# [***81 FR 61538***](https://advance.lexis.com/api/document?collection=administrative-codes&id=urn:contentItem:5KMV-H600-006W-841C-00000-00&context=)

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Rules and Regulations

**Reporter**

81 FR 61538 \*

***Federal Register* > *2016* > *September* > *Tuesday, September 6, 2016* > *Rules and Regulations* > *DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) -- Office of the Assistant Secretary for Financial Resources***

**Title:** **Adjustment of Civil Monetary Penalties for Inflation**

**Action:**  Interim final rule.

**Agency**

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) > Office of the Assistant Secretary for Financial Resources

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) > Centers for Medicare & Medicaid Services (CMS)

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) > Office of the Secretary of Health and Human Services > Office of the Inspector General (OIG)

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) > Administration for Children and Families (ACF)

**Identifier:** **RIN 0991-AC0**

**Administrative Code Citation**

**42 CFR Part 3**

**42 CFR Parts 402, 403, 411, 412, 422, 423, 460, 483, 488, and 493**

**42 CFR Part 1003**

**45 CFR Parts 79, 93, 102, 147, 150, 155, 156, 158, and 160**

**45 CFR Part 303**

**Synopsis**

**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***.

**Text**

**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. n1

n1 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.

**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*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GP01-NRF4-44H2-00000-00&context=) 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 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 **[\*61539]** 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 n2 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.

n2 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/*](http://www.bls.gov/cpi/)*.*

