .....	45 CFR 79.3(a)(1)(iv) .....	Penalty for failure to provide statement regarding lobbying for loan guarantee and loan insurance transactions:					
		Minimum .....	10,000	1989	89.361	8,936	18,936
		Maximum .....	100,000	1989	89.361	89,361	189,361
		Penalty against any individual who—with knowledge or reason to know—makes, presents or submits a false, fictitious or fraudulent claim to the Department.	5,000	1988	97.869	4,894	9,894
	45 CFR 79.3(b)(1)(ii) .....	Penalty against any individual who—with knowledge or reason to know—makes, presents or submits a false, fictitious or fraudulent claim to the Department.	5,000	1988	97.869	4,894	9,894

<sup>1</sup> Some HHS components have not promulgated regulations regarding their civil monetary penalties-specific statutory authorities.

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

<sup>3</sup> Statutory, or non-Inflation Act Adjustment.

<sup>4</sup> Based on the lesser of the CPI-U multiplier for October 2015, or 150%.

<sup>5</sup> Rounded to the nearest dollar.

### III. Environmental Impact

HHS has determined that this interim final rule (IFR) does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental impact assessment nor an environmental impact statement is required.

### IV. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35) and its implementing regulations (5 CFR part 1320), HHS reviewed this IFR and determined that there are no new collections of information contained therein.

### V. Regulatory Flexibility Act

When an agency promulgates a final rule under 5 U.S.C. 553, after being required by that section or any other law to publish a general notice of proposed rulemaking, the Regulatory Flexibility Act (RFA) mandates that the agency prepare an RFA analysis. 5 U.S.C. 604(a). An RFA analysis is not required when a rule is exempt from notice and comment rulemaking under 5 U.S.C. 553(b). This interim final rule is exempt from notice and comment rulemaking. Therefore, no RFA analysis is required under 5 U.S.C. 604 and none was prepared.

### VI. Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits

(including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Agencies must prepare a regulatory impact analysis for major rules with economically significant effects (\$100 million or more in any 1 year). HHS has determined that this IFR is not economically significant.

HHS analyzed the economic significance of this IFR, by collecting data for fiscal years 2010 through 2014 on the total value of civil monetary penalties collected by Operating/Staff Divisions, except in the case of CMS, for which HHS used collections data through FY 2015. Such data included the statutory authority for the civil monetary penalty, which HHS used to apply the appropriate multiplier for each of the penalties collected. With respect to CMS, HHS determined the multiplier for the CMS collections by pro rating all of the multipliers for the civil monetary penalty authorities attributed to CMS.

HHS then applied the multiplier to collections for each Fiscal Year (2010 through 2014) to calculate the collections for each Fiscal Year with the inflation adjustment. HHS also performed an additional calculation for FY 2014/2015 using the inflated collections amount for FY 2015 for CMS and using the inflated collections amount for all other Operating/Staff Divisions for FY 2014. When collections

were adjusted for inflation, the Department's lowest collection amount was \$58,332,000 for FY 2012 and the highest total was \$168,000,000 for FY 2014/2015.

Finally, HHS subtracted the collections value for a Fiscal Year (for example, FY 2010) from the collections value for the same Fiscal Year with the inflation adjustment (for example, FY 2010 with inflation adjustment) to assess the economic significance of this IFR for that Fiscal Year (for example, FY 2010 Economic Significance). When the calculations were completed, the Fiscal Year Economic Significance values ranged from a low of \$23,698,917 for FY 2013, to a high of \$70,913,713 for FY 2014/2015. Based on these calculations, HHS does not believe this IFR will be economically significant as defined in Executive Order 12866.

### VII. Unfunded Mandates Reform Act of 1995 Determination

Section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act) (2 U.S.C. 1532) requires that covered agencies prepare a budgetary impact statement before promulgating a rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any one year. If a budgetary impact statement is required, section 205 of the Unfunded Mandates Act also requires covered agencies to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. HHS has

determined that this IFR does not result in expenditures by State, local, and tribal governments, or by the private sector, of \$100 million or more in any one year. Accordingly, HHS has not prepared a budgetary impact statement or specifically addressed the regulatory alternatives considered.

#### **VIII. Executive Order 13132 Determination**

HHS has determined that this IFR does not have any Federalism implications, as required by Executive Order 13132.

#### **List of Subjects**

##### *42 CFR Part 3*

Administrative practice and procedure, Conflicts of interests, Health records, Privacy, Reporting and recordkeeping requirements.

##### *42 CFR Part 402*

Administrative practice and procedure, Medicaid, Medicare, Penalties.

##### *42 CFR Part 403*

Grant programs—health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

##### *42 CFR Part 411*

Kidney diseases, Medicare, Physician referral, Reporting and recordkeeping requirements.

##### *42 CFR Part 412*

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

##### *42 CFR Part 422*

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

##### *42 CFR Part 423*

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

##### *42 CFR Part 438*

Grant programs—health, Medicaid, Reporting and recordkeeping requirements.

##### *42 CFR Part 460*

Aged, Health care, Health records, Medicaid, Medicare, Reporting and recordkeeping requirements.

##### *42 CFR Part 483*

Grant programs—health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

##### *42 CFR Part 488*

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

##### *42 CFR Part 493*

Administrative practice and procedure, Grant programs—health, Health facilities, Laboratories, Medicaid, Medicare, Penalties, Reporting and recordkeeping requirements.

##### *42 CFR Part 1003*

Fraud, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping.

##### *45 CFR Part 79*

Administrative practice and procedure, Claims, Fraud, Penalties.

##### *45 CFR Part 93*

Government contracts, Grants programs, Loan programs, Lobbying, Penalties.

##### *45 CFR Part 102*

Administrative practice and procedure, Penalties.

##### *45 CFR Part 147*

Health care, Health insurance, Reporting and recordkeeping requirements.

##### *45 CFR Part 155*

Administrative practice and procedure, Advertising, Brokers, Conflict of interest, Consumer protection, Grant programs—health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs—health, Organization and functions (Government agencies), Medicaid, Public assistance programs, Reporting and recordkeeping requirements, Safety, State and local governments, Technical assistance, Women, and Youth.

##### *45 CFR Part 156*

Administrative practice and procedure, Advertising, Advisory committees, Brokers, Conflict of interest, Consumer protection, Grant programs—health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records,

Hospitals, Indians, Individuals with disabilities, Loan programs—health, Organization and functions (Government agencies), Medicaid, Public assistance programs, Reporting and recordkeeping requirements, Safety, State and local governments, Sunshine Act, Technical assistance, Women, and Youth.

##### *45 CFR Part 158*

Administrative practice and procedure, Claims, Health care, Health insurance, Health plans, penalties, Reporting and recordkeeping requirements, Premium revenues, Medical loss ratio, Rebating.

##### *45 CFR Part 160*

Administrative practice and procedures, Penalties, Records and recordkeeping requirements.

##### *45 CFR Part 303*

Child support, Standards for program operations, Penalties.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 42 CFR chapter I and 45 CFR subtitle A, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV, the Office of the Inspector General amends 42 CFR chapter 42 CFR chapter V, and the Administration for Children and Families amends 45 CFR chapter III as follows:

#### **Title 42—Public Health**

#### **Chapter I—Public Health Service, Department of Health and Human Services**

#### **PART 3—PATIENT SAFETY ORGANIZATIONS AND PATIENT SAFETY WORK PRODUCT**

- 1. The authority citation for part 3 continues to read as follows:

**Authority:** 42 U.S.C. 216, 299b–21 through 299b–26; 42 U.S.C. 299c–6.

- 2. Section 3.404 is revised to read as follows:

##### **§ 3.404 Amount of a civil money penalty.**

(a) The amount of a civil money penalty will be determined in accordance with paragraph (b) of this section and § 3.408.

(b) The Secretary may impose a civil monetary penalty in the amount of not more than \$11,000. This amount has been updated and will be updated annually, in accordance with the Federal Civil Monetary penalty Inflation Adjustment Act of 1990 (Pub. L. 101–140), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114–74). The amount, as

updated, is published at 45 CFR part 102.