| **Calculation of CMP Adjustments** | | | | |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Citation** | | **Description fn2** | **Pre-** | **Date of** |
|  |  |  | **inflation** | **last** |
|  |  |  | **penalty** | **penalty** |
|  |  |  | **(]** | **figure or** |
|  |  |  |  | **adjust-** |
|  |  |  |  | **ment fn3** |
| **U.S.C.** | **CFR fn1** |  |  |  |
| 21 U.S.C. (FDA): |  |  |  |  |
| 333(b)fn2(A) |  | Penalty for | 50,000 | 1988 |
|  |  | violations related to |  |  |
|  |  | drug samples |  |  |
|  |  | resulting in a |  |  |
|  |  | conviction of any |  |  |
|  |  | representative of |  |  |
|  |  | manufacturer or |  |  |
|  |  | distributor in any |  |  |
|  |  | 10-year period |  |  |
| 333(b)fn2(B) |  | Penalty for violation | 1,000,000 | 1988 |
|  |  | related to drug |  |  |
|  |  | samples resulting in |  |  |
|  |  | a conviction of any |  |  |
|  |  | representative of |  |  |
|  |  | manufacturer or |  |  |
|  |  | distributor after the |  |  |
|  |  | second conviction in |  |  |
|  |  | any 10-yr period |  |  |
| 333(b)fn3 |  | Penalty for failure | 100,000 | 1988 |
|  |  | to make a report |  |  |
|  |  | required by 21 U.S.C. |  |  |
|  |  | 353(d)fn3(E) relating |  |  |
|  |  | to drug samples |  |  |
| 333(f)fn1(A) |  | Penalty for any | 15,000 | 1990 |
|  |  | person who violates a |  |  |
|  |  | requirement related |  |  |
|  |  | to devices for each |  |  |
|  |  | such violation |  |  |
|  |  | Penalty for aggregate | 1,000,000 | 1990 |
|  |  | of all violations |  |  |
|  |  | related to devices in |  |  |
|  |  | a single proceeding |  |  |
| 333(f)fn2(A) |  | Penalty for any | 50,000 | 1996 |
|  |  | individual who |  |  |
|  |  | introduces or |  |  |
|  |  | delivers for |  |  |
|  |  | introduction into |  |  |
|  |  | interstate commerce |  |  |
|  |  | food that is |  |  |
|  |  | adulterated per 21 |  |  |
|  |  | U.S.C. 342(a)fn2(B) |  |  |
|  |  | or any individual who |  |  |
|  |  | does not comply with |  |  |
|  |  | a recall order under |  |  |
|  |  | [*21 U.S.C. 350l*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:520M-GGV1-NRF4-4001-00000-00&context=) |  |  |
|  |  | Penalty in the case | 250,000 | 1996 |
|  |  | of any other person |  |  |
|  |  | other than an |  |  |
|  |  | individual for such |  |  |
|  |  | introduction or |  |  |
|  |  | delivery of |  |  |
|  |  | adulterated food |  |  |
|  |  | Penalty for aggregate | 500,000 | 1996 |
|  |  | of all such |  |  |
|  |  | violations related to |  |  |
|  |  | adulterated food |  |  |
|  |  | adjudicated in a |  |  |
|  |  | single proceeding |  |  |
| 333(f)fn3(A) |  | Penalty for all | 10,000 | 2007 |
|  |  | 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 |  |  |
| 333(f)fn3(B) |  | Penalty for each day | 10,000 | 2007 |
|  |  | the above violation |  |  |
|  |  | is not corrected |  |  |
|  |  | after a 30-day period |  |  |
|  |  | following |  |  |
|  |  | notification until |  |  |
|  |  | the violation is |  |  |
|  |  | corrected |  |  |
| 333(f)fn4(A)(i) |  | Penalty for any | 250,000 | 2007 |
|  |  | 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*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GN81-NRF4-425F-00000-00&context=) |  |  |
|  |  | (REMS) |  |  |
|  |  | Penalty for aggregate | 1,000,000 | 2007 |
|  |  | of all such above |  |  |
|  |  | violations in a |  |  |
|  |  | single proceeding |  |  |
| 333(f)fn4(A)(ii) |  | Penalty for REMS | 250,000 | 2007 |
|  |  | violation that |  |  |
|  |  | continues after |  |  |
|  |  | written notice to the |  |  |
|  |  | responsible person |  |  |
|  |  | for the first 30-day |  |  |
|  |  | period (or any |  |  |
|  |  | portion thereof) the |  |  |
|  |  | responsible person |  |  |
|  |  | continues to be in |  |  |
|  |  | violation |  |  |
|  |  | Penalty for REMS | 1,000,000 | 2007 |
|  |  | violation that |  |  |
|  |  | continues after |  |  |
|  |  | written notice to |  |  |
|  |  | responsible person |  |  |
|  |  | doubles for every 30- |  |  |
|  |  | day period thereafter |  |  |
|  |  | the violation |  |  |
|  |  | continues, but may |  |  |
|  |  | not exceed penalty |  |  |
|  |  | amount for any 30-day |  |  |
|  |  | period |  |  |
|  |  | Penalty for aggregate | 10,000,00 | 2007 |
|  |  | of all such above | 0 |  |
|  |  | violations |  |  |
|  |  | adjudicated in a |  |  |
|  |  | single proceeding |  |  |
| 333(f)(9)(A) |  | Penalty for any | 15,000 | 2009 |
|  |  | person who violates a |  |  |
|  |  | requirement which |  |  |
|  |  | relates to tobacco |  |  |
|  |  | products for each |  |  |
|  |  | such violation |  |  |
|  |  | Penalty for aggregate | 1,000,000 | 2009 |
|  |  | of all such |  |  |
|  |  | violations of tobacco |  |  |
|  |  | product requirement |  |  |
|  |  | adjudicated in a |  |  |
|  |  | single proceeding |  |  |
| 333(f)(9)(B)(i) |  | Penalty per violation | 250,000 | 2009 |
| (I) |  | related to violations |  |  |
|  |  | of tobacco |  |  |
|  |  | requirements |  |  |
|  |  | Penalty for aggregate | 1,000,000 | 2009 |
|  |  | of all such |  |  |
|  |  | violations of tobacco |  |  |
|  |  | product requirements |  |  |
|  |  | adjudicated in a |  |  |
|  |  | single proceeding |  |  |
| 333(f)(9)(B)(i) |  | Penalty in the case | 250,000 | 2009 |
| (II) |  | of a violation of |  |  |
|  |  | tobacco product |  |  |
|  |  | requirements that |  |  |
|  |  | continues after |  |  |
|  |  | written notice to |  |  |
|  |  | such person, for the |  |  |
|  |  | first 30-day period |  |  |
|  |  | (or any portion |  |  |
|  |  | thereof) the person |  |  |
|  |  | continues to be in |  |  |
|  |  | violation |  |  |
|  |  | Penalty for violation | 1,000,000 | 2009 |
|  |  | of tobacco product |  |  |
|  |  | requirements that |  |  |
|  |  | continues after |  |  |
|  |  | written notice to |  |  |
|  |  | such person shall |  |  |
|  |  | double for every 30- |  |  |
|  |  | day period thereafter |  |  |
|  |  | the violation |  |  |
|  |  | continues, but may |  |  |
|  |  | not exceed penalty |  |  |
|  |  | amount for any 30-day |  |  |
|  |  | period |  |  |
|  |  | Penalty for aggregate | 10,000,00 | 2009 |
|  |  | of all such | 0 |  |
|  |  | violations related to |  |  |
|  |  | tobacco product |  |  |
|  |  | requirements |  |  |
|  |  | adjudicated in a |  |  |
|  |  | single proceeding |  |  |
| 333(f)(9)(B)(ii)( |  | Penalty for any | 250,000 | 2009 |
| I) |  | 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 |  |  |
|  |  | Penalty for aggregate | 1,000,000 | 2009 |
|  |  | of for all such above |  |  |
|  |  | violations |  |  |
|  |  | adjudicated in a |  |  |
|  |  | single proceeding |  |  |
| 333(f)(9)(B)(ii)( |  | Penalty for violation | 250,000 | 2009 |
| II) |  | 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 |  |  |
|  |  | Penalty for post- | 1,000,000 | 2009 |
|  |  | 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 |  |  |
|  |  | Penalty for aggregate | 10,000,00 | 2009 |
|  |  | above tobacco product | 0 |  |
|  |  | requirement |  |  |
|  |  | violations |  |  |
|  |  | adjudicated in a |  |  |
|  |  | single proceeding |  |  |
| 333(g)fn1 |  | Penalty for any | 250,000 | 2007 |
|  |  | person who |  |  |
|  |  | disseminates or |  |  |
|  |  | causes another party |  |  |
|  |  | to disseminate a |  |  |
|  |  | direct-to-consumer |  |  |
|  |  | advertisement that is |  |  |
|  |  | false or misleading |  |  |
|  |  | for the first such |  |  |
|  |  | violation in any 3- |  |  |
|  |  | year period |  |  |
|  |  | Penalty for each | 500,000 | 2007 |
|  |  | subsequent above |  |  |
|  |  | violation in any 3- |  |  |
|  |  | year period |  |  |
| 333 note |  | Penalty to be applied | 250 | 2009 |
|  |  | 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 |  |  |
|  |  | Penalty in the case | 500 | 2009 |
|  |  | of a third tobacco |  |  |
|  |  | product ***regulation*** |  |  |
|  |  | violation within a |  |  |
|  |  | 24-month period |  |  |
|  |  | Penalty in the case | 2,000 | 2009 |
|  |  | of a fourth tobacco |  |  |
|  |  | product ***regulation*** |  |  |
|  |  | violation within a |  |  |
|  |  | 24-month period |  |  |
|  |  | Penalty in the case | 5,000 | 2009 |
|  |  | of a fifth tobacco |  |  |
|  |  | product ***regulation*** |  |  |
|  |  | violation within a |  |  |
|  |  | 36-month period |  |  |
|  |  | Penalty in the case | 10,000 | 2009 |
|  |  | of a sixth or |  |  |
|  |  | subsequent tobacco |  |  |
|  |  | product ***regulation*** |  |  |
|  |  | violation within a |  |  |
|  |  | 48-month period as |  |  |
|  |  | determined on a case- |  |  |
|  |  | by-case basis |  |  |
|  |  | Penalty to be applied | 250 | 2009 |
|  |  | 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 |  |  |
|  |  | Penalty in the case | 500 | 2009 |
|  |  | of a second tobacco |  |  |
|  |  | product ***regulation*** |  |  |
|  |  | violation within a |  |  |
|  |  | 12-month period |  |  |
|  |  | Penalty in the case | 1,000 | 2009 |
|  |  | of a third tobacco |  |  |
|  |  | product ***regulation*** |  |  |
|  |  | violation within a |  |  |
|  |  | 24-month period |  |  |
|  |  | Penalty in the case | 2,000 | 2009 |
|  |  | of a fourth tobacco |  |  |
|  |  | product ***regulation*** |  |  |
|  |  | violation within a |  |  |
|  |  | 24-month period |  |  |
|  |  | Penalty in the case | 5,000 | 2009 |
|  |  | of a fifth tobacco |  |  |
|  |  | product ***regulation*** |  |  |
|  |  | violation within a |  |  |
|  |  | 36-month period |  |  |
|  |  | Penalty in the case | 10,000 | 2009 |
|  |  | of a sixth or |  |  |
|  |  | subsequent tobacco |  |  |
|  |  | product ***regulation*** |  |  |
|  |  | violation within a |  |  |
|  |  | 48-month period as |  |  |
|  |  | determined on a case- |  |  |
|  |  | by-case basis |  |  |
| 335b(a) |  | Penalty for each | 250,000 | 1992 |
|  |  | 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 |  |  |
|  |  | Penalty in the case | 1,000,000 | 1992 |
|  |  | of any other person |  |  |
|  |  | (other than an |  |  |
|  |  | individual) per above |  |  |
|  |  | violation |  |  |
| 360pp(b)fn1 |  | Penalty for any | 1,100 | 1968 |
|  |  | person who violates |  |  |
|  |  | any such requirements |  |  |
|  |  | for electronic |  |  |
|  |  | products, with each |  |  |
|  |  | unlawful act or |  |  |
|  |  | omission constituting |  |  |
|  |  | a separate violation |  |  |
|  |  | Penalty imposed for | 375,000 | 1968 |
|  |  | any related series of |  |  |
|  |  | violations of |  |  |
|  |  | requirements relating |  |  |
|  |  | to electronic |  |  |
|  |  | products |  |  |
| 42 U.S.C. (FDA): |  |  |  |  |
| 262(d) |  | Penalty per day for | 100,000 | 1986 |
|  |  | violation of order of |  |  |
|  |  | recall of biological |  |  |
|  |  | product presenting |  |  |
|  |  | imminent or |  |  |
|  |  | substantial hazard |  |  |
| 263b(h)fn3 |  | Penalty for failure | 10,000 | 1992 |
|  |  | to obtain a |  |  |
|  |  | mammography |  |  |
|  |  | certificate as |  |  |
|  |  | required |  |  |
| 300aa-28(b)fn1 |  | Penalty per | 100,000 | 1986 |
|  |  | occurrence for any |  |  |
|  |  | vaccine manufacturer |  |  |
|  |  | that intentionally |  |  |
|  |  | destroys, alters, |  |  |
|  |  | falsifies, or |  |  |
|  |  | conceals any record |  |  |
|  |  | or report required |  |  |
| 42 U.S.C. (HRSA): |  |  |  |  |
| 256b(d)fn1(B)(vi) |  | Penalty for each | 5,000 | 2010 |
|  |  | instance of |  |  |
|  |  | overcharging a 340B |  |  |