**CHAPTER IV—CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**PART 402—CIVIL MONEY PENALTIES, ASSESSMENTS, AND EXCLUSIONS**

■ 3. The authority citation for part 402 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

**§ 402.105 [Amended]**

■ 4. In the table below, § 402.105 is amended in each paragraph indicated in the first column, by removing the phrase indicated in the second column and adding in its place the phrase in the third column:

Paragraph	Remove	Add
(a) .....	“\$2,000 for each service” .....	“\$2,000 as adjusted annually under 45 CFR part 102 for each service”.
(b) introductory text .....	“not more than \$1,000 for” .....	“not more than \$1,000 as adjusted annually under 45 CFR part 102 for”.
(c) introductory text .....	“not more than \$5,000 for” .....	“not more than \$5,000 as adjusted annually under 45 CFR part 102 for”.
(d)(1) .....	“not more than \$10,000 for” .....	“not more than \$10,000 as adjusted annually under 45 CFR part 102 for”.
(d)(2) introductory text .....	“not more than \$10,000 for” .....	“not more than \$10,000 as adjusted annually under 45 CFR part 102 for”.
(d)(3) .....	“not more than \$10,000 for” .....	“not more than \$10,000 as adjusted annually under 45 CFR part 102 for”.
(d)(4) .....	“not more than \$10,000 for” .....	“not more than \$10,000 as adjusted annually under 45 CFR part 102 for”.
(d)(5) .....	“not more than \$10,000 for” .....	“not more than \$10,000 as adjusted annually under 45 CFR part 102 for”.
(d)(5) .....	“will not exceed \$150,000” .....	“will not exceed \$150,000 as annually adjusted under 45 CFR part 102”.
(e) .....	“not more than \$15,000 for” .....	“not more than \$15,000 as adjusted annually under 45 CFR part 102 for”.
(f) introductory text .....	“not more than \$25,000 for” .....	“not more than \$25,000 as adjusted annually under 45 CFR part 102 for”.
(g) .....	“not more than \$100 for” .....	“not more than \$100 as adjusted annually under 45 CFR part 102 for”.
(h) .....	“not more than \$100,000 for” .....	“not more than \$10,000 as adjusted annually under 45 CFR part 102 for”.
(h) .....	“will not exceed \$1,000,000” .....	“will not exceed \$1,000,000 as annually adjusted under 45 CFR part 102”.

**PART 403—SPECIAL PROGRAMS AND PROJECTS**

■ 5. The authority citation for part 403 continues to read as follows:

**Authority:** 42 U.S.C. 1395b–3 and Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

**§ 403.912 [Amended]**

■ 6. In the table below, § 403.912 is amended in each paragraph indicated in

the first column, by removing the phrase indicated in the third column and adding in its place the phrase indicated in the fourth column:

Paragraph	Remove	Add
(a)(1) .....	“not less than \$1,000, but not more than \$10,000 for”.	“not less than \$10,000, but not more than \$100,000, as adjusted annually under 45 CFR part 102 for”.
(a)(2) .....	“will not exceed \$150,000” .....	“will not exceed \$150,000 as adjusted annually under 45 CFR part 102”.
(b)(1) .....	“not less than \$10,000, but not more than \$100,000 for”.	“not less than \$10,000, but not more than \$100,000, as adjusted annually under 45 CFR part 102 for”.
(b)(2) .....	“will not exceed \$1,000,000” .....	“will not exceed \$1,000,000 as adjusted annually under 45 CFR part 102”.
(c)(2) .....	“with a maximum combined annual total of \$1,150,000”.	“with a maximum combined annual total of \$1,150,000 as adjusted annually under 45 CFR part 102”.

**PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT**

■ 7. The authority citation for part 411 continues to read as follows:

**Authority:** Secs. 1102, 1860D–1 through 1860D–42, 1871, and 1877 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn).

**§§ 411.103 and 411.361 [Amended]**

■ 8. In the table below, for each section and paragraph indicated in the first two columns, remove the phrase indicated in the third column and add in its place



the phrase indicated in the fourth column:

Section	Paragraphs	Remove	Add
§ 411.103 .....	(b)(1) .....	“up to \$5,000 for” .....	“up to \$5,000 as adjusted annually under 45 CFR part 102 for”.
	(b)(2) .....	“up to \$5,000” .....	“up to \$5,000 as adjusted annually under 45 CFR part 102”.
§ 411.361 .....	(f) .....	“up to \$10,000 for” .....	“up to \$10,000 as adjusted annually under 45 CFR part 102 for”.

#### PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 12. The authority citation for part 412 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), sec. 124 of Pub. L. 106–113 (113 Stat. 1501A–332), sec. 1206 of Pub. L. 113–67, and sec. 112 of Pub. L. 113–93.

#### § 412.612 [Amended]

■ 13. Section 412.612 is amended as follows:

■ a. In paragraph (b)(1)(i), by removing the phrase “not more than \$1,000 for” and adding in its place the phrase “not more than \$1,000 as adjusted annually under 45 CFR part 102 for”; and

■ b. In paragraph (b)(1)(ii), by removing the phrase “not more than \$5,000 for” and adding in its place the phrase “not more than \$5,000 as adjusted annually under 45 CFR part 102 for”.

#### PART 422—MEDICARE ADVANTAGE PROGRAM

■ 14. The authority citation for part 422 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

#### § 422.760 [Amended]

■ 15. In the table below, § 422.760 is amended in each paragraph indicated in the first column, by removing the phrase indicated in the second column and add in its place the phrase indicated in the third column:

Paragraph	Remove	Add
(b)(1) .....	“up to \$25,000 for each” .....	“up to \$25,000 as adjusted annually under 45 CFR part 102 for each”.
(b)(2) .....	“up to \$25,000 for each” .....	“up to \$25,000 as adjusted annually under 45 CFR part 102 for each”.
(b)(3) .....	“determination—up to \$10,000” ....	“determination—up to \$10,000 as adjusted annually under 45 CFR part 102”.
(b)(4) .....	“\$250 per Medicare enrollee” .....	“\$250 as adjusted annually under 45 CFR part 102 per Medicare enrollee”.
(b)(4) .....	“or \$100,000, whichever is greater”.	“or \$100,000 as adjusted annually under 45 CFR part 102, whichever is greater”.
(c)(1) .....	“not more than \$25,000 for” .....	“not more than \$25,000 as adjusted annually under 45 CFR part 102 for”.
(c)(2) .....	“not more than \$100,000 for” .....	“not more than \$100,000 as adjusted annually under 45 CFR part 102 for”.
(c)(4) .....	“\$15,000 for each individual” .....	“\$15,000 as adjusted annually under 45 CFR part 102 for each individual”.

#### PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 16. The authority citation for part 423 continues to read as follows:

**Authority:** Sections 1102, 1106, 1860D–1 through 1860D–42, and 1871 of the Social

Security Act (42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh).

#### § 423.760 [Amended]

■ 17. In the table below, § 423.760 is amended in each paragraph indicated by the first column, by removing the

phrase indicated in the second column and add in its place the phrase indicated in the third column:

Paragraph	Remove	Add
(b)(1) .....	“enrollees—up to \$25,000 for each determination”.	“enrollees—up to \$25,000 as adjusted annually under 45 CFR part 102 for each determination”.
(b)(2) .....	“of up to \$25,000 for each Part D enrollee”.	“of up to \$25,000 as adjusted annually under 45 CFR part 102 for each Part D enrollee”.
(b)(3) .....	“up to \$10,000” .....	“up to \$10,000 as adjusted annually under 45 CFR part 102”.
(b)(4) .....	“\$250 per Medicare enrollee” .....	“\$250 as adjusted annually under 45 CFR part 102 per Medicare enrollee”.
(b)(4) .....	“or \$100,000, whichever is greater”.	“or \$100,000 as adjusted annually under 45 CFR part 102, whichever is greater”.
(c)(1) .....	“of not more than \$25,000 for each”.	“of not more than \$25,000 as adjusted annually under 45 CFR part 102 for each”.