|  |  | covered entity |  |  |
| 42 U.S.C. (AHRQ): |  |  |  |  |
| 299c-fn3(d) |  | Penalty for an | 10,000 | 1999 |
|  |  | establishment or |  |  |
|  |  | person supplying |  |  |
|  |  | information obtained |  |  |
|  |  | in the course of |  |  |
|  |  | activities for any |  |  |
|  |  | purpose other than |  |  |
|  |  | the purpose for which |  |  |
|  |  | it was supplied |  |  |
| 42 U.S.C. ACF: |  |  |  |  |
| 653(l)fn2 | 45 CFR 303.21(f) | Penalty for Misuse of | 1,000 | 1998 |
|  |  | Information in the |  |  |
|  |  | National Directory of |  |  |
|  |  | New Hires |  |  |
| 42 U.S.C. (OIG): |  |  |  |  |
| 262a(i)fn1 | 42 CFR Part 1003 | Penalty for each | 250,000 | 2002 |
|  |  | individual who |  |  |
|  |  | violates safety and |  |  |
|  |  | security procedures |  |  |
|  |  | related to handling |  |  |
|  |  | dangerous biological |  |  |
|  |  | agents and toxins |  |  |
|  |  | Penalty for any other | 500,000 | 2002 |
|  |  | person who violates |  |  |
|  |  | safety and security |  |  |
|  |  | procedures related to |  |  |
|  |  | handling dangerous |  |  |
|  |  | biological agents and |  |  |
|  |  | toxins |  |  |
| 1320a-7a(a) | 42 CFR Part 1003 | Penalty for knowingly | 10,000 | 1996 |
|  |  | presenting or causing |  |  |
|  |  | to be presented to an |  |  |
|  |  | officer, employee, or |  |  |
|  |  | agent of the United |  |  |
|  |  | States a false claim |  |  |
|  |  | Penalty for knowingly | 10,000 | 1996 |
|  |  | presenting or causing |  |  |
|  |  | to be presented a |  |  |
|  |  | request for payment |  |  |
|  |  | which violates the |  |  |
|  |  | terms of an |  |  |
|  |  | assignment, |  |  |
|  |  | agreement, or PPS |  |  |
|  |  | agreement |  |  |
|  |  | Penalty for knowingly | 15,000 | 1996 |
|  |  | 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 |  |  |
|  |  | Penalty for an | 10,000 | 1996 |
|  |  | excluded party |  |  |
|  |  | retaining ownership |  |  |
|  |  | or control interest |  |  |
|  |  | in a participating |  |  |
|  |  | entity |  |  |
|  |  | Penalty for | 10,000 | 1996 |
|  |  | remuneration offered |  |  |
|  |  | to induce program |  |  |
|  |  | beneficiaries to use |  |  |
|  |  | particular providers, |  |  |
|  |  | practitioners, or |  |  |
|  |  | suppliers |  |  |
|  |  | Penalty for employing | 10,000 | 1997 |
|  |  | or contracting with |  |  |
|  |  | an excluded |  |  |
|  |  | individual |  |  |
|  |  | Penalty for knowing | 50,000 | 1997 |
|  |  | 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 |  |  |
|  |  | Penalty for ordering | 10,000 | 2010 |
|  |  | or prescribing |  |  |
|  |  | medical or other item |  |  |
|  |  | or service during a |  |  |
|  |  | period in which the |  |  |
|  |  | person was excluded |  |  |
|  |  | Penalty for knowingly | 50,000 | 2010 |
|  |  | 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 |  |  |
|  |  | Penalty for knowing | 10,000 | 2010 |
|  |  | of an overpayment and |  |  |
|  |  | failing to report and |  |  |
|  |  | return |  |  |
|  |  | Penalty for making or | 50,000 | 2010 |
|  |  | using a false record |  |  |
|  |  | or statement that is |  |  |
|  |  | material to a false |  |  |
|  |  | or fraudulent claim |  |  |
|  |  | Penalty for failure | 15,000 | 2010 |
|  |  | to grant timely |  |  |
|  |  | access to HHS OIG for |  |  |
|  |  | audits, |  |  |
|  |  | investigations, |  |  |
|  |  | evaluations, and |  |  |
|  |  | other statutory |  |  |
|  |  | functions of HHS OIG |  |  |
| 1320a-7a(b) | 42 CFR Part 1003 | Penalty for payments | 2,000 | 1986 |
|  |  | by a hospital or |  |  |
|  |  | critical access |  |  |
|  |  | hospital to induce a |  |  |
|  |  | physician to reduce |  |  |
|  |  | or limit services to |  |  |
|  |  | individuals under |  |  |
|  |  | direct care of |  |  |
|  |  | physician or who are |  |  |
|  |  | entitled to certain |  |  |
|  |  | medical assistance |  |  |
|  |  | benefits |  |  |
|  |  | Penalty for | 2,000 | 1986 |
|  |  | 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 |  |  |
|  |  | Penalty for a | 5,000 | 1996 |
|  |  | physician who |  |  |
|  |  | executes a document |  |  |
|  |  | that falsely |  |  |
|  |  | certifies home health |  |  |
|  |  | needs for Medicare |  |  |
|  |  | beneficiaries |  |  |
| 1320a-7e(b)(6)(A) | 42 CFR Part 1003 | Penalty for failure | 25,000 | 1997 |
|  |  | to report any final |  |  |
|  |  | adverse action taken |  |  |
|  |  | against a health care |  |  |
|  |  | provider, supplier, |  |  |
|  |  | or practitioner |  |  |
| 1320b-10(b)fn1 | 42 CFR Part 1003 | Penalty for the | 5,000 | 1988 |
|  |  | 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 |  |  |
| 1320b-10(b)(2) | 42 CFR Part 1003 | Penalty for the | 25,000 | 1988 |
|  |  | 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 |  |  |
| 1395i- |  | Penalty for | 1,000 | 1987 |
| 3(b)(3)(B)(ii)(1) |  | certification of a |  |  |
|  |  | false statement in |  |  |
|  |  | assessment of |  |  |
|  |  | functional capacity |  |  |
|  |  | of a Skilled Nursing |  |  |
|  |  | Facility resident |  |  |
|  |  | assessment |  |  |
| 1395i- |  | Penalty for causing | 5,000 | 1987 |
| 3(b)(3)(B)(ii)(2) |  | another to certify or |  |  |
|  |  | make a false |  |  |
|  |  | statement in |  |  |
|  |  | assessment of |  |  |
|  |  | functional capacity |  |  |
|  |  | of a Skilled Nursing |  |  |
|  |  | Facility resident |  |  |
|  |  | assessment |  |  |
| 1395i-3(g)(2)(A) |  | Penalty for any | 2,000 | 1987 |
|  |  | 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 |  |  |
| 1395w-27(g)(2)(A) | 42 CFR 422.752; | Penalty for a | 25,000 | 1996 |
|  | 42 CFR Part 1003 | Medicare Advantage |  |  |
|  |  | organization that |  |  |
|  |  | substantially fails |  |  |
|  |  | to provide medically |  |  |
|  |  | necessary, required |  |  |
|  |  | items and services |  |  |
|  |  | Penalty for a | 25,000 | 1997 |
|  |  | Medicare Advantage |  |  |
|  |  | organization that |  |  |
|  |  | charges excessive |  |  |
|  |  | premiums |  |  |
|  |  | Penalty for a | 25,000 | 1997 |
|  |  | Medicare Advantage |  |  |
|  |  | organization that |  |  |
|  |  | improperly expels or |  |  |
|  |  | refuses to reenroll a |  |  |
|  |  | beneficiary |  |  |
|  |  | Penalty for a | 100,000 | 1997 |
|  |  | Medicare Advantage |  |  |
|  |  | organization that |  |  |
|  |  | engages in practice |  |  |
|  |  | that would reasonably |  |  |
|  |  | be expected to have |  |  |
|  |  | the effect of denying |  |  |
|  |  | or discouraging |  |  |
|  |  | enrollment |  |  |
|  |  | Penalty per | 15,000 | 1997 |
|  |  | 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 |  |  |
|  |  | Penalty for a | 100,000 | 1997 |
|  |  | Medicare Advantage |  |  |
|  |  | organization |  |  |
|  |  | misrepresenting or |  |  |
|  |  | falsifying |  |  |
|  |  | information to |  |  |
|  |  | Secretary |  |  |
|  |  | Penalty for a | 25,000 | 1997 |
|  |  | Medicare Advantage |  |  |
|  |  | organization |  |  |
|  |  | misrepresenting or |  |  |
|  |  | falsifying |  |  |
|  |  | information to |  |  |
|  |  | individual or other |  |  |
|  |  | entity |  |  |
|  |  | Penalty for Medicare | 25,000 | 1997 |
|  |  | Advantage |  |  |
|  |  | organization |  |  |
|  |  | interfering with |  |  |
|  |  | provider's advice to |  |  |
|  |  | enrollee and non-MCO |  |  |
|  |  | affiliated providers |  |  |
|  |  | that balance bill |  |  |
|  |  | enrollees |  |  |
|  |  | Penalty for a | 25,000 | 1997 |
|  |  | Medicare Advantage |  |  |
|  |  | organization that |  |  |
|  |  | employs or contracts |  |  |
|  |  | with excluded |  |  |
|  |  | individual or entity |  |  |
|  |  | Penalty for a | 25,000 | 2010 |
|  |  | Medicare Advantage |  |  |
|  |  | organization |  |  |
|  |  | enrolling an |  |  |
|  |  | individual in without |  |  |
|  |  | prior written consent |  |  |
|  |  | Penalty for a | 25,000 | 2010 |
|  |  | Medicare Advantage |  |  |
|  |  | organization |  |  |
|  |  | transferring an |  |  |
|  |  | enrollee to another |  |  |
|  |  | plan without consent |  |  |
|  |  | or solely for the |  |  |
|  |  | purpose of earning a |  |  |
|  |  | commission |  |  |
|  |  | Penalty for a | 25,000 | 2010 |
|  |  | Medicare Advantage |  |  |
|  |  | organization failing |  |  |
|  |  | to comply with |  |  |
|  |  | marketing |  |  |
|  |  | restrictions or |  |  |
|  |  | applicable |  |  |
|  |  | implementing |  |  |
|  |  | ***regulations*** or |  |  |
|  |  | guidance |  |  |
|  |  | Penalty for a | 25,000 | 2010 |
|  |  | Medicare Advantage |  |  |
|  |  | organization |  |  |
|  |  | employing or |  |  |
|  |  | contracting with an |  |  |
|  |  | individual or entity |  |  |
|  |  | who violates 1395w- |  |  |
|  |  | 27(g)fn1(A)-(J) |  |  |
| 1395w-141(i)(3) | 42 CFR Part 1003 | Penalty for a | 10,000 | 2003 |
|  |  | prescription drug |  |  |
|  |  | card sponsor that |  |  |
|  |  | falsifies or |  |  |
|  |  | misrepresents |  |  |
|  |  | marketing materials, |  |  |
|  |  | overcharges program |  |  |
|  |  | enrollees, or misuse |  |  |
|  |  | transitional |  |  |
|  |  | assistance funds |  |  |
| 1395cc(g) | 42 CFR Part 1003 | Penalty for improper | 2,000 | 1972 |
|  |  | billing by Hospitals, |  |  |
|  |  | Critical Access |  |  |
|  |  | Hospitals, or Skilled |  |  |
|  |  | Nursing Facilities |  |  |
| 1395dd(d)(1) | 42 CFR Part 1003 | Penalty for a | 50,000 | 1987 |
|  |  | hospital or |  |  |
|  |  | responsible physician |  |  |
|  |  | dumping patients |  |  |
|  |  | needing emergency |  |  |
|  |  | medical care, if the |  |  |
|  |  | hospital has 100 beds |  |  |
|  |  | or more |  |  |
|  |  | Penalty for a | 25,000 | 1987 |
|  |  | hospital or |  |  |
|  |  | responsible physician |  |  |
|  |  | dumping patients |  |  |
|  |  | needing emergency |  |  |
|  |  | care, if the hospital |  |  |
|  |  | has less than 100 |  |  |
|  |  | beds |  |  |
| 1395mm(i)(6)(B) | 42 CFR Part 1003 | Penalty for a HMO or | 25,000 | 1987 |
| (i) |  | ***competitive*** plan is |  |  |
|  |  | such plan |  |  |
|  |  | substantially fails |  |  |
|  |  | to provide medically |  |  |
|  |  | necessary, required |  |  |
|  |  | items or services |  |  |
|  |  | Penalty for | 25,000 | 1987 |
|  |  | HMOs/***competitive*** |  |  |
|  |  | medical plans that |  |  |
|  |  | charge premiums in |  |  |
|  |  | excess of permitted |  |  |
|  |  | amounts |  |  |
|  |  | Penalty for a HMO or | 25,000 | 1987 |
|  |  | ***competitive*** medical |  |  |
|  |  | plan that expels or |  |  |
|  |  | refuses to reenroll |  |  |
|  |  | an individual per |  |  |
|  |  | prescribed conditions |  |  |
|  |  | Penalty for a HMO or | 100,000 | 1987 |
|  |  | ***competitive*** medical |  |  |
|  |  | plan that implements |  |  |
|  |  | practices to |  |  |
|  |  | discourage enrollment |  |  |
|  |  | of individuals |  |  |
|  |  | needing services in |  |  |
|  |  | future |  |  |
|  |  | Penalty per | 15,000 | 1988 |
|  |  | individual not |  |  |
|  |  | enrolled in a plan as |  |  |
|  |  | a result of a HMO or |  |  |
|  |  | ***competitive*** medical |  |  |
|  |  | plan that implements |  |  |
|  |  | practices to |  |  |
|  |  | discourage enrollment |  |  |
|  |  | of individuals |  |  |
|  |  | needing services in |  |  |
|  |  | the future |  |  |
|  |  | Penalty for a HMO or | 100,000 | 1987 |
|  |  | ***competitive*** medical |  |  |
|  |  | plan that |  |  |
|  |  | misrepresents or |  |  |