Paragraph	Remove	Add
(c)(2) .....	"not more than \$100,000 for each"	"not more than \$100,000 as adjusted annually under 45 CFR part 102 for each".
(c)(4) .....	"\$15,000 for each individual" .....	"\$15,000 as adjusted annually under 45 CFR part 102 for each individual".

## PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

■ 18. The authority citation for part 483 continues to read as follows:

**Authority:** Secs. 1102, 1128I, 1819, 1871 and 1919 of the Social Security Act (42 U.S.C. 1302, 1320a–7, 1395i, 1395hh and 1396r).

### § 483.20 [Amended]

■ 19. Section 483.20 is amended as follows:

- a. In paragraph (j)(1)(i), by removing the phrase "not more than \$1,000 for" and adding in its place the phrase "not more than \$1,000 as adjusted annually under 45 CFR part 102 for"; and
- b. In paragraph (j)(1)(ii), by removing the phrase "not more than \$5,000 for" and adding in its place the phrase "not

more than \$5,000 as adjusted annually under 45 CFR part 102 for".

### § 483.151 [Amended]

■ 20. Section 483.151 is amended as follows:

- a. In paragraph (b)(2)(iv), by removing the phrase "not less than \$5,000; or" and adding in its place the phrase "not less than \$5,000 as adjusted annually under 45 CFR part 102; or";
- b. In paragraph (b)(3)(iii), by removing the phrase "not less than \$5,000 for" and adding in its place the phrase "not less than \$5,000 as adjusted annually under 45 CFR part 102 for"; and
- c. In paragraph (c)(1), by removing the phrase "not less than \$5,000" and adding in its place the phrase "not less than \$5,000 as adjusted annually under 45 CFR part 102".

## PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 21. The authority citation for part 488 continues to read as follows:

**Authority:** Secs. 1102, 1128I, 1864, 1865, 1871 and 1875 of the Social Security Act, unless otherwise noted (42 U.S.C. 1302, 1320a–7j, 1395aa, 1395bb, 1395hh) and 1395ll.

### §§ 488.307, 488.408, 488.438, 488.446, 488.725, and 488.845 [Amended]

■ 22. In the table below, for each section and paragraph indicated in the first two columns, remove the phrase indicated in the third column and add in its place the phrase indicated in the fourth column:

Section	Paragraph	Remove	Add
488.307 .....	(c) .....	"not to exceed \$2,000" .....	"not to exceed \$2,000 as adjusted annually under 45 CFR part 102".
488.408 .....	(d)(1)(iii) .....	"\$50–\$3,000 per day" .....	"\$50–\$3,000 as adjusted annually under 45 CFR part 102 per day".
	(d)(1)(iv) .....	"\$1,000–\$10,000 per instance".	"\$1,000–\$10,000 as adjusted annually under 45 CFR part 102 per instance".
	(e)(1)(iii) .....	"\$3,050–\$10,000 per day"	"\$3,050–\$10,000 as adjusted annually under 45 CFR part 102 per day".
	(e)(1)(iv) .....	"\$1,000–\$10,000 per instance".	"\$1,000–\$10,000 as adjusted annually under 45 CFR part 102 per instance".
	(e)(2)(ii) .....	"\$3,050–\$10,000 per day or \$1,000–\$10,000 per instance".	"\$3,050–\$10,000 as adjusted annually under 45 CFR part 102 per day or \$1,000–\$10,000 as adjusted annually under 45 CFR part 102 per instance".
488.438 .....	(a)(1)(i) .....	"Upper range—\$3,050–\$10,000".	"Upper range".
	(a)(1)(i) .....	"\$3,050–\$10,000 per day"	"\$3,050–\$10,000 as adjusted annually under 45 CFR part 102 per day".
	(a)(1)(ii) .....	"Lower range—\$50–\$3,000".	"Upper range".
	(a)(1)(ii) .....	"\$50–\$3,000 per day" .....	"\$50–\$3,000 as adjusted annually under 45 CFR part 102 per day".
	(a)(2) .....	"\$1,000–\$10,000 per instance".	"\$1,000–\$10,000 as adjusted annually under 45 CFR part 102 per instance".
488.446 .....	(a)(1) .....	"A minimum of \$500 for" ..	"A minimum of \$500 as adjusted annually under 45 CFR part 102 for".
	(a)(2) .....	"A minimum of \$1,500 for"	"A minimum of \$1,500 as adjusted annually under 45 CFR part 102 for".
	(a)(3) .....	"A minimum of \$3,000 for"	"A minimum of \$3,000 as adjusted annually under 45 CFR part 102 for".
488.725 .....	(c) .....	"not to exceed \$2,000" .....	"not to exceed \$2,000 as adjusted annually under 45 CFR part 102".
488.845 .....	(b)(2)(iii) .....	"shall exceed \$10,000 for"	"will exceed \$10,000 as adjusted under 45 CFR part 102 for".
	(b)(3) introductory text .....	"upper range of \$8,500 to \$10,000 per day".	"upper range of \$8,500 to \$10,000 as adjusted annually under 45 CFR part 102 per day".
	(b)(3)(i) .....	"\$10,000 per day" .....	"\$10,000 as adjusted annually under 45 CFR part 102 per day".
	(b)(3)(ii) .....	"\$9,000 per day" .....	"\$9,000 as adjusted annually under 45 CFR part 102 per day".

Section	Paragraph	Remove	Add
	(b)(3)(iii) .....	“\$8,500 per day” .....	“\$8,500 as adjusted annually under 45 CFR part 102 per day”.
	(b)(4) .....	“range of \$1,500–\$8,500 per day”.	“range of \$1,500–\$8,500 as adjusted annually under 45 CFR part 102 per day”.
	(b)(5) .....	“range of \$500–\$4,000 are imposed”.	“range of \$500–\$4,000 as adjusted annually under 45 CFR part 102 are imposed”.
	(b)(6) .....	“range of \$1,000 to \$10,000 per instance, not to exceed \$10,000 each day”.	“range of \$1,000 to \$10,000 as adjusted annually under 45 CFR part 102 per instance, not to exceed \$10,000 as adjusted annually under 45 CFR part 102 each day”.
	(d)(1)(ii) .....	“maximum of \$10,000 per day”.	“maximum of \$10,000 as adjusted annually under 45 CFR part 102 per day”.

## PART 493—LABORATORY REQUIREMENTS

■ 23. The authority citation for part 493 continues to read as follows:

**Authority:** Sec. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following sections 1861(s)(11) through 1861(s)(16) of the Social Security Act (42 U.S.C. 263a, 1302, 1395x(e), the sentence following 1395x(s)(11) through 1395x(s)(16)), and the Pub. L. 112–202 amendments to 42 U.S.C. 263a.

### § 493.1834 [Amended]

■ 24. Section 493.1834 is amended as follows:

■ a. In paragraph (d)(2)(i), by removing the phrase “\$3,050–\$10,000 per day” and adding in its place the phrase

“\$3,050–\$10,000 as adjusted annually under 45 CFR part 102 per day”; and  
 ■ b. In paragraph (d)(2)(ii), by removing the phrase “\$50–\$3,000 per day” and adding in its place the phrase “\$50–\$3,000 as adjusted annually under 45 CFR part 102 per day”.

## CHAPTER V—OFFICE OF INSPECTOR GENERAL—HEALTH CARE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

## PART 1003—CIVIL MONEY PENALTIES, ASSESSMENTS AND EXCLUSIONS

■ 25. The authority citation for part 1003 continues to read as follows:

**Authority:** 42 U.S.C. 262a, 1302, 1320–7, 1320a–7a, 1320b–10, 1395u(j), 1395u(k),

1395cc(j), 1395w–141(i)(3), 1395dd(d)(1), 1395mm, 1395nn(g), 1395ss(d), 1396b(m), 11131(c), and 11137(b)(2).

### § 1003.103 [Amended]

■ 26. Section 1003.103 is amended:

■ a. In paragraph (c)—

■ i. By removing the footnote in paragraph (c); and

■ ii. In paragraph (c) by removing the phrase “not more than \$11,000 for each payment” and adding in its place the phrase “not more than \$10,000 for each payment”; and

■ b. In the table below, § 1003.103 is further amended in each paragraph indicated by the first column by adding the footnote in the third column after the phrase in the second column:

Paragraph	Text	Add footnote
(a)(1) .....	“\$2,000” .....	“1. This penalty amount is updated annually, as adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101–140), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114–74). Annually adjusted amounts are published at 45 CFR part 102.”
(a)(2) .....	“\$10,000” .....	“2. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
(b) .....	“not more than \$15,000” .....	“3. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
	“not more than \$100,000” .....	“4. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
(c) .....	“not more than \$10,000” .....	“5. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
(d)(1) .....	“not more than \$5,000” .....	“6. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
	“not more than \$25,000” .....	“7. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
(e)(1) .....	“not more than \$50,000” .....	“8. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
	“will not exceed \$25,000;” .....	“9. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
(e)(2) .....	“not more than \$50,000” .....	“10. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
(f)(1) introductory text .....	“up to \$25,000” .....	“11. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
(f)(2) introductory text .....	“up to \$25,000” .....	“12. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
(f)(3) introductory text .....	“up to \$100,000” .....	“13. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
(f)(5) .....	“an additional \$15,000” .....	“14. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
(g) .....	“not more than \$25,000” .....	“15. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”

Paragraph	Text	Add footnote
(h)(1) .....	“not more than \$50,000” .....	“16. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
(h)(2)(i)(1) .....	“\$5,000” .....	“17. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
(j) .....	“not more than \$10,000” .....	“18. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
(k) .....	“not more than \$2,000” .....	“19. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
(l) .....	“not more than \$250,000” .....	“20. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
(l) .....	“and not more than \$500,000” .....	“21. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”
(m) .....	“not more than \$10,000” .....	“22. This penalty amount is adjusted annually for inflation, and is published at 45 CFR part 102.”

## Title 45—Public Welfare

### Subtitle A—Department of Health and Human Services

#### PART 79—PROGRAM FRAUD CIVIL PENALTIES

■ 27. The authority for part 79 continues to read as follows:

**Authority:** 31 U.S.C. 3801–3812.

■ 28. In § 79.3, paragraph (a)(1)(iv) is amended by revising footnote 1 and paragraph (b)(1)(ii) is amended by revising footnote 2 to read as follows:

#### § 79.3 Basis for civil penalties and assessments.

- (a) \* \* \*  
(1) \* \* \*  
(iv) \* \* \*

<sup>1</sup> The amounts specified in this section are updated annually, as adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101–140), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114–74). Annually adjusted amounts are published at 45 CFR part 102.

\* \* \* \* \*

- (b) \* \* \*  
(1) \* \* \*  
(ii) \* \* \*

<sup>2</sup> The amounts specified in this section are updated annually, as adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101–140), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114–74). Annually adjusted amounts are published at 45 CFR part 102.

\* \* \* \* \*

#### PART 93—NEW RESTRICTIONS ON LOBBYING

■ 29. The authority for part 93 continues to read as follows:

**Authority:** Section 319, Public Law 101–121 (31 U.S.C. 1352); (5 U.S.C. 301).

■ 30. Section § 93.400 is amended in paragraph (a) by adding a footnote at the end of the phrase “not less than \$10,000 and not more than \$100,000” to read as follows:

#### § 93.400 Penalties.

- (a) \* \* \*

<sup>1</sup> The amounts specified in this section are updated annually, as adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101–140), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114–74). Annually adjusted amounts are published at 45 CFR part 102.

\* \* \* \* \*

■ 31. Appendix A to part 93 is amended in the undesignated paragraph following paragraph (3), under “Certification for Contracts, Grants, Loans, and Cooperative Agreements,” by adding a footnote at the end of the phrase “of not less than \$10,000 and not more than 100,000” to read as follows:

#### Appendix A—Certification Regarding Lobbying

##### Certification for Contracts, Grants, Loans, and Cooperative Agreements

\* \* \* \* \*

- (3) \* \* \*

<sup>1</sup> The amounts specified in Appendix A to Part 93 are updated annually, as adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101–140), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114–74). Annually adjusted amounts are published at 45 CFR part 102.

\* \* \* \* \*

■ 32. Part 102 is added to subchapter A to read as follows:

#### 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.

#### § 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 enforced 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.

**CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS**  
[Effective September 6, 2016]

Citation		HHS agency	Description <sup>2</sup>	Date of last penalty figure or adjustment <sup>3</sup>	Pre-inflation penalty (\$)	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>					
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.	1988	50,000	98,935
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.	1988	1,000,000	1,978,690
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.	1988	100,000	197,869
333(f)(1)(A) .....	.....	FDA	Penalty for any person who violates a requirement related to devices for each such violation.	1990	15,000	26,723
333(f)(2)(A) .....	.....	FDA	Penalty for aggregate of all violations related to devices in a single proceeding.	1990	1,000,000	1,781,560
			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.	1996	50,000	75,123
			Penalty in the case of any other person other than an individual for such introduction or delivery of adulterated food.	1996	250,000	375,613
333(f)(3)(A) .....	.....	FDA	Penalty for aggregate of all such violations related to adulterated food adjudicated in a single proceeding.	1996	500,000	751,225
			Penalty for all violations adjudicated in a single proceeding for any person who fails to submit certification required by 42 U.S.C. 282(j)(5)(B) or knowingly submitting a false certification.	2007	10,000	11,383
			Penalty for each day the above violation is not corrected after a 30-day period following notification until the violation is corrected.	2007	10,000	11,383
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).	2007	250,000	284,583
333(f)(4)(A)(ii) .....	.....	FDA	Penalty for aggregate of all such above violations in a single proceeding.	2007	1,000,000	1,138,330
			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.	2007	250,000	284,583
			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.	2007	1,000,000	1,138,330
333(f)(9)(A) .....	.....	FDA	Penalty for aggregate of all such above violations adjudicated in a single proceeding.	2007	10,000,000	11,383,300
			Penalty for any person who violates a requirement which relates to tobacco products for each such violation.	2009	15,000	16,503
			Penalty for aggregate of all such violations of tobacco product requirement adjudicated in a single proceeding.	2009	1,000,000	1,100,200
333(f)(9)(B)(i)(I) .....	.....	FDA	Penalty per violation related to violations of tobacco requirements.	2009	250,000	275,050
			Penalty for aggregate of all such violations of tobacco product requirements adjudicated in a single proceeding.	2009	1,000,000	1,100,200
			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.	2009	250,000	275,050

**CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued**  
 [Effective September 6, 2016]

Citation		HHS agency	Description <sup>2</sup>	Date of last penalty figure or adjustment <sup>3</sup>	Pre-inflation penalty (\$)	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>					
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.	2009	1,000,000	1,100,200
			Penalty for aggregate of all such violations related to tobacco product requirements adjudicated in a single proceeding.	2009	10,000,000	11,002,000
			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.	2009	250,000	275,050
333(f)(9)(B)(ii)(II) .....		FDA	Penalty for aggregate of for all such above violations adjudicated in a single proceeding.	2009	1,000,000	1,100,200
			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.	2009	250,000	275,050
			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.	2009	1,000,000	1,100,200
333(g)(1) .....		FDA	Penalty for aggregate above tobacco product requirement violations adjudicated in a single proceeding.	2009	10,000,000	11,002,000
			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.	2007	250,000	284,583
			Penalty for each subsequent above violation in any 3-year period.	2007	500,000	569,165
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.	2009	250	275
			Penalty in the case of a third tobacco product regulation violation within a 24-month period.	2009	500	550
			Penalty in the case of a fourth tobacco product regulation violation within a 24-month period.	2009	2,000	2,200
			Penalty in the case of a fifth tobacco product regulation violation within a 36-month period.	2009	5,000	5,501
			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.	2009	10,000	11,002
			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.	2009	250	275
			Penalty in the case of a second tobacco product regulation violation within a 12-month period.	2009	500	550

**CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued**  
[Effective September 6, 2016]

Citation		HHS agency	Description <sup>2</sup>	Date of last penalty figure or adjustment <sup>3</sup>	Pre-inflation penalty (\$)	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>					
			Penalty in the case of a third tobacco product regulation violation within a 24-month period.	2009	1,000	1,100
			Penalty in the case of a fourth tobacco product regulation violation within a 24-month period.	2009	2,000	2,200
			Penalty in the case of a fifth tobacco product regulation violation within a 36-month period.	2009	5,000	5,501
			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.	2009	10,000	11,002
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.	1992	250,000	419,320
			Penalty in the case of any other person (other than an individual) per above violation.	1992	1,000,000	1,677,280
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.	1968	1,100	2,750
			Penalty imposed for any related series of violations of requirements relating to electronic products.	1968	375,000	937,500
42 U.S.C.: 262(d) .....	.....	FDA	Penalty per day for violation of order of recall of biological product presenting imminent or substantial hazard.	1986	100,000	215,628
263b(h)(3) .....	.....	FDA	Penalty for failure to obtain a mammography certificate as required.	1992	10,000	16,773
300aa-28(b)(1) .....	.....	FDA	Penalty per occurrence for any vaccine manufacturer that intentionally destroys, alters, falsifies, or conceals any record or report required.	1986	100,000	215,628
256b(d)(1)(B)(vi) .....	.....	HRSA	Penalty for each instance of overcharging a 340B covered entity.	2010	5,000	5,437
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.	1999	10,000	14,140
653(l)(2) .....	45 CFR 303.21(f) .....	ACF	Penalty for Misuse of Information in the National Directory of New Hires.	1998	1,000	1,450
262a(i)(1) .....	42 CFR Part 1003 .....	OIG	Penalty for each individual who violates safety and security procedures related to handling dangerous biological agents and toxins.	2002	250,000	327,962
			Penalty for any other person who violates safety and security procedures related to handling dangerous biological agents and toxins.	2002	500,000	655,925
1320a-7a(a) .....	42 CFR Part 1003 .....	OIG	Penalty for knowingly presenting or causing to be presented to an officer, employee, or agent of the United States a false claim.	1996	10,000	15,024
			Penalty for knowingly presenting or causing to be presented a request for payment which violates the terms of an assignment, agreement, or PPS agreement.	1996	10,000	15,024
			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.	1996	15,000	22,537
			Penalty for an excluded party retaining ownership or control interest in a participating entity.	1996	10,000	15,024
			Penalty for remuneration offered to induce program beneficiaries to use particular providers, practitioners, or suppliers.	1996	10,000	15,024

**CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued**  
[Effective September 6, 2016]

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U.S.C.	CFR <sup>1</sup>					
			Penalty for employing or contracting with an excluded individual.	1997	10,000	14,718
			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.	1997	50,000	73,588
			Penalty for ordering or prescribing medical or other item or service during a period in which the person was excluded.	2010	10,000	10,874
			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.	2010	50,000	54,372
			Penalty for knowing of an overpayment and failing to report and return.	2010	10,000	10,874
			Penalty for making or using a false record or statement that is material to a false or fraudulent claim.	2010	50,000	54,372
			Penalty for failure to grant timely access to HHS OIG for audits, investigations, evaluations, and other statutory functions of HHS OIG.	2010	15,000	16,312
1320a–7a(b) .....	42 CFR Part 1003 .....	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.	1986	2,000	4,313
			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.	1986	2,000	4,313
			Penalty for a physician who executes a document that falsely certifies home health needs for Medicare beneficiaries.	1996	5,000	7,512
1320a–7e(b)(6)(A) .....	42 CFR Part 1003 .....	OIG	Penalty for failure to report any final adverse action taken against a health care provider, supplier, or practitioner.	1997	25,000	36,794
1320b–10(b)(1) .....	42 CFR Part 1003 .....	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.	1988	5,000	9,893
1320b–10(b)(2) .....	42 CFR Part 1003 .....	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.	1988	25,000	49,467
1395i–3(b)(3)(B)(iii)(1) .....	.....	OIG	Penalty for certification of a false statement in assessment of functional capacity of a Skilled Nursing Facility resident assessment.	1987	1,000	2,063
1395i–3(b)(3)(B)(iii)(2) .....	.....	OIG	Penalty for causing another to certify or make a false statement in assessment of functional capacity of a Skilled Nursing Facility resident assessment.	1987	5,000	10,314
1395i–3(g)(2)(A) .....	.....	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.	1987	2,000	4,126
1395w–27(g)(2)(A) .....	42 CFR 422.752; 42 CFR Part 1003.	OIG	Penalty for a Medicare Advantage organization that substantially fails to provide medically necessary, required items and services.	1996	25,000	37,561
			Penalty for a Medicare Advantage organization that charges excessive premiums.	1997	25,000	36,794
			Penalty for a Medicare Advantage organization that improperly expels or refuses to re-enroll a beneficiary.	1997	25,000	36,794
			Penalty for a Medicare Advantage organization that engages in practice that would reasonably be expected to have the effect of denying or discouraging enrollment.	1997	100,000	147,177



**CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued**  
[Effective September 6, 2016]

Citation		HHS agency	Description <sup>2</sup>	Date of last penalty figure or adjustment <sup>3</sup>	Pre-inflation penalty (\$)	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>					
			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.	1997	15,000	22,077
			Penalty for a Medicare Advantage organization misrepresenting or falsifying information to Secretary.	1997	100,000	147,177
			Penalty for a Medicare Advantage organization misrepresenting or falsifying information to individual or other entity.	1997	25,000	36,794
			Penalty for Medicare Advantage organization interfering with provider's advice to enrollee and non-MCO affiliated providers that balance bill enrollees.	1997	25,000	36,794
			Penalty for a Medicare Advantage organization that employs or contracts with excluded individual or entity.	1997	25,000	36,794
			Penalty for a Medicare Advantage organization enrolling an individual in without prior written consent.	2010	25,000	36,794
			Penalty for a Medicare Advantage organization transferring an enrollee to another plan without consent or solely for the purpose of earning a commission.	2010	25,000	36,794
			Penalty for a Medicare Advantage organization failing to comply with marketing restrictions or applicable implementing regulations or guidance.	2010	25,000	36,794
			Penalty for a Medicare Advantage organization employing or contracting with an individual or entity who violates 1395w-27(g)(1)(A)–(J).	2010	25,000	36,794
1395w-141(i)(3) .....	42 CFR Part 1003 .....	OIG	Penalty for a prescription drug card sponsor that falsifies or misrepresents marketing materials, overcharges program enrollees, or misuse transitional assistance funds.	2003	10,000	12,856
1395cc(g) .....	42 CFR Part 1003 .....	OIG	Penalty for improper billing by Hospitals, Critical Access Hospitals, or Skilled Nursing Facilities.	1972	2,000	5,000
1395dd(d)(1) .....	42 CFR Part 1003 .....	OIG	Penalty for a hospital or responsible physician dumping patients needing emergency medical care, if the hospital has 100 beds or more.	1987	50,000	103,139
			Penalty for a hospital or responsible physician dumping patients needing emergency medical care, if the hospital has less than 100 beds.	1987	25,000	51,570
1395mm(i)(6)(B)(i) .....	42 CFR Part 1003 .....	OIG	Penalty for a HMO or competitive plan is such plan substantially fails to provide medically necessary, required items or services.	1987	25,000	51,570
			Penalty for HMOs/competitive medical plans that charge premiums in excess of permitted amounts.	1987	25,000	51,570
			Penalty for a HMO or competitive medical plan that expels or refuses to reenroll an individual per prescribed conditions.	1987	25,000	51,570
			Penalty for a HMO or competitive medical plan that implements practices to discourage enrollment of individuals needing services in future.	1987	100,000	206,278
			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.	1988	15,000	29,680
			Penalty for a HMO or competitive medical plan that misrepresents or falsifies information to the Secretary.	1987	100,000	206,278
			Penalty for a HMO or competitive medical plan that misrepresents or falsifies information to an individual or any other entity.	1987	25,000	51,570
			Penalty for failure by HMO or competitive medical plan to assure prompt payment of Medicare risk sharing contracts or incentive plan provisions.	1987	25,000	51,570

**CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued**  
[Effective September 6, 2016]

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U.S.C.	CFR <sup>1</sup>					
1395nn(g)(3) .....	42 CFR Part 1003 .....	OIG	Penalty for HMO that employs or contracts with excluded individual or entity.	1989	25,000	47,340
			Penalty for submitting or causing to be submitted claims in violation of the Stark Law's restrictions on physician self-referrals.	1994	15,000	23,863
1395nn(g)(4) .....	42 CFR Part 1003 .....	OIG	Penalty for circumventing Stark Law's restrictions on physician self-referrals.	1994	100,000	159,089
1395ss(d)(1) .....	42 CFR Part 1003 .....	OIG	Penalty for a material misrepresentation regarding Medigap compliance policies.	1988	5,000	9,893
1395ss(d)(2) .....	42 CFR Part 1003 .....	OIG	Penalty for selling Medigap policy under false pretense.	1988	5,000	9,893
1395ss(d)(3)(A)(ii) .....	42 CFR Part 1003 .....	OIG	Penalty for an issuer that sells health insurance policy that duplicates benefits.	1990	25,000	44,539
			Penalty for someone other than issuer that sells health insurance that duplicates benefits.	1990	15,000	26,723
1395ss(d)(4)(A) .....	42 CFR Part 1003 .....	OIG	Penalty for using mail to sell a non-approved Medigap insurance policy.	1988	5,000	9,893
1396b(m)(5)(B)(i) .....	42 CFR Part 1003 .....	OIG	Penalty for a Medicaid MCO that substantially fails to provide medically necessary, required items or services.	1988	25,000	49,467
			Penalty for a Medicaid MCO that charges excessive premiums.	1988	25,000	49,467
			Penalty for a Medicaid MCO that improperly expels or refuses to reenroll a beneficiary.	1988	100,000	197,869
			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.	1988	15,000	29,680
			Penalty for a Medicaid MCO misrepresenting or falsifying information to the Secretary.	1988	100,000	197,869
			Penalty for a Medicaid MCO misrepresenting or falsifying information to an individual or another entity.	1988	25,000	49,467
			Penalty for a Medicaid MCO that fails to comply with contract requirements with respect to physician incentive plans.	1990	25,000	44,539
1396r(b)(3)(B)(ii)(I) .....	42 CFR Part 1003 .....	OIG	Penalty for willfully and knowingly certifying a material and false statement in a Skilled Nursing Facility resident assessment.	1987	1,000	2,063
1396r(b)(3)(B)(ii)(II) .....	42 CFR Part 1003 .....	OIG	Penalty for willfully and knowingly causing another individual to certify a material and false statement in a Skilled Nursing Facility resident assessment.	1987	5,000	10,314
1396r(g)(2)(A)(i) .....	42 CFR Part 1003 .....	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.	1987	2,000	4,126
1396r–8(b)(3)(B) .....	42 CFR Part 1003 .....	OIG	Penalty for the knowing provision of false information or refusing to provide information about charges or prices of a covered outpatient drug.	1990	100,000	178,156
1396r–8(b)(3)(C)(i) .....	42 CFR Part 1003 .....		Penalty per day for failure to timely provide information by drug manufacturer with rebate agreement.	1990	10,000	17,816
1396r–8(b)(3)(C)(ii) .....	42 CFR Part 1003 .....		Penalty for knowing provision of false information by drug manufacturer with rebate agreement.	1990	100,000	178,156
1396t(i)(3)(A) .....	42 CFR Part 1003 .....	OIG	Penalty for notifying home and community-based providers or settings of survey.	1990	2,000	3,563
11131(c) .....	42 CFR Part 1003 .....	OIG	Penalty for failing to report a medical malpractice claim to National Practitioner Data Bank.	1986	10,000	21,563
11137(b)(2) .....	42 CFR Part 1003 .....	OIG	Penalty for breaching confidentiality of information reported to National Practitioner Data Bank.	1986	10,000	21,563
299b–22(f)(1) .....	42 CFR 3.404 .....	OCR	Penalty for violation of confidentiality provision of the Patient Safety and Quality Improvement Act.	2005	10,000	11,940
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.	1996	100	150
			Calendar Year Cap .....	1996	25,000	37,561

**CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued**  
[Effective September 6, 2016]

Citation		HHS agency	Description <sup>2</sup>	Date of last penalty figure or adjustment <sup>3</sup>	Pre-inflation penalty (\$)	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>					
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: Minimum ..... Maximum ..... Calendar Year Cap .....	2009	100	110
				2009	50,000	55,010
				2009	1,500,000	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 ..... Maximum ..... Calendar Year Cap .....	2009	1,000	1,100
				2009	50,000	55,010
				2009	1,500,000	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 ..... Maximum ..... Calendar Year Cap .....	2009	10,000	11,002
				2009	50,000	55,010
				2009	1,500,000	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 ..... Maximum ..... Calendar Year Cap .....	2009	50,000	55,010
				2009	1,500,000	1,650,300
				2009	1,500,000	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 ..... Maximum ..... Calendar Year Cap .....	1988	3,050	6,035
				1988	10,000	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 ..... Maximum ..... Calendar Year Cap .....	1988	50	99
				1988	3,000	5,936
300gg–15(f) .....	45 CFR 147.200(e) .....	CMS	Failure to provide the Summary of Benefits and Coverage.	2010	1,000	1,087
300gg–18 .....	45 CFR 158.606 .....	CMS	Penalty for violations of regulations related to the medical loss ratio reporting and rebating.	2010	100	109
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 ..... Maximum ..... Calendar Year Cap .....	2010	1,000	1,087
				2010	10,000	10,874
				2010	150,000	163,117
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 ..... Maximum ..... Calendar Year Cap .....	2010	10,000	10,874
				2010	100,000	108,745
				2010	1,000,000	1,087,450

**CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued**  
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U.S.C.	CFR <sup>1</sup>					
1320a–7(h)(3)(A) .....	.....	CMS	Penalty for an administrator of a facility that fails to comply with notice requirements for the closure of a facility.	2010	100,000	108,745
	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.	2010	500	544
			Minimum penalty for the second offense of an administrator who fails to provide notice of facility closure.	2010	1,500	1,631
			Minimum penalty for the third and subsequent offenses of an administrator who fails to provide notice of facility closure.	2010	3,000	3,262
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.	1994	5,000	7,954
			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.	2015	7,500	7,500
1320a–8(a)(3) .....	.....	CMS	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.	2004	5,000	6,229
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.	2010	200,000	217,490
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.	2010	300,000	326,235
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.	2010	200,000	217,490
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.	1997	100	147
1395i–3(h)(2)(B)(iii)(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 .....	1987	50	103
			Maximum .....	1987	3,000	6,188
	42 CFR 488.408(d)(1)(iv) .....	CMS	Penalty per instance of Category 2 non-compliance by a Skilled Nursing Facility:			
			Minimum .....	1987	1,000	2,063
			Maximum .....	1987	10,000	20,628
	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 .....	1987	3,050	6,291
			Maximum .....	1987	10,000	20,628
	42 CFR 488.408(e)(1)(iv) .....	CMS	Penalty per instance of Category 3 non-compliance by a Skilled Nursing Facility:			
			Minimum .....	1987	1,000	2,063
			Maximum .....	1987	10,000	20,628

**CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued**  
[Effective September 6, 2016]

Citation		HHS agency	Description <sup>2</sup>	Date of last penalty figure or adjustment <sup>3</sup>	Pre-inflation penalty (\$)	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>					
	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) ..... Per Instance (Minimum) ..... Per Instance (Maximum) .....	1987 1987 1987 1987	3,050 10,000 1,000 10,000	6,291 20,628 2,063 20,628
	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 ..... Maximum .....	1987 1987	3,050 10,000	6,291 20,628
	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 ..... Maximum .....	1987 1987	50 3,000	103 6,188
	42 CFR 488.438(a)(2) .....	CMS	Penalty per instance of a Skilled Nursing Facility that fails to meet certification requirements: Minimum ..... Maximum .....	1987 1987	1,000 10,000	2,063 20,628
1395l(h)(5)(D) .....	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)).	1996	10,000	15,024
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.	1988	2,000	3,957
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.	1989	2,000	3,787
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(j)(2)(B), which is assessed according to 1320a-7a(a)).	1996	10,000	15,024
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(j)(2)(B), which is assessed according to 1320a-7a(a)).	1996	10,000	15,024
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(j)(2)(B), which is assessed according to 1320a-7a(a)).	1996	10,000	15,024
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(j)(2)(B), which is assessed according to 1320a-7a(a)).	1996	10,000	15,024

**CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued**  
[Effective September 6, 2016]

Citation		HHS agency	Description <sup>2</sup>	Date of last penalty figure or adjustment <sup>3</sup>	Pre-inflation penalty (\$)	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>					
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.	1994	1,000	1,591
1395m(j)(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 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)).	1996	10,000	15,024
1395m(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(j)(2)(B), which is assessed according to 1320a-7a(a)).	1996	10,000	15,024
1395m(l)(6) .....	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)).	1996	10,000	15,024
1395u(b)(18)(B) .....	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)).	1996	10,000	15,024
1395u(j)(2)(B) .....	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)).	1996	10,000	15,024
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(j)(2)(B), which is assessed according to 1320a-7a(a)).	1996	10,000	15,024
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(j)(2)(B), which is assessed according to 1320a-7a(a)).	1996	10,000	15,024

**CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued**  
[Effective September 6, 2016]

Citation		HHS agency	Description <sup>2</sup>	Date of last penalty figure or adjustment <sup>3</sup>	Pre-inflation penalty (\$)	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>					
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(j)(2)(B), which is assessed according to 1320a–7a(a)).	1996	10,000	15,024
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(j)(2)(B), which is assessed according to 1320a–7a(a)).	1996	10,000	15,024
1395u(o)(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–7a(a)).	1996	10,000	15,024
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.	1988	2,000	3,957
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.	2003	10,000	12,856
1395w–4(g)(1)(B) .....	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)).	1996	10,000	15,024
1395w–4(g)(3)(B) .....	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)).	1996	10,000	15,024
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.	1997	25,000	36,794
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.	1997	10,000	14,718
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.	2000	100,000	136,689

**CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued**  
[Effective September 6, 2016]

Citation		HHS agency	Description <sup>2</sup>	Date of last penalty figure or adjustment <sup>3</sup>	Pre-inflation penalty (\$)	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>					
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.	1990	5,000	8,908
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.	1998	1,000	1,450
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.	1994	2,000	3,182
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.	2007	1,000	1,138
1395y(b)(8)(E) .....	.....	CMS	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.	2007	1,000	1,138
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.	1989	10,000	18,936
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)).	1996	10,000	15,024
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.	1987	25,000	51,569
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.	1990	15,000	26,723
1395ss(d)(3)(B)(iv) .....	.....	CMS	Penalty for an issuer that sells or issues a Medicare supplemental policy without disclosure statement.	1990	25,000	44,539
			Penalty for someone other than issuer that sells or issues a Medicare supplemental policy without acknowledgement form.	1990	15,000	26,723
			Penalty for issuer that sells or issues a Medicare supplemental policy without an acknowledgement form.	1990	25,000	44,539
1395ss(p)(8) .....	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 NAIC or Federal standards established by statute.	1990	15,000	26,723
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.	1990	25,000	44,539
	42 CFR 402.1(c)(26), 402.105(e).	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.	1990	15,000	26,723



**CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued**  
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U.S.C.	CFR <sup>1</sup>					
	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.	1990	25,000	44,539
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.	1990	25,000	44,539
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).	1990	25,000	44,539
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.	1990	5,000	18,908
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.	1990	25,000	44,539
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.	2003	15,000	19,284
			Penalty for an issuer who sells, issues, or renews a Medigap Rx policy who is a Part D enrollee.	2003	25,000	32,140
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.	1987	2,000	4,126
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.	1988	10,000	19,787
			Penalty per day for home health agency's noncompliance (Upper Range):			
			Minimum .....	1988	8,500	16,819
			Maximum .....	1988	10,000	19,787
	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.	1988	10,000	19,787
	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.	1988	9,000	17,808
	42 CFR 488.845(b)(3)(iii) .....		Penalty for an isolated incident of noncompliance in violation of established HHA policy.	1988	8,500	16,819
	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 .....	1988	1,500	2,968
			Maximum .....	1988	8,500	16,819
	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 predominantly to structure or process-oriented conditions (Lower Range):			
			Minimum .....	1988	500	989
			Maximum .....	1988	4,000	7,915
	42 CFR 488.845(b)(6) .....		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:			

**CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued**  
[Effective September 6, 2016]

Citation		HHS agency	Description <sup>2</sup>	Date of last penalty figure or adjustment <sup>3</sup>	Pre-inflation penalty (\$)	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>					
1396b(m)(5)(B) .....	42 CFR 488.845(d)(1)(ii) .....	CMS	Minimum .....	1988	1,000	1,979
			Maximum .....	1988	10,000	19,787
			Penalty for each day of noncompliance (Maximum).	1988	10,000	19,787
			Penalty for each day of noncompliance (Maximum).	1988	10,000	19,787
			Penalty for PACE organization's practice that would reasonably be expected to have the effect of denying or discouraging enrollment:			
			Minimum .....	1997	15,000	22,077
			Maximum .....	1997	100,000	147,177
			Penalty for a PACE organization that charges excessive premiums.	1997	25,000	36,794
			Penalty for a PACE organization misrepresenting or falsifying information to CMS, the State, or an individual or other entity.	1997	100,000	147,177
			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.	1997	25,000	36,794
			Penalty for involuntarily disenrolling a participant.	1997	25,000	36,794
			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.	1997	25,000	36,794
			Penalty per day for a nursing facility's failure to meet a Category 2 Certification:			
			Minimum .....	1987	50	103
1396r(h)(3)(C)(ii)(I) .....	42 CFR 488.408(d)(1)(iii) .....	CMS	Maximum .....	1987	3,000	6,188
			Penalty per instance for a nursing facility's failure to meet Category 2 certification:			
			Minimum .....	1987	1,000	2,063
			Maximum .....	1987	10,000	20,628
			Penalty per day for a nursing facility's failure to meet Category 3 certification:			
			Minimum .....	1987	3,050	6,291
			Maximum .....	1987	10,000	20,628
			Penalty per instance for a nursing facility's failure to meet Category 3 certification:			2,063
			Minimum .....	1987	1,000	20,628
			Maximum .....	1987	10,000	20,628
			Penalty per instance for a nursing facility's failure to meet Category 3 certification, which results in immediate jeopardy:			2,063
			Minimum .....	1987	1,000	20,628
			Maximum .....	1987	10,000	20,628
			Penalty per day for nursing facility's failure to meet certification (Upper Range):			6,291
1396r(h)(3)(C)(ii)(I) .....	42 CFR 488.438(a)(1)(i) .....	CMS	Minimum .....	1987	3,050	20,628
			Maximum .....	1987	10,000	2,063
			Penalty per day for nursing facility's failure to meet certification (Lower Range):			
			Minimum .....	1987	50	103
			Maximum .....	1987	3,000	6,188
			Penalty per instance for nursing facility's failure to meet certification:			
			Minimum .....	1987	1,000	2,063
			Maximum .....	1987	10,000	20,628
			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].	1987	5,000	10,314
			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].	1987	5,000	10,314

**CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued**  
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U.S.C.	CFR <sup>1</sup>					
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 .....	1990 1990	1 10,000	2 17,816
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.	1997 1997 1997 1997	25,000 25,000 25,000 25,000	36,794 36,794 36,794 36,794
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. Penalty for Medicaid managed care organization that acts to discriminate among enrollees on the basis of their health status.	1997 1997	100,000 100,000	147,177 147,177
1396u-2(e)(2)(A)(iv) .....	42 CFR 438.704 .....	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.	1997	15,000	22,077
1396u(h)(2) .....	42 CFR 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.	1990	10,000	20,628
1396w-2(c)(1) .....	.....	CMS	Penalty for disclosing information related to eligibility determinations for medical assistance programs.	2009	10,000	11,002
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)).	1996	100	150
18081(h)(1)(A)(i)(II) .....	42 CFR 155.285 .....	CMS	Penalty for providing false information on Exchange application.	2010	25,000	27,186
18081(h)(1)(B) .....	42 CFR 155.285 .....	CMS	Penalty for knowingly or willfully providing false information on Exchange application.	2010	250,000	271,862
18081(h)(2) .....	42 CFR 155.260 .....	CMS	Penalty for knowingly or willfully disclosing protected information from Exchange.	2010	25,000	27,186
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 ..... Penalty for the first time an individual fails to file or amend a lobbying disclosure form, absent aggravating circumstances. Penalty for second and subsequent offenses by individuals who fail to file or amend a lobbying disclosure form, absent aggravating circumstances: Minimum ..... Maximum ..... Penalty for failure to provide certification regarding lobbying in the award documents for all sub-awards of all tiers: Minimum ..... Maximum .....	1989   1989 1989 1989  1989 1989  1989 1989	10,000   10,000 100,000 10,000  10,000 100,000  10,000 100,000	18,936   18,936 189,361 18,936  18,936 189,361  18,936 189,361
	45 CFR 93, Appendix A .....	HHS				

**CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS AGENCIES AND PENALTY AMOUNTS—Continued**  
[Effective September 6, 2016]

Citation		HHS agency	Description <sup>2</sup>	Date of last penalty figure or adjustment <sup>3</sup>	Pre-inflation penalty (\$)	Maximum adjusted penalty (\$)
U.S.C.	CFR <sup>1</sup>					
3801–3812 .....	45 CFR 79.3(a)(1)(iv) .....	HHS	Penalty for failure to provide statement regarding lobbying for loan guarantee and loan insurance transactions:			
			Minimum .....	1989	10,000	18,936
	Maximum .....		1989	100,000	189,361	
	45 CFR 79.3(b)(1)(ii) .....		Penalty against any individual who—with knowledge or reason to know—makes, presents or submits a false, fictitious or fraudulent claim to the Department.	1988	5,000	9,894
Penalty against any individual who—with knowledge or reason to know—makes, presents or submits a false, fictitious or fraudulent claim to the Department.		1988	5,000	9,894		

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

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

<sup>3</sup> Statutory, or non-Inflation Act Adjustment.

## **PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS**

■ 33. The authority citation for part 147 continues to read as follows:

**Authority:** Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

### **§ 147.200 [Amended]**

■ 34. Section 147.200(e) is amended by removing the phrase “not more than \$1,000 for” and adding in its place the phrase “not more than \$1,000 as adjusted annually under 45 CFR part 102 for”.

## **PART 150—CMS ENFORCEMENT IN GROUP AND INDIVIDUAL INSURANCE MARKETS**

■ 35. The authority citation for part 150 continues to read as follows:

**Authority:** Secs. 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92).

### **§ 150.315 [Amended]**

■ 36. Section 150.315 is amended by removing the phrase “may not exceed \$100 for” and adding in its place the phrase “may not exceed \$100 as adjusted annually under 45 CFR part 102 for”.

## **PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT**

■ 37. The authority citation for part 155 continues to read as follows:

**Authority:** Title I of the Affordable Care Act, sections 1301, 1302, 1303, 1304, 1311,

1312, 1313, 1321, 1322, 1331, 1332, 1334, 1402, 1411, 1412, 1413, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18033, 18041–18042, 18051, 18054, 18071, and 18081–18083).

### **§ 155.260 [Amended]**

■ 38. In § 155.260, paragraph (g) is amended by removing the phrase “not more than \$25,000 per” and adding in its place the phrase “not more than \$25,000 as adjusted annually under 45 CFR part 102 per”.

### **§ 155.285 [Amended]**

■ 39. Amend § 155.285 as follows:

■ a. In paragraph (c)(1)(i), by removing the phrase “of \$25,000 for” and adding in its place the phrase “of \$25,000 as adjusted annually under 45 CFR part 102 for”;

■ b. In paragraph (c)(1)(ii), removing the phrase “of \$250,000 for” and adding in its place the phrase “of \$250,000 as adjusted annually under 45 CFR part 102 for”; and

■ c. In paragraph (c)(2)(i), removing the phrase “not more than \$25,000 per” and adding in its place the phrase “not more than \$25,000 as adjusted annually under 45 CFR part 102 per”.

## **PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES**

■ 40. The authority citation for part 156 continues to read as follows:

**Authority:** Title I of the Affordable Care Act, sections 1301–1304, 1311–1313, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

### **§ 156.805 [Amended]**

■ 41. In § 156.805, paragraph (c) is amended by removing the phrase “\$100 for” and adding in its place the phrase “\$100 as adjusted annually under 45 CFR part 102 for”.

## **PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS**

■ 42. The authority citation for part 158 continues to read as follows:

**Authority:** Section 2718 of the Public Health Service Act (42 U.S.C. 300gg–18), as amended.

### **§ 158.606 [Amended]**

■ 43. Section 158.606 is amended by removing the phrase “may not exceed \$100 for” and adding in its place the phrase “may not exceed \$100 as adjusted annually under 45 CFR part 102 for”.

## **PART 160—GENERAL ADMINISTRATIVE REQUIREMENTS**

■ 44. The authority for part 160 continues to read as follows:

**Authority:** 42 U.S.C. 1302(a); 42 U.S.C. 1320d–1320d–9; sec. 264, Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)); 5 U.S.C. 552; secs. 13400–13424, Pub. L. 111–5, 123 Stat. 258–279; and sec. 1104 of Pub. L. 111–148, 124 Stat. 146–154.

■ 45. Section 160.404 is amended by revising paragraph (a) to read as follows:

### **§ 160.404 Amount of a civil money penalty.**

(a) The amount of a civil money penalty will be determined in accordance with paragraph (b) of this section, and §§ 160.406, 160.408, and 160.412. These amounts were adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment

Act of 1990, (Pub. L. 101–140), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, (section 701 of Pub. L. 114–74), and appear at 45 CFR part 102. These amounts will be updated annually and published at 45 CFR part 102.

\* \* \* \* \*

**Subtitle B—Regulations Related to Public Welfare**  
**Chapter II—Office of Family Assistance (Assistance Programs), Administration for Children and Families, Department of Health and Human Services**

**PART 303—STANDARDS FOR PROGRAM OPERATIONS**

■ 46. The authority citation for part 303 continues to read as follows:

**Authority:** 42 U.S.C. 651 through 658, 659a, 660, 663, 664, 666, 667, 1302, 1396a(a)(25), 1396b(d)(2), 1396b(o), 1396b(p), and 1396(k).

■ 47. Section 303.21 is amended by revising paragraph (f) to read as follows:

**§ 303.21 Safeguarding and disclosure of confidential information.**

\* \* \* \* \*

(f) Penalties for unauthorized disclosure. Any disclosure or use of confidential information in violation of 42 U.S.C. 653(l)(2) and implementing regulations shall be subject to:

- (1) Any State and Federal statutes that impose legal sanctions for such disclosure; and
- (2) The maximum civil monetary penalties associated with the statutory provisions authorizing civil monetary

penalties under 42 U.S.C. 653(l)(2) as shown in the table at 45 CFR 102.3.

Dated: July 21, 2016.

**Sylvia M. Burwell,**  
*Secretary, Department of Health and Human Services.*

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