|  |  | falsifies information |  |  |
|  |  | to the Secretary |  |  |
|  |  | Penalty for a HMO or | 25,000 | 1987 |
|  |  | ***competitive*** medical |  |  |
|  |  | plan that |  |  |
|  |  | misrepresents or |  |  |
|  |  | falsifies information |  |  |
|  |  | to an individual or |  |  |
|  |  | any other entity |  |  |
|  |  | Penalty for failure | 25,000 | 1987 |
|  |  | by HMO or ***competitive*** |  |  |
|  |  | medical plan to |  |  |
|  |  | assure prompt payment |  |  |
|  |  | of Medicare risk |  |  |
|  |  | sharing contracts or |  |  |
|  |  | incentive plan |  |  |
|  |  | provisions |  |  |
|  |  | Penalty for HMO that | 25,000 | 1989 |
|  |  | employs or contracts |  |  |
|  |  | with excluded |  |  |
|  |  | individual or entity |  |  |
| 1395nn(g)(3) | 42 CFR Part 1003 | Penalty for | 15,000 | 1994 |
|  |  | submitting or causing |  |  |
|  |  | to be submitted |  |  |
|  |  | claims in violation |  |  |
|  |  | of the Stark Law's |  |  |
|  |  | restrictions on |  |  |
|  |  | physician self- |  |  |
|  |  | referrals |  |  |
| 1395nn(g)(4) | 42 CFR Part 1003 | Penalty for | 100,000 | 1994 |
|  |  | circumventing Stark |  |  |
|  |  | Law's restrictions on |  |  |
|  |  | physician self- |  |  |
|  |  | referrals |  |  |
| 1395ss(d)(1) | 42 CFR Part 1003 | Penalty for a | 5,000 | 1988 |
|  |  | material |  |  |
|  |  | misrepresentation |  |  |
|  |  | regarding Medigap |  |  |
|  |  | compliance policies |  |  |
| 1395ss(d)(2) | 42 CFR Part 1003 | Penalty for selling | 5,000 | 1988 |
|  |  | Medigap policy under |  |  |
|  |  | false pretense |  |  |
| 1395ss(d)(3)(A) | 42 CFR Part 1003 | Penalty for an issuer | 25,000 | 1990 |
| (ii) |  | that sells health |  |  |
|  |  | insurance policy that |  |  |
|  |  | duplicates benefits |  |  |
|  |  | Penalty for someone | 15,000 | 1990 |
|  |  | other than issuer |  |  |
|  |  | that sells health |  |  |
|  |  | insurance that |  |  |
|  |  | duplicates benefits |  |  |
| 1395ss(d)(4)(A) | 42 CFR Part 1003 | Penalty for using | 5,000 | 1988 |
|  |  | mail to sell a non- |  |  |
|  |  | approved Medigap |  |  |
|  |  | insurance policy |  |  |
| 1396b(m)(5)(B)(i) | 42 CFR Part 1003 | Penalty for a | 25,000 | 1988 |
|  |  | Medicaid MCO that |  |  |
|  |  | substantially fails |  |  |
|  |  | to provide medically |  |  |
|  |  | necessary, required |  |  |
|  |  | items or services |  |  |
|  |  | Penalty for a | 25,000 | 1988 |
|  |  | Medicaid MCO that |  |  |
|  |  | charges excessive |  |  |
|  |  | premiums |  |  |
|  |  | Penalty for a | 100,000 | 1988 |
|  |  | Medicaid MCO that |  |  |
|  |  | improperly expels or |  |  |
|  |  | refuses to reenroll a |  |  |
|  |  | beneficiary |  |  |
|  |  | Penalty per | 15,000 | 1988 |
|  |  | 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 |  |  |
|  |  | Penalty for a | 100,000 | 1988 |
|  |  | Medicaid MCO |  |  |
|  |  | misrepresenting or |  |  |
|  |  | falsifying |  |  |
|  |  | information to the |  |  |
|  |  | Secretary |  |  |
|  |  | Penalty for a | 25,000 | 1988 |
|  |  | Medicaid MCO |  |  |
|  |  | misrepresenting or |  |  |
|  |  | falsifying |  |  |
|  |  | information to an |  |  |
|  |  | individual or another |  |  |
|  |  | entity |  |  |
|  |  | Penalty for a | 25,000 | 1990 |
|  |  | Medicaid MCO that |  |  |
|  |  | fails to comply with |  |  |
|  |  | contract requirements |  |  |
|  |  | with respect to |  |  |
|  |  | physician incentive |  |  |
|  |  | plans |  |  |
| 1396r(b)(3)(B) | 42 CFR Part 1003 | Penalty for willfully | 1,000 | 1987 |
| (ii)(I) |  | and knowingly |  |  |
|  |  | certifying a material |  |  |
|  |  | and false statement |  |  |
|  |  | in a Skilled Nursing |  |  |
|  |  | Facility resident |  |  |
|  |  | assessment |  |  |
| 1396r(b)(3)(B) | 42 CFR Part 1003 | Penalty for willfully | 5,000 | 1987 |
| (ii)(II) |  | and knowingly causing |  |  |
|  |  | another individual to |  |  |
|  |  | certify a material |  |  |
|  |  | and false statement |  |  |
|  |  | in a Skilled Nursing |  |  |
|  |  | Facility resident |  |  |
|  |  | assessment |  |  |
| 1396r(g)(2)(A)(i) | 42 CFR Part 1003 | Penalty for notifying | 2,000 | 1987 |
|  |  | or causing to be |  |  |
|  |  | notified a Skilled |  |  |
|  |  | Nursing Facility of |  |  |
|  |  | the time or date on |  |  |
|  |  | which a survey is to |  |  |
|  |  | be conducted |  |  |
| 1396r-8(b)(3)(B) | 42 CFR Part 1003 | Penalty for the | 100,000 | 1990 |
|  |  | knowing provision of |  |  |
|  |  | false information or |  |  |
|  |  | refusing to provide |  |  |
|  |  | information about |  |  |
|  |  | charges or prices of |  |  |
|  |  | a covered outpatient |  |  |
|  |  | drug |  |  |
| 1396r- | 42 CFR Part 1003 | Penalty per day for | 10,000 | 1990 |
| 8(b)(3)(C)(i) |  | failure to timely |  |  |
|  |  | provide information |  |  |
|  |  | by drug manufacturer |  |  |
|  |  | with rebate agreement |  |  |
| 1396r- | 42 CFR Part 1003 | Penalty for knowing | 100,000 | 1990 |
| 8(b)(3)(C)(ii) |  | provision of false |  |  |
|  |  | information by drug |  |  |
|  |  | manufacturer with |  |  |
|  |  | rebate agreement |  |  |
| 1396t(i)(3)(A) | 42 CFR Part 1003 | Penalty for notifying | 2,000 | 1990 |
|  |  | home and community- |  |  |
|  |  | based providers or |  |  |
|  |  | settings of survey |  |  |
| 11131(c) | 42 CFR Part 1003 | Penalty for failing | 10,000 | 1986 |
|  |  | to report a medical |  |  |
|  |  | malpractice claim to |  |  |
|  |  | National Practitioner |  |  |
|  |  | Data Bank |  |  |
| 11137(b)(2) | 42 CFR Part 1003 | Penalty for breaching | 10,000 | 1986 |
|  |  | confidentiality of |  |  |
|  |  | information reported |  |  |
|  |  | to National |  |  |
|  |  | Practitioner Data |  |  |
|  |  | Bank |  |  |
| 42 U.S.C. (OCR): |  |  |  |  |
| 299b-22(f)(1) | 42 CFR 3.404(b) | Penalty for violation | 10,000 | 2005 |
|  |  | of confidentiality |  |  |
|  |  | provision of the |  |  |
|  |  | Patient Safety and |  |  |
|  |  | Quality Improvement |  |  |
|  |  | Act |  |  |
| 1320(d)-5(a) | 45 CFR | Penalty for each pre- | 100 | 1996 |
|  | 160.404(b)(1)(i), | February 18, 2009 |  |  |
|  | (ii) | violation of the |  |  |
|  |  | HIPAA administrative |  |  |
|  |  | simplification |  |  |
|  |  | provisions |  |  |
|  |  | Calendar Year Cap | 25,000 | 1996 |
|  | 45 CFR 160.404(b) | Penalty for each |  |  |
|  | (2)(i)(A),(B) | 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 | 2009 |
|  |  | Maximum | 50,000 | 2009 |
|  |  | Calendar Year Cap | 1,500,000 | 2009 |
|  | 45 CFR | Penalty for each |  |  |
|  | 160.404(b)(2)(ii) | February 18, 2009 or |  |  |
|  | (A), (B) | 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 | 2009 |
|  |  | Maximum | 50,000 | 2009 |
|  |  | Calendar Year Cap | 1,500,000 | 2009 |
|  | 45 CFR 160.404 | Penalty for each |  |  |
|  | (b)(2)(iii)(A), | February 18, 2009 or |  |  |
|  | (B) | 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 | 2009 |
|  |  | Maximum | 50,000 | 2009 |
|  |  | Calendar Year Cap | 1,500,000 | 2009 |
|  | 45 CFR | Penalty for each |  |  |
|  | 160.404(b)(2)(iv) | February 18, 2009 or |  |  |
|  | (A), (B) | 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 | 2009 |
|  |  | Maximum | 1,500,000 | 2009 |
|  |  | Calendar Year Cap | 1,500,000 | 2009 |
| 42 U.S.C. (CMS): |  |  |  |  |
| 263a(h)(2)(B) & | 42 CFR | Penalty for a |  |  |
| 1395w- | 493.1834(d)(2)(i) | clinical laboratory's |  |  |
| 2(b)(2)(A)(ii) |  | failure to meet |  |  |
|  |  | participation and |  |  |
|  |  | certification |  |  |
|  |  | requirements and |  |  |
|  |  | poses immediate |  |  |
|  |  | jeopardy: |  |  |
|  |  | Minimum | 3,050 | 1988 |
|  |  | Maximum | 10,000 | 1988 |
|  | 42 CFR 493.1834 | Penalty for a |  |  |
|  | (d)(2)(ii) | clinical laboratory's |  |  |
|  |  | failure to meet |  |  |
|  |  | participation and |  |  |
|  |  | certification |  |  |
|  |  | requirements and the |  |  |
|  |  | failure does not pose |  |  |
|  |  | immediate jeopardy: |  |  |
|  |  | Minimum | 50 | 1988 |
|  |  | Maximum | 3,000 | 1988 |
| 300gg-15(f) | 45 CFR 147.200(e) | Failure to provide | 1,000 | 2010 |
|  |  | the Summary of |  |  |
|  |  | Benefits and Coverage |  |  |
|  |  | (SBC) |  |  |
| 300gg-18 | 45 CFR 158.606 | Penalty for | 100 | 2010 |
|  |  | violations of |  |  |
|  |  | ***regulations*** related |  |  |
|  |  | to the medical loss |  |  |
|  |  | ratio reporting and |  |  |
|  |  | rebating |  |  |
| 1320a-7h(b)(1) | 42 CFR | Penalty for |  |  |
|  | 402.105(d)(5), 42 | manufacturer or group |  |  |
|  | CFR 403.912(a) & | purchasing |  |  |
|  | (c) | 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 |
|  |  | Maximum | 10,000 | 2010 |
|  |  | Calendar Year Cap | 150,000 | 2010 |
| 1320a-7h(b)(2) | 42 CFR | Penalty for |  |  |
|  | 402.105(h), 42 | manufacturer or group |  |  |
|  | CFR 403 912(b) & | purchasing |  |  |
|  | (c) | 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 |
|  |  | Maximum | 100,000 | 2010 |
|  |  | Calendar Year Cap | 1,000,000 | 2010 |
| 1320a-7j(h)(3)(A) |  | Penalty for an | 100,000 | 2010 |
|  |  | administrator of a |  |  |
|  |  | facility that fails |  |  |
|  |  | to comply with notice |  |  |
|  |  | requirements for the |  |  |
|  |  | closure of a facility |  |  |
|  | 42 CFR | Minimum penalty for | 500 | 2010 |
|  | 488.446(a)(1),(2) | the first offense of |  |  |
|  | , & (3) | an administrator who |  |  |
|  |  | fails to provide |  |  |
|  |  | notice of facility |  |  |
|  |  | closure |  |  |
|  |  | Minimum penalty for | 1,500 | 2010 |
|  |  | the second offense of |  |  |
|  |  | an administrator who |  |  |
|  |  | fails to provide |  |  |
|  |  | notice of facility |  |  |
|  |  | closure |  |  |
|  |  | Minimum penalty for | 3,000 | 2010 |
|  |  | the third and |  |  |
|  |  | subsequent offenses |  |  |
|  |  | of an administrator |  |  |
|  |  | who fails to provide |  |  |
|  |  | notice of facility |  |  |
|  |  | closure |  |  |
| 1320a-8(a)(1) |  | Penalty for an entity | 5,000 | 1994 |
|  |  | 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 |  |  |
|  |  | Penalty for the | 7,500 | 2015 |
|  |  | 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 |  |  |
| 1320a-8(a)(3) |  | Penalty for a | 5,000 | 2004 |
|  |  | 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 |  |  |
| 1320b-25(c)(1)(A) |  | Penalty for failure | 200,000 | 2010 |
|  |  | 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 |  |  |
| 1320b-25(c)(2)(A) |  | Penalty for failure | 300,000 | 2010 |
|  |  | 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 |  |  |
| 1320b-25(d)(2) |  | Penalty for a long- | 200,000 | 2010 |
|  |  | 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 |  |  |
| 1395b-7(b)(2)(B) | 42 CFR 402.105(g) | Penalty for any | 100 | 1997 |
|  |  | 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 |  |  |
| 1395i- | 42 CFR 488.408 | Penalty per day for a |  |  |
| 3(h)(2)(B)(ii)(I) | (d)(1)(iii) | Skilled Nursing |  |  |
|  |  | Facility that has a |  |  |
|  |  | Category 2 violation |  |  |
|  |  | of certification |  |  |
|  |  | requirements: |  |  |
|  |  | Minimum | 50 | 1987 |
|  |  | Maximum | 3,000 | 1987 |
|  | 42 CFR | Penalty per instance |  |  |
|  | 488.408(d)(1)(iv) | of Category 2 |  |  |
|  |  | noncompliance by a |  |  |
|  |  | Skilled Nursing |  |  |
|  |  | Facility: |  |  |
|  |  | Minimum | 1,000 | 1987 |
|  |  | Maximum | 10,000 | 1987 |
|  | 42 CFR 488.408 | Penalty per day for a |  |  |
|  | (e)(1)(iii) | Skilled Nursing |  |  |
|  |  | Facility that has a |  |  |
|  |  | Category 3 violation |  |  |
|  |  | of certification |  |  |
|  |  | requirements: |  |  |
|  |  | Minimum | 3,050 | 1987 |
|  |  | Maximum | 10,000 | 1987 |
|  | 42 CFR | Penalty per instance |  |  |
|  | 488.408(e)(1)(iv) | of Category 3 |  |  |
|  |  | noncompliance by a |  |  |
|  |  | Skilled Nursing |  |  |
|  |  | Facility: |  |  |
|  |  | Minimum | 1,000 | 1987 |
|  |  | Maximum | 10,000 | 1987 |
|  |  | 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 |
|  |  | Per Day (Maximum) | 10,000 | 1987 |
|  |  | Per Instance | 1,000 | 1987 |
|  |  | (Minimum) |  |  |
|  |  | Per Instance | 10,000 | 1987 |
|  |  | (Maximum) |  |  |
|  | 42 CFR | Penalty per day of a |  |  |
|  | 488.438(a)(1)(i) | Skilled Nursing |  |  |
|  |  | Facility that fails |  |  |
|  |  | to meet certification |  |  |
|  |  | requirements. These |  |  |
|  |  | amounts represent the |  |  |
|  |  | upper range per day: |  |  |
|  |  | Minimum | 3,050 | 1987 |
|  |  | Maximum | 10,000 | 1987 |
|  | 42 CFR | Penalty per day of a |  |  |
|  | 488.438(a)(1)(ii) | Skilled Nursing |  |  |
|  |  | Facility that fails |  |  |
|  |  | to meet certification |  |  |
|  |  | requirements. These |  |  |
|  |  | amounts represent the |  |  |
|  |  | lower range per day: |  |  |
|  |  | Minimum | 50 | 1987 |
|  |  | Maximum | 3,000 | 1987 |
|  | 42 CFR | Penalty per instance |  |  |
|  | 488.438(a)(2) | of a Skilled Nursing |  |  |
|  |  | Facility that fails |  |  |
|  |  | to meet certification |  |  |
|  |  | requirements: |  |  |
|  |  | Minimum | 1,000 | 1987 |
|  |  | Maximum | 10,000 | 1987 |
| 1395l(h)(5)(D) | 42 CFR | Penalty for | 10,000 | 1996 |
|  | 402.105(d)(2)(i) | 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)) |  |  |
| 1395l(i)(6) |  | Penalty for knowingly | 2,000 | 1988 |
|  |  | 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 |  |  |
| 1395l(q)(2)(B)(i) | 42 CFR 402.105(a) | Penalty for knowingly | 2,000 | 1989 |
|  |  | and willfully failing |  |  |
|  |  | to provide |  |  |
|  |  | information about a |  |  |
|  |  | referring physician |  |  |
|  |  | when seeking payment |  |  |
|  |  | on an unassigned |  |  |
|  |  | basis |  |  |
| 1395m(a)(11)(A) | 42 CFR | Penalty for any | 10,000 | 1996 |
|  | 402.1(c)(4), | durable medical |  |  |
|  | 402.105(d)(2)(ii) | 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)) |  |  |
| 1395m(a)(18)(B) | 42 CFR | Penalty for any | 10,000 | 1996 |
|  | 402.1(c)(5), | nonparticipating |  |  |
|  | 402.105(d)(2) | durable medical |  |  |
|  | (iii) | 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)) |  |  |
| 1395m(b)(5)(C) | 42 CFR | Penalty for any | 10,000 | 1996 |
|  | 402.1(c)(6), | nonparticipating |  |  |
|  | 402.105(d)(2)(iv) | 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)) |  |  |
| 1395m(h)(3) | 42 CFR | Penalty for any | 10,000 | 1996 |
|  | 402.1(c)(8), | supplier of |  |  |
|  | 402.105(d)(2)(vi) | prosthetic devices, |  |  |
|  |  | orthotics, and |  |  |
|  |  | prosthetics that |  |  |
|  |  | knowing 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)) |  |  |
| 1395m(j)(2)(A) |  | Penalty for any | 1,000 | 1994 |
| (iii) |  | 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 |  |  |
| 1395m(j)(4) | 42 CFR | Penalty for any | 10,000 | 1996 |
|  | 402.1(c)(10), | supplier of durable |  |  |
|  | 402.105(d)(2) | medical equipment, |  |  |
|  | (vii) | 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 as |  |  |
|  |  | 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)) |  |  |
| 1395m(k)(6) | 42 CFR | Penalty for any | 10,000 | 1996 |
|  | 402.1(c)(31), | person or entity who |  |  |
|  | 402.105(d)(3) | 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)) |  |  |
| 1395m(l)(6) | 42 CFR | Penalty for any | 10,000 | 1996 |
|  | 402.1(c)(32), | supplier of ambulance |  |  |
|  | 402.105(d)(4) | 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)) |  |  |
| 1395u(b)(18)(B) | 42 CFR | Penalty for any | 10,000 | 1996 |
|  | 402.1(c)(11), | practitioner |  |  |
|  | 402.105(d)(2) | specified in Section |  |  |
|  | (viii) | 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)) |  |  |
| 1395u(j)(2)(B) | 42 CFR 402.1(c) | Penalty for any | 10,000 | 1996 |
|  |  | 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)) |  |  |
| 1395u(k) | 42 CFR | Penalty for any | 10,000 | 1996 |
|  | 402.1(c)(12), | physician who |  |  |
|  | 402.105(d)(2)(ix) | 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)) |  |  |
| 1395u(l)(3) | 42 CFR | Penalty for any | 10,000 | 1996 |
|  | 402.1(c)(13), | nonparticipating |  |  |
|  | 402.105(d)(2)(x) | 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)) |  |  |
| 1395u(m)(3) | 42 CFR | Penalty for any | 10,000 | 1996 |
|  | 402.1(c)(14), | nonparticipating |  |  |
|  | 402.105(d)(2)(xi) | 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)) |  |  |
| 1395u(n)(3) | 42 CFR | Penalty for any | 10,000 | 1996 |
|  | 402.1(c)(15), | physician who |  |  |
|  | 402.105(d)(2) | knowingly, willfully, |  |  |
|  | (xii) | 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)) |  |  |
| 1395u(o)(3)(B) | 42 CFR 414.707(b) | Penalty for any | 10,000 | 1996 |
|  |  | 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)) |  |  |
| 1395u(p)(3)(A) |  | Penalty for any | 2,000 | 1988 |
|  |  | 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 |  |  |
| 1395w-3a(d)(4)(A) | 42 CFR 414.806 | Penalty for a | 10,000 | 2003 |
|  |  | pharmaceutical |  |  |
|  |  | manufacturer's |  |  |
|  |  | misrepresentation of |  |  |
|  |  | average sales price |  |  |
|  |  | of a drug, or |  |  |
|  |  | biologic |  |  |
| 1395w-4(g)(1)(B) | 42 CFR | Penalty for any | 10,000 | 1996 |
|  | 402.1(c)(17), | nonparticipating |  |  |
|  | 402.105(d)(2) | physician, supplier, |  |  |
|  | (xiii) | 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)) |  |  |
| 1395w-4(g)(3)(B) | 42 CFR | Penalty for any | 10,000 | 1996 |
|  | 402.1(c)(18), | person that knowingly |  |  |
|  | 402.105(d)(2) | and willfully bills |  |  |
|  | (xiv) | 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)) |  |  |
| 1395w- | 42 CFR | Penalty for each | 25,000 | 1997 |
| 27(g)(3)(A); | 422.760(b); 42 | termination |  |  |
| 1857(g)(3) | CFR 423.760(b) | 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 |  |  |
| 1395w- |  | Penalty for each week | 10,000 | 1997 |
| 27(g)(3)(B); |  | beginning after the |  |  |
| 1857(g)(3) |  | 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*** |  |  |
| 1395w- |  | Penalty for a | 100,000 | 2000 |
| 27(g)(3)(D); |  | Medicare Advantage |  |  |
| 1857(g)(3) |  | organization's or |  |  |
|  |  | Part D sponsor's |  |  |
|  |  | early termination of |  |  |
|  |  | its contract |  |  |
| 1395y(b)(3)(C) | 42 CFR 411.103(b) | Penalty for an | 5,000 | 1990 |
|  |  | 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 |  |  |
| 1395y(b)(5)(C) | 42 CFR | Penalty for any non- | 1,000 | 1998 |
| (ii) | 402.1(c)(20), | governmental employer |  |  |
|  | 402.105(b)(2) | 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 |  |  |
| 1395y(b)(6)(B) | 42 CFR | Penalty for any | 2,000 | 1994 |
|  | 402.1(c)(21), | entity that |  |  |
|  | 402.105(a) | 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 |  |  |
| 1395y(b)(7)(B)(i) |  | Penalty for any | 1,000 | 2007 |
|  |  | 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 |  |  |
| 1395y(b)(8)(E) |  | Penalty for any non- | 1,000 | 2007 |
|  |  | 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 |  |  |
| 1395nn(g)(5) | 42 CFR 411.361 | Penalty for any | 10,000 | 1989 |
|  |  | person that fails to |  |  |
|  |  | report information |  |  |
|  |  | required by HHS under |  |  |
|  |  | Section 1877(f) |  |  |
|  |  | concerning ownership, |  |  |
|  |  | investment, and |  |  |
|  |  | compensation |  |  |
|  |  | arrangements |  |  |
| 1395pp(h) | 42 CFR | Penalty for any | 10,000 | 1996 |
|  | 402.1(c)(23), | durable medical |  |  |
|  | 402.105(d)(2)(xv) | 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)) |  |  |
| 1395ss(a)(2) | 42 CFR | Penalty for any | 25,000 | 1987 |
|  | 402.1(c)(24), | person that issues a |  |  |
|  | 405.105(f)(1) | 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 |  |  |
| 1395ss(d)(3)(A) |  | Penalty for someone | 15,000 | 1990 |
| (vi) (II) |  | other than issuer |  |  |
|  |  | that sells or issues |  |  |
|  |  | a Medicare |  |  |
|  |  | supplemental policy |  |  |
|  |  | to beneficiary |  |  |
|  |  | without a disclosure |  |  |
|  |  | statement |  |  |
|  |  | Penalty for an issuer | 25,000 | 1990 |
|  |  | that sells or issues |  |  |
|  |  | a Medicare |  |  |
|  |  | supplemental policy |  |  |
|  |  | without disclosure |  |  |
|  |  | statement |  |  |
| 1395ss(d)(3)(B) |  | Penalty for someone | 15,000 | 1990 |
| (iv) |  | other than issuer |  |  |
|  |  | that sells or issues |  |  |
|  |  | a Medicare |  |  |
|  |  | supplemental policy |  |  |
|  |  | without |  |  |
|  |  | acknowledgement form |  |  |
|  |  | Penalty for issuer | 25,000 | 1990 |
|  |  | that sells or issues |  |  |
|  |  | a Medicare |  |  |
|  |  | supplemental policy |  |  |
|  |  | without an |  |  |
|  |  | acknowledgement form |  |  |
| 1395ss(p)(8) | 42 CFR | Penalty for any | 15,000 | 1990 |
|  | 402.1(c)(25), | person that sells or |  |  |
|  | 402.105(e) | issues Medicare |  |  |
|  |  | supplemental polices |  |  |
|  |  | after a given date |  |  |
|  |  | that fail to conform |  |  |
|  |  | to the NAIC or |  |  |
|  |  | Federal standards |  |  |
|  |  | established by |  |  |
|  |  | statute |  |  |
|  | 42 CFR | Penalty for any | 25,000 | 1990 |
|  | 402.1(c)(25), | person that sells or |  |  |
|  | 405.105(f)(2) | issues Medicare |  |  |
|  |  | supplemental polices |  |  |
|  |  | after a given date |  |  |
|  |  | that fail to conform |  |  |
|  |  | to the NAIC or |  |  |
|  |  | Federal standards |  |  |
|  |  | established by |  |  |
|  |  | statute |  |  |
| 1395ss(p)(9)(C) | 42 CFR | Penalty for any | 15,000 | 1990 |
|  | 402.1(c)(26), | person that sells a |  |  |
|  | 402.105(e) | 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 |  |  |
|  | 42 CFR | Penalty for any | 25,000 | 1990 |
|  | 402.1(c)(26), | person that sells a |  |  |
|  | 405.105(f)(3), | Medicare supplemental |  |  |
|  | (4) | 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 |  |  |
| 1395ss(q)(5)(C) | 42 CFR | Penalty for any | 25,000 | 1990 |
|  | 402.1(c)(27), | person that fails to |  |  |
|  | 405.105(f)(5) | 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 |  |  |
| 1395ss(r)(6)(A) | 42 CFR | Penalty for any | 25,000 | 1990 |
|  | 402.1(c)(28), | person that fails to |  |  |
|  | 405.105(f)(6) | provide refunds or |  |  |
|  |  | credits as required |  |  |
|  |  | by section |  |  |
|  |  | 1882(r)(1)(B) |  |  |
| 1395ss(s)(4) | 42 CFR | Penalty for any | 5,000 | 1990 |
|  | 402.1(c)(29), | issuer of a Medicare |  |  |
|  | 405.105(c) | 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 |  |  |
| 1395ss(t)(2) | 42 CFR | Penalty for any | 25,000 | 1990 |
|  | 402.1(c)(30), | issuer of a Medicare |  |  |
|  | 405.105(f)(7) | supplemental policy |  |  |
|  |  | that fails to fulfill |  |  |
|  |  | listed |  |  |
|  |  | responsibilities |  |  |
| 1395ss(v)(4)(A) |  | Penalty someone other | 15,000 | 2003 |
|  |  | than issuer who |  |  |
|  |  | sells, issues, or |  |  |
|  |  | renews a medigap Rx |  |  |
|  |  | policy to an |  |  |
|  |  | individual who is a |  |  |
|  |  | Part D enrollee |  |  |
|  |  | Penalty for an issuer | 25,000 | 2003 |
|  |  | who sells, issues, or |  |  |
|  |  | renews a Medigap Rx |  |  |
|  |  | policy who is a Part |  |  |
|  |  | D enrollee |  |  |
| 1395bbb(c)(1) | 42 CFR 488.725(c) | Penalty for any | 2,000 | 1987 |
|  |  | 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 |  |  |  |
| 1395bbb(f)(2)(A) | 42 CFR 488.845 | Maximum daily penalty | 10,000 | 1988 |
| (i) | (b)(2)(iii) | amount for each day a |  |  |
|  |  | home health agency is |  |  |
|  |  | not in compliance |  |  |
|  |  | with statutory |  |  |
|  |  | requirements |  |  |
|  | 42 CFR | Penalty per day for |  |  |
|  | 488.845(b)(3) | home health agency's |  |  |
|  |  | noncompliance (Upper |  |  |
|  |  | Range): |  |  |
|  |  | Minimum | 8,500 | 1988 |
|  |  | Maximum | 10,000 | 1988 |
|  | 42 CFR | Penalty for a home | 10,000 | 1988 |
|  | 488.845(b)(3)(i) | health agency's |  |  |
|  |  | deficiency or |  |  |
|  |  | deficiencies that |  |  |
|  |  | cause immediate |  |  |
|  |  | jeopardy and result |  |  |
|  |  | in actual harm |  |  |
|  | 42 CFR | Penalty for a home | 9,000 | 1988 |
|  | 488.845(b)(3)(ii) | health agency's |  |  |
|  |  | deficiency or |  |  |
|  |  | deficiencies that |  |  |
|  |  | cause immediate |  |  |
|  |  | jeopardy and result |  |  |
|  |  | in potential for harm |  |  |
|  | 42 CFR | Penalty for an | 8,500 | 1988 |
|  | 488.845(b)(3)(iii | isolated incident of |  |  |
|  | ) | noncompliance in |  |  |
|  |  | violation of |  |  |
|  |  | established HHA |  |  |
|  |  | policy |  |  |
|  | 42 CFR | Penalty for a repeat |  |  |
|  | 488.845(b)(4) | 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 |
|  |  | Maximum | 8,500 | 1988 |
|  | 42 CFR | Penalty for a repeat |  |  |
|  | 488.845(b)(5) | 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 | 500 | 1988 |
|  |  | Maximum | 4,000 | 1988 |
| 42 CFR |  | Penalty imposed for |  |  |
| 488.845(b)(6) |  | 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 | 1,000 | 1988 |
|  |  | Maximum | 10,000 | 1988 |
|  |  | Penalty for each day | 10,000 | 1988 |
|  |  | of noncompliance |  |  |
|  |  | (Maximum) |  |  |
|  | 42 CFR | Penalty for each day | 10,000 | 1988 |
|  | 488.845(d)(1)(ii) | of noncompliance |  |  |
|  |  | (Maximum) |  |  |
| 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 | 15,000 | 1997 |
|  |  | Maximum | 100,000 | 1997 |
|  |  | Penalty for a PACE | 25,000 | 1997 |
|  |  | organization that |  |  |
|  |  | charges excessive |  |  |
|  |  | premiums |  |  |
|  |  | Penalty for a PACE | 100,000 | 1997 |
|  |  | organization |  |  |
|  |  | misrepresenting or |  |  |
|  |  | falsifying |  |  |
|  |  | information to CMS, |  |  |
|  |  | the State, or an |  |  |
|  |  | individual or other |  |  |
|  |  | entity |  |  |
|  |  | Penalty for each | 25,000 | 1997 |
|  |  | 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 | 25,000 | 1997 |
|  |  | involuntarily |  |  |
|  |  | disenrolling a |  |  |
|  |  | participant |  |  |
|  |  | Penalty for | 25,000 | 1997 |
|  |  | discriminating or |  |  |
|  |  | discouraging |  |  |
|  |  | enrollment or |  |  |
|  |  | disenrollment of |  |  |
|  |  | participants on the |  |  |
|  |  | basis of an |  |  |
|  |  | individual's health |  |  |
|  |  | status or need for |  |  |
|  |  | health care services |  |  |
| 1396r(h)(3)(C) | 42 CFR 488.408 | Penalty per day for a |  |  |
| (ii)(I) | (d)(1)(iii) | nursing facility's |  |  |
|  |  | failure to meet a |  |  |
|  |  | Category 2 |  |  |
|  |  | Certification: |  |  |
|  |  | Minimum | 50 | 1987 |
|  |  | Maximum | 3,000 | 1987 |
|  | 42 CFR | Penalty per instance |  |  |
|  | 488.408(d)(1)(iv) | for a nursing |  |  |
|  |  | facility's failure to |  |  |
|  |  | meet Category 2 |  |  |
|  |  | certification: |  |  |
|  |  | Minimum | 1,000 | 1987 |
|  |  | Maximum | 10,000 | 1987 |
|  | 42 CFR 488.408 | Penalty per day for a |  |  |
|  | (e)(1)(iii) | nursing facility's |  |  |
|  |  | failure to meet |  |  |
|  |  | Category 3 |  |  |
|  |  | certification: |  |  |
|  |  | Minimum | 3,050 | 1987 |
|  |  | Maximum | 10,000 | 1987 |
|  | 42 CFR | Penalty per instance |  |  |
|  | 488.408(e)(1)(iv) | for a nursing |  |  |
|  |  | facility's failure to |  |  |
|  |  | meet Category 3 |  |  |
|  |  | certification: |  |  |
|  |  | Minimum | 1,000 | 1987 |
|  |  | Maximum | 10,000 | 1987 |
|  | 42 CFR | Penalty per instance |  |  |
|  | 488.408(e)(2)(ii) | for a nursing |  |  |
|  |  | facility's failure to |  |  |
|  |  | meet Category 3 |  |  |
|  |  | certification, which |  |  |
|  |  | results in immediate |  |  |
|  |  | jeopardy: |  |  |
|  |  | Minimum | 1,000 | 1987 |
|  |  | Maximum | 10,000 | 1987 |
|  | 42 CFR | Penalty per day for |  |  |
|  | 488.438(a)(1)(i) | nursing facility's |  |  |
|  |  | failure to meet |  |  |
|  |  | certification (Upper |  |  |
|  |  | Range): |  |  |
|  |  | Minimum | 3,050 | 1987 |
|  |  | Maximum | 10,000 | 1987 |
|  | 42 CFR | Penalty per day for |  |  |
|  | 488.438(a)(1)(ii) | nursing facility's |  |  |
|  |  | failure to meet |  |  |
|  |  | certification (Lower |  |  |
|  |  | Range): |  |  |
|  |  | Minimum | 50 | 1987 |
|  |  | Maximum | 3,000 | 1987 |
|  | 42 CFR | Penalty per instance |  |  |
|  | 488.438(a)(2) | for nursing |  |  |
|  |  | facility's failure to |  |  |
|  |  | meet certification: |  |  |
|  |  | Minimum | 1,000 | 1987 |
|  |  | Maximum | 10,000 | 1987 |
| 1396r(f)(2)(B) | 42 CFR | Grounds to prohibit | 5,000 | 1987 |
| (iii)(I)(c) | 483.151(b)(2)(iv) | approval of Nurse |  |  |
|  | and (b)(3)(iii) | 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] |  |  |
| 1396r(h)(3)(C) | 42 CFR | Grounds to waive | 5,000 | 1987 |
| (ii)(I) | 483.151(c)(2) | 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] |  |  |
| 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 |
|  |  | Maximum | 10,000 | 1990 |
| 1396u- | 42 CFR 438.704 | Penalty for a | 25,000 | 1997 |
| 2(e)(2)(A)(i) |  | Medicaid managed care |  |  |
|  |  | organization that |  |  |
|  |  | fails substantially |  |  |
|  |  | to provide medically |  |  |
|  |  | necessary items and |  |  |
|  |  | services |  |  |
|  |  | Penalty for Medicaid | 25,000 | 1997 |
|  |  | managed care |  |  |
|  |  | organization that |  |  |
|  |  | imposes premiums or |  |  |
|  |  | charges on enrollees |  |  |
|  |  | in excess of the |  |  |
|  |  | premiums or charges |  |  |
|  |  | permitted |  |  |
|  |  | Penalty for a | 25,000 | 1997 |
|  |  | Medicaid managed care |  |  |
|  |  | organization that |  |  |
|  |  | misrepresents or |  |  |
|  |  | falsifies information |  |  |
|  |  | to another individual |  |  |
|  |  | or entity |  |  |
|  |  | Penalty for a | 25,000 | 1997 |
|  |  | Medicaid managed care |  |  |
|  |  | organization that |  |  |
|  |  | fails to comply with |  |  |
|  |  | the applicable |  |  |
|  |  | statutory |  |  |
|  |  | requirements for such |  |  |
|  |  | organizations |  |  |
| 1396u- | 42 CFR 438.704 | Penalty for a | 100,000 | 1997 |
| 2(e)(2)(A)(ii) |  | Medicaid managed care |  |  |
|  |  | organization that |  |  |
|  |  | misrepresents or |  |  |
|  |  | falsifies information |  |  |
|  |  | to the HHS Secretary |  |  |
|  |  | Penalty for Medicaid | 100,000 | 1997 |
|  |  | managed care |  |  |
|  |  | organization that |  |  |
|  |  | acts to discriminate |  |  |
|  |  | among enrollees on |  |  |
|  |  | the basis of their |  |  |
|  |  | health status |  |  |
| 1396u- | 42 CFR 438.704 | Penalty for each | 15,000 | 1997 |
| 2(e)(2)(A)(iv) |  | 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 |  |  |
| 1396u(h)(2) | 42 CFR 441, | Penalty for a | 10,000 | 1990 |
|  | Subpart I | 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 |  |  |
| 1396w-2(c)(1) |  | Penalty for | 10,000 | 2009 |
|  |  | disclosing |  |  |
|  |  | information related |  |  |
|  |  | to eligibility |  |  |
|  |  | determinations for |  |  |
|  |  | medical assistance |  |  |
|  |  | programs |  |  |
| 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 |
|  |  | Maximum | 100,000 | 1997 |
|  |  | Penalty for a PACE | 25,000 | 1997 |
|  |  | organization that |  |  |
|  |  | charges excessive |  |  |
|  |  | premiums |  |  |
|  |  | Penalty for a PACE | 100,000 | 1997 |
|  |  | organization |  |  |
|  |  | misrepresenting or |  |  |
|  |  | falsifying |  |  |
|  |  | information to CMS, |  |  |
|  |  | the State, or an |  |  |
|  |  | individual or other |  |  |
|  |  | entity |  |  |
|  |  | Penalty for each | 25,000 | 1997 |
|  |  | 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 | 25,000 | 1997 |
|  |  | involuntarily |  |  |
|  |  | disenrolling a |  |  |
|  |  | participant |  |  |
|  |  | Penalty for | 25,000 | 1997 |
|  |  | discriminating or |  |  |
|  |  | discouraging |  |  |
|  |  | enrollment or |  |  |
|  |  | disenrollment of |  |  |
|  |  | participants on the |  |  |
|  |  | basis of an |  |  |
|  |  | individual's health |  |  |
|  |  | status or need for |  |  |
|  |  | health care services |  |  |
| 18041(c)(2) | 45 CFR 150.315 | Failure to comply | 100 | 1996 |
|  | and 45 CFR | with requirements of |  |  |
|  | 156.805(c) | 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)) |  |  |
| 18081(h)(1)(A)(i) | 42 CFR 155.285 | Penalty for providing | 25,000 | 2010 |
| (II) |  | false information on |  |  |
|  |  | Exchange application |  |  |
| 18081(h)(1)(B) | 42 CFR 155.285 | Penalty for knowingly | 250,000 | 2010 |
|  |  | or willfully |  |  |
|  |  | providing false |  |  |
|  |  | information on |  |  |
|  |  | Exchange application |  |  |
| 18081(h)(2) | 42 CFR 155.260 | Penalty for knowingly | 25,000 | 2010 |
|  |  | or willfully |  |  |
|  |  | disclosing protected |  |  |
|  |  | information from |  |  |
|  |  | Exchange |  |  |
| 31 U.S.C. (HHS): |  |  |  |  |
| 1352 | 45 CFR 93.400(e) | Penalty for the first | 10,000 | 1989 |
|  |  | 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 | 10,000 | 1989 |
|  |  | Maximum | 100,000 | 1989 |
|  |  | Penalty for the first | 10,000 | 1989 |
|  |  | 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 | 10,000 | 1989 |
|  |  | Maximum | 100,000 | 1989 |
|  | 45 CFR 93, | Penalty for failure |  |  |
|  | Appendix A | to provide |  |  |
|  |  | certification |  |  |
|  |  | regarding lobbying in |  |  |
|  |  | the award documents |  |  |
|  |  | for all sub-awards of |  |  |
|  |  | all tiers: |  |  |
|  |  | Minimum | 10,000 | 1989 |
|  |  | Maximum | 100,000 | 1989 |
|  |  | Penalty for failure |  |  |
|  |  | to provide statement |  |  |
|  |  | regarding lobbying |  |  |
|  |  | for loan guarantee |  |  |
|  |  | and loan insurance |  |  |
|  |  | transactions: |  |  |
|  |  | Minimum | 10,000 | 1989 |
|  |  | Maximum | 100,000 | 1989 |
| 3801-3812 | 45 CFR | Penalty against any | 5,000 | 1988 |
|  | 79.3(a)(1(iv) | individual who--with |  |  |
|  |  | knowledge or reason |  |  |
|  |  | to know--makes, |  |  |
|  |  | presents or submits a |  |  |
|  |  | false, fictitious or |  |  |
|  |  | fraudulent claim to |  |  |
|  |  | the Department |  |  |
|  | 45 CFR | Penalty against any | 5,000 | 1988 |
|  | 79.3(b)(1)(ii) | individual who--with |  |  |
|  |  | knowledge or reason |  |  |
|  |  | to know--makes, |  |  |
|  |  | presents or submits a |  |  |
|  |  | false, fictitious or |  |  |
|  |  | fraudulent claim to |  |  |
|  |  | the Department |  |  |

| **Calculation of CMP Adjustments** | | | | |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Citation** | | **Percentage** | **Increase** | **Maximum** |
|  |  | **increase (4)** | **(] (5)** | **adjusted** |
|  |  |  |  | **penalty** |
|  |  |  |  | **(]** |
| **U.S.C.** | **CFR (1)** |  |  |  |
| 21 U.S.C. (FDA): |  |  |  |  |
| 333(b)(2)(A) |  | 97.869 | 48,935 | 98,935 |
| 333(b)(2)(B) |  | 97.869 | 978,690 | 1,978,690 |
| 333(b)(3) |  | 97.869 | 97,869 | 197,869 |
| 333(f)(1)(A) |  | 78.156 | 11,723 | 26,723 |
|  |  | 78.156 | 781,560 | 1,781,560 |
| 333(f)(2)(A) |  | 50.425 | 25,123 | 75,123 |
|  |  | 50.425 | 125,613 | 375,613 |
|  |  | 50.425 | 251,225 | 751,225 |
| 333(f)(3)(A) |  | 13.833 | 1,383 | 11,383 |
| 333(f)(3)(B) |  | 13.833 | 1,383 | 11,383 |
| 333(f)(4)(A)(i) |  | 13.833 | 34,583 | 284,583 |
|  |  | 13.833 | 138,330 | 1,138,330 |
| 333(f)(4)(A)(ii) |  | 13.833 | 34,583 | 284,583 |
|  |  | 13.833 | 138,330 | 1,138,330 |
|  |  | 13.833 | 1,383,300 | 11,383,300 |
| 333(f)(9)(A) |  | 10.02 | 1,503 | 16,503 |
|  |  | 10.02 | 100,200 | 1,100,200 |
| 333(f)(9)(B)(i) |  | 10.02 | 25,050 | 275,050 |
| (I) |  |  |  |  |
|  |  | 10.02 | 100,200 | 1,100,200 |
| 333(f)(9)(B)(i) |  | 10.02 | 25,050 | 275,050 |
| (II) |  |  |  |  |
|  |  | 10.02 | 100,200 | 1,100,200 |
|  |  | 10.02 | 1,002,000 | 11,002,000 |
| 333(f)(9)(B)(ii) |  | 10.02 | 25,050 | 275,050 |
| (I) |  |  |  |  |
|  |  | 10.02 | 100,200 | 1,100,200 |
| 333(f)(9)(B)(ii) |  | 10.02 | 25,050 | 275,050 |
| (II) |  |  |  |  |
|  |  | 10.02 | 100,200 | 1,100,200 |
|  |  | 10.02 | 1,002,000 | 11,002,000 |
| 333(g)(1) |  | 13.833 | 34,583 | 284,583 |
|  |  | 13.833 | 69165 | 569,165 |
| 333 note |  | 10.02 | 25 | 275 |
|  |  | 10.02 | 50 | 550 |
|  |  | 10.02 | 200 | 2,200 |
|  |  | 10.02 | 501 | 5,501 |
|  |  | 10.02 | 1,002 | 11,002 |
|  |  | 10.02 | 25 | 275 |
|  |  | 10.02 | 50 | 550 |
|  |  | 10.02 | 100 | 1,100 |
|  |  | 10.02 | 200 | 2,200 |
|  |  | 10.02 | 501 | 5,501 |
|  |  | 10.02 | 1002 | 11,002 |
| 335b(a) |  | 67.728 | 169,320 | 419,320 |
|  |  | 67.728 | 677,280 | 1,677,280 |
| 360pp(b)(1) |  | 150 | 1,500 | 2,750 |
|  |  | 150 | 562,500 | 937,500 |
| 42 U.S.C. (FDA): |  |  |  |  |
| 262(d) |  | 115.628 | 115,628 | 215,628 |
| 263b(h)(3) |  | 67.728 | 6,773 | 16,773 |
| 300aa-28(b)(1) |  | 115.628 | 115,628 | 215,628 |
| 42 U.S.C. (HRSA): |  |  |  |  |
| 256b(d)(1)(B)(vi) |  | 8.745 | 437 | 5,437 |
| 42 U.S.C. (AHRQ): |  |  |  |  |
| 299c-(3)(d) |  | 41.402 | 4,140 | 14,140 |
| 42 U.S.C. ACF: |  |  |  |  |
| 653(l)(2) | 45 CFR 303.21(f) | 45.023 | 450 | 1,450 |
| 42 U.S.C. (OIG): |  |  |  |  |
| 262a(i)(1) | 42 CFR Part 1003 | 31.185 | 77,962 | 327,962 |
|  |  | 31.185 | 155,925 | 655,925 |
| 1320a-7a(a) | 42 CFR Part 1003 | 50.245 | 5,024 | 15,024 |
|  |  | 50.245 | 5,024 | 15,024 |
|  |  | 50.245 | 7,537 | 22,537 |
|  |  | 50.245 | 5,024 | 15,024 |
|  |  | 50.245 | 5,024 | 15,024 |
|  |  | 47.177 | 4,718 | 14,718 |
|  |  | 47.177 | 23,588 | 73,588 |
|  |  | 8.745 | 874 | 10,874 |
|  |  | 8.745 | 4,372 | 54,372 |
|  |  | 8.745 | 874 | 10,874 |
|  |  | 8.745 | 4,372 | 54,372 |
|  |  | 8.745 | 1,312 | 16,312 |
| 1320a-7a(b) | 42 CFR Part 1003 | 115.628 | 2,313 | 4,313 |
|  |  | 115.628 | 2,313 | 4,313 |
|  |  | 50.245 | 2,512 | 7,512 |
| 1320a-7e(b)(6)(A) | 42 CFR Part 1003 | 47.177 | 11,794 | 36,794 |
| 1320b-10(b)(1) | 42 CFR Part 1003 | 97.869 | 4,893 | 9,893 |
| 1320b-10(b)(2) | 42 CFR Part 1003 | 97.869 | 24,467 | 49,467 |
| 1395i- |  | 106.278 | 1,063 | 2,063 |
| 3(b)(3)(B)(ii)(1) |  |  |  |  |
| 1395i- |  | 106.278 | 5,314 | 10,314 |
| 3(b)(3)(B)(ii)(2) |  |  |  |  |
| 1395i-3(g)(2)(A) |  | 106.278 | 2,126 | 4,126 |
| 1395w-27(g)(2)(A) | 42 CFR 422.752; | 50.245 | 12,561 | 37,561 |
|  | 42 CFR Part 1003 |  |  |  |
|  |  | 47.177 | 11,794 | 36,794 |
|  |  | 47.177 | 11,794 | 36,794 |
|  |  | 47.177 | 47,177 | 147,177 |
|  |  | 47.177 | 7,077 | 22,077 |
|  |  | 47.177 | 47,177 | 147,177 |
|  |  | 47.177 | 11,794 | 36,794 |
|  |  | 47.177 | 11,794 | 36,794 |
|  |  | 47.177 | 11,794 | 36,794 |
|  |  | 47.177 | 11,794 | 36,794 |
|  |  | 47.177 | 11,794 | 36,794 |
|  |  | 47.177 | 11,794 | 36,794 |
|  |  | 47.177 | 11,794 | 36,794 |
| 1395w-141(i)(3) | 42 CFR Part 1003 | 28.561 | 2,856 | 12,856 |
| 1395cc(g) | 42 CFR Part 1003 | 150 | 3,000 | 5,000 |
| 1395dd(d)(1) | 42 CFR Part 1003 | 106.278 | 53,139 | 103,139 |
|  |  | 106.278 | 26,570 | 51,570 |
| 1395mm(i)(6)(B) | 42 CFR Part 1003 | 106.278 | 26,570 | 51,570 |
| (i) |  |  |  |  |
|  |  | 106.278 | 26,570 | 51,570 |
|  |  | 106.278 | 26,570 | 51,570 |
|  |  | 106.278 | 106,278 | 206,278 |
|  |  | 97.869 | 14,680 | 29,680 |
|  |  | 106.278 | 106,278 | 206,278 |
|  |  | 106.278 | 26,570 | 51,570 |
|  |  | 106.278 | 26,570 | 51,570 |
|  |  | 89.361 | 22,340 | 47,340 |
| 1395nn(g)(3) | 42 CFR Part 1003 | 59.089 | 8,863 | 23,863 |
| 1395nn(g)(4) | 42 CFR Part 1003 | 59.089 | 59,089 | 159,089 |
| 1395ss(d)(1) | 42 CFR Part 1003 | 97.869 | 4,893 | 9,893 |
| 1395ss(d)(2) | 42 CFR Part 1003 | 97.869 | 4,893 | 9,893 |
| 1395ss(d)(3)(A) | 42 CFR Part 1003 | 78.156 | 19,539 | 44,539 |
| (ii) |  |  |  |  |
|  |  | 78.156 | 11,723 | 26,723 |
| 1395ss(d)(4)(A) | 42 CFR Part 1003 | 97.869 | 4,893 | 9,893 |
| 1396b(m)(5)(B)(i) | 42 CFR Part 1003 | 97.869 | 24,467 | 49,467 |
|  |  | 97.869 | 24,467 | 49,467 |
|  |  | 97.869 | 97,869 | 197,869 |
|  |  | 97.869 | 14,680 | 29,680 |
|  |  | 97.869 | 97,869 | 197,869 |
|  |  | 97.869 | 24,467 | 49,467 |
|  |  | 78.156 | 19,539 | 44,539 |
| 1396r(b)(3)(B) | 42 CFR Part 1003 | 106.278 | 1,063 | 2,063 |
| (ii)(I) |  |  |  |  |
| 1396r(b)(3)(B) | 42 CFR Part 1003 | 106.278 | 5,314 | 10,314 |
| (ii)(II) |  |  |  |  |
| 1396r(g)(2)(A)(i) | 42 CFR Part 1003 | 106.278 | 2,126 | 4,126 |
| 1396r-8(b)(3)(B) | 42 CFR Part 1003 | 78.156 | 78,156 | 178,156 |
| 1396r- | 42 CFR Part 1003 | 78.156 | 7,816 | 17,816 |
| 8(b)(3)(C)(i) |  |  |  |  |
| 1396r- | 42 CFR Part 1003 | 78.156 | 78,156 | 178,156 |
| 8(b)(3)(C)(ii) |  |  |  |  |
| 1396t(i)(3)(A) | 42 CFR Part 1003 | 78.156 | 1,563 | 3,563 |
| 11131(c) | 42 CFR Part 1003 | 115.628 | 11,563 | 21,563 |
| 11137(b)(2) | 42 CFR Part 1003 | 115.628 | 11,563 | 21,563 |
| 42 U.S.C. (OCR): |  |  |  |  |
| 299b-22(f)(1) | 42 CFR 3.404(b) | 19.40 | 1,940 | 11,940 |
| 1320(d)-5(a) | 45 CFR | 50.245 | 50 | 150 |
|  | 160.404(b)(1)(i), |  |  |  |
|  | (ii) |  |  |  |
|  |  | 50.245 | 12,561 | 37,561 |
|  | 45 CFR 160.404(b) |  |  |  |
|  | (2)(i)(A),(B) |  |  |  |
|  |  | 10.02 | 10 | 110 |
|  |  | 10.02 | 5,010 | 55,010 |
|  |  | 10.02 | 150,300 | 1,650,300 |
|  | 45 CFR 160.404(b) |  |  |  |
|  | (2)(ii)(A), (B) |  |  |  |
|  |  | 10.02 | 100 | 1100 |
|  |  | 10.02 | 5,010 | 55,010 |
|  |  | 10.02 | 150,300 | 1,650,300 |
|  | 45 CFR 160.404(b) |  |  |  |
|  | (2)(iii)(A), (B) |  |  |  |
|  |  | 10.02 | 100 | 11,002 |
|  |  | 10.02 | 5,010 | 55,010 |
|  |  | 10.02 | 150,300 | 1,650,300 |
|  | 45 CFR |  |  |  |
|  | 160.404(b)(2)(iv) |  |  |  |
|  | (A), (B) |  |  |  |
|  |  | 10.02 | 5,010 | 55,010 |
|  |  | 10.02 | 150,300 | 1,650,300 |
|  |  | 10.02 | 150,300 | 1,650,300 |
| 42 U.S.C. (CMS): |  |  |  |  |
| 263a(h)(2)(B) & | 42 CFR |  |  |  |
| 1395w- | 493.1834(d)(2)(i) |  |  |  |
| 2(b)(2)(A)(ii) |  |  |  |  |
|  |  | 97.869 | 2,985 | 6,035 |
|  |  | 97.869 | 9,787 | 19,787 |
|  | 42 CFR 493.1834 |  |  |  |
|  | (d)(2)(ii) |  |  |  |
|  |  | 97.869 | 49 | 99 |
|  |  | 97.869 | 2,936 | 5,936 |
| 300gg-15(f) | 45 CFR 147.200(e) | 8.745 | 87 | 1,087 |
| 300gg-18 | 45 CFR 158.606 | 8.745 | 9 | 109 |
| 1320a-7h(b)(1) | 42 CFR |  |  |  |
|  | 402.105(d)(5), 42 |  |  |  |
|  | CFR 403.912(a) & |  |  |  |
|  | (c) |  |  |  |
|  |  | 8.745 | 87 | 1,087 |
|  |  | 8.745 | 874 | 10,874 |
|  |  | 8.745 | 13,117 | 163,117 |
| 1320a-7h(b)(2) | 42 CFR |  |  |  |
|  | 402.105(h), 42 |  |  |  |
|  | CFR 403 912(b) & |  |  |  |
|  | (c) |  |  |  |
|  |  | 8.745 | 874 | 10,874 |
|  |  | 8.745 | 8,745 | 108,745 |
|  |  | 8.745 | 87,450 | 1,087,450 |
| 1320a-7j(h)(3)(A) |  | 8.745 | 8,745 | 108,745 |
|  | 42 CFR | 8.745 | 44 | 544 |
|  | 488.446(a)(1),(2) |  |  |  |
|  | , & (3) |  |  |  |
|  |  | 8.745 | 131 | 1,631 |
|  |  | 8.745 | 262 | 3,262 |
| 1320a-8(a)(1) |  | 59.089 | 2,954 | 7,954 |
|  |  | 1 | 4,431 | 7,500 |
| 1320a-8(a)(3) |  | 24.588 | 1,229 | 6,229 |
| 1320b-25(c)(1)(A) |  | 8.745 | 17,490 | 217,490 |
| 1320b-25(c)(2)(A) |  | 8.745 | 26,235 | 326,235 |
| 1320b-25(d)(2) |  | 8.745 | 17,490 | 217,490 |
| 1395b-7(b)(2)(B) | 42 CFR 402.105(g) | 47.177 | 47 | 147 |
| 1395i- | 42 CFR 488.408(d) |  |  |  |
| 3(h)(2)(B)(ii)(I) | (1)(iii) |  |  |  |
|  |  | 106.278 | 53 | 103 |
|  |  | 106.278 | 3,188 | 6,188 |
|  | 42 CFR |  |  |  |
|  | 488.408(d)(1)(iv) |  |  |  |
|  |  | 106.278 | 1,063 | 2,063 |
|  |  | 106.278 | 10,628 | 20,628 |
|  | 42 CFR |  |  |  |
|  | 488.408(e)(1)(iii |  |  |  |
|  | ) |  |  |  |
|  |  | 106.278 | 3,241 | 6,291 |
|  |  | 106.278 | 10,628 | 20,628 |
|  | 42 CFR |  |  |  |
|  | 488.408(e)(1)(iv) |  |  |  |
|  |  | 106.278 | 1,063 | 2,063 |
|  |  | 106.278 | 10,628 | 20,628 |
|  |  |  |  |  |
|  |  | 106.278 | 3,241 | 6,291 |
|  |  | 106.278 | 10,628 | 20,628 |
|  |  | 106.278 | 1,063 | 2,063 |
|  |  | 106.278 | 10,628 | 20,628 |
|  | 42 CFR |  |  |  |
|  | 488.438(a)(1)(i) |  |  |  |
|  |  | 106.278 | 3,241 | 6,291 |
|  |  | 106.278 | 10,628 | 20,628 |
|  | 42 CFR |  |  |  |
|  | 488.438(a)(1)(ii) |  |  |  |
|  |  | 106.278 | 53 | 103 |
|  |  | 106.278 | 3,188 | 6,188 |
|  | 42 CFR |  |  |  |
|  | 488.438(a)(2) |  |  |  |
|  |  | 106.278 | 1,063 | 2,063 |
|  |  | 106.278 | 10,628 | 20,628 |
| 1395l(h)(5)(D) | 42 CFR | 50.245 | 5,024 | 15,024 |
|  | 402.105(d)(2)(i) |  |  |  |
| 1395l(i)(6) |  | 197.869 | 1,957 | 3,957 |
| 1395l(q)(2)(B)(i) | 42 CFR 402.105(a) | 89.361 | 1,787 | 3,787 |
| 1395m(a)(11)(A) | 42 CFR | 50.245 | 5,024 | 15,024 |
|  | 402.1(c)(4), |  |  |  |
|  | 402.105(d)(2)(ii) |  |  |  |
| 1395m(a)(18)(B) | 42 CFR | 50.245 | 5,024 | 15,024 |
|  | 402.1(c)(5), |  |  |  |
|  | 402.105(d)(2) |  |  |  |
|  | (iii) |  |  |  |
| 1395m(b)(5)(C) | 42 CFR | 50.245 | 5,024 | 15,024 |
|  | 402.1(c)(6), |  |  |  |
|  | 402.105(d)(2)(iv) |  |  |  |
| 1395m(h)(3) | 42 CFR | 50.245 | 5,024 | 15,024 |
|  | 402.1(c)(8), |  |  |  |
|  | 402.105(d)(2)(vi) |  |  |  |
| 1395m(j)(2)(A) |  | 59.089 | 591 | 1,591 |
| (iii) |  |  |  |  |
| 1395m(j)(4) | 42 CFR | 50.245 | 5,024 | 15,024 |
|  | 402.1(c)(10), |  |  |  |
|  | 402.105(d)(2) |  |  |  |
|  | (vii) |  |  |  |
| 1395m(k)(6) | 42 CFR | 50.245 | 5,024 | 15,024 |
|  | 402.1(c)(31), |  |  |  |
|  | 402.105(d)(3) |  |  |  |
| 1395m(l)(6) | 42 CFR | 50.245 | 5,024 | 15,024 |
|  | 402.1(c)(32), |  |  |  |
|  | 402.105(d)(4) |  |  |  |
| 1395u(b)(18)(B) | 42 CFR | 50.245 | 5,024 | 15,024 |
|  | 402.1(c)(11), |  |  |  |
|  | 402.105(d)(2) |  |  |  |
|  | (viii) |  |  |  |
| 1395u(j)(2)(B) | 42 CFR 402.1(c) | 50.245 | 5,024 | 15,024 |
| 1395u(k) | 42 CFR | 50.245 | 5,024 | 15,024 |
|  | 402.1(c)(12), |  |  |  |
|  | 402.105(d)(2)(ix) |  |  |  |
| 1395u(l)(3) | 42 CFR | 50.245 | 5,024 | 15,024 |
|  | 402.1(c)(13), |  |  |  |
|  | 402.105(d)(2)(x) |  |  |  |
| 1395u(m)(3) | 42 CFR | 50.245 | 5,024 | 15,024 |
|  | 402.1(c)(14), |  |  |  |
|  | 402.105(d)(2)(xi) |  |  |  |
| 1395u(n)(3) | 42 CFR | 50.245 | 5,024 | 15,024 |
|  | 402.1(c)(15), |  |  |  |
|  | 402.105(d)(2) |  |  |  |
|  | (xii) |  |  |  |
| 1395u(o)(3)(B) | 42 CFR 414.707(b) | 50.245 | 5,024 | 15,024 |
| 1395u(p)(3)(A) |  | 97.869 | 1,957 | 3,957 |
| 1395w-3a(d)(4)(A) | 42 CFR 414.806 | 28.561 | 2,856 | 12,856 |
| 1395w-4(g)(1)(B) | 42 CFR | 50.245 | 5,024 | 15,024 |
|  | 402.1(c)(17), |  |  |  |
|  | 402.105(d)(2) |  |  |  |
|  | (xiii) |  |  |  |
| 1395w-4(g)(3)(B) | 42 CFR | 50.245 | 5,024 | 15,024 |
|  | 402.1(c)(18), |  |  |  |
|  | 402.105(d)(2) |  |  |  |
|  | (xiv) |  |  |  |
| 1395w- | 42 CFR | 47.177 | 11,794 | 36,794 |
| 27(g)(3)(A); | 422.760(b); 42 |  |  |  |
| 1857(g)(3) | CFR 423.760(b) |  |  |  |
| 1395w- |  | 47.177 | 4,718 | 14,718 |
| 27(g)(3)(B); |  |  |  |  |
| 1857(g)(3) |  |  |  |  |
| 1395w- |  | 36.689 | 36,689 | 136,689 |
| 27(g)(3)(D); |  |  |  |  |
| 1857(g)(3) |  |  |  |  |
| 1395y(b)(3)(C) | 42 CFR 411.103(b) | 78.156 | 3,908 | 8,908 |
| 1395y(b)(5)(C) | 42 CFR | 89.361 | 450 | 1,450 |
| (ii) | 402.1(c)(20), |  |  |  |
|  | 402.105(b)(2) |  |  |  |
| 1395y(b)(6)(B) | 42 CFR | 59.089 | 1,182 | 3,182 |
|  | 402.1(c)(21), |  |  |  |
|  | 402.105(a) |  |  |  |
| 1395y(b)(7)(B)(i) |  | 13.833 | 138 | 1,138 |
| 1395y(b)(8)(E) |  | 13.833 | 138 | 1,138 |
| 1395nn(g)(5) | 42 CFR 411.361 | 89.361 | 8,936 | 18,936 |
| 1395pp(h) | 42 CFR | 50.245 | 5,024 | 15,024 |
|  | 402.1(c)(23), |  |  |  |
|  | 402.105(d)(2)(xv) |  |  |  |
| 1395ss(a)(2) | 42 CFR | 106.278 | 26,569 | 51,569 |
|  | 402.1(c)(24), |  |  |  |
|  | 405.105(f)(1) |  |  |  |
| 1395ss(d)(3)(A) |  | 78.156 | 11,723 | 26,723 |
| (vi) (II) |  |  |  |  |
|  |  | 78.156 | 19,539 | 44,539 |
| 1395ss(d)(3)(B) |  | 78.156 | 11,723 | 26,723 |
| (iv) |  |  |  |  |
|  |  | 78.156 | 19,539 | 44,539 |
| 1395ss(p)(8) | 42 CFR | 78.156 | 11,723 | 26,723 |
|  | 402.1(c)(25), |  |  |  |
|  | 402.105(e) |  |  |  |
|  | 42 CFR | 78.156 | 19,539 | 44,539 |
|  | 402.1(c)(25), |  |  |  |
|  | 405.105(f)(2) |  |  |  |
| 1395ss(p)(9)(C) | 42 CFR | 78.156 | 11,723 | 26,723 |
|  | 402.1(c)(26), |  |  |  |
|  | 402.105(e) |  |  |  |
|  | 42 CFR | 78.156 | 19,539 | 44,539 |
|  | 402.1(c)(26), |  |  |  |
|  | 405.105(f)(3), |  |  |  |
|  | (4) |  |  |  |
| 1395ss(q)(5)(C) | 42 CFR | 78.156 | 19,539 | 44,539 |
|  | 402.1(c)(27), |  |  |  |
|  | 405.105(f)(5) |  |  |  |
| 1395ss(r)(6)(A) | 42 CFR | 78.156 | 19,539 | 44,539 |
|  | 402.1(c)(28), |  |  |  |
|  | 405.105(f)(6) |  |  |  |
| 1395ss(s)(4) | 42 CFR | 78.156 | 3,908 | 8,908 |
|  | 402.1(c)(29), |  |  |  |
|  | 405.105(c) |  |  |  |
| 1395ss(t)(2) | 42 CFR | 78.156 | 19,539 | 44,539 |
|  | 402.1(c)(30), |  |  |  |
|  | 405.105(f)(7) |  |  |  |
| 1395ss(v)(4)(A) |  | 28.561 | 4,284 | 19,284 |
|  |  | 28.561 | 7,140 | 32,140 |
| 1395bbb(c)(1) | 42 CFR 488.725(c) | 106.278 | 2,126 | 4,126 |
| 1395bbb(f)(2)(A) | 42 CFR 488.845 | 97.869 | 9,787 | 19,787 |
| (i) | (b)(2)(iii) |  |  |  |
|  | 42 CFR |  |  |  |
|  | 488.845(b)(3) |  |  |  |
|  |  | 97.869 | 8,319 | 16,819 |
|  |  | 97.869 | 9,787 | 19,787 |
|  | 42 CFR | 97.869 | 9,787 | 19,787 |
|  | 488.845(b)(3)(i) |  |  |  |
|  | 42 CFR | 97.869 | 8,808 | 17,808 |
|  | 488.845(b)(3)(ii) |  |  |  |
|  | 42 CFR 488.845 | 97.869 | 8,319 | 16,819 |
|  | (b)(3)(iii) |  |  |  |
|  | 42 CFR |  |  |  |
|  | 488.845(b)(4) |  |  |  |
|  |  | 97.869 | 1,468 | 2,968 |
|  |  | 97.869 | 8,319 | 16,819 |
|  | 42 CFR |  |  |  |
|  | 488.845(b)(5) |  |  |  |
|  |  | 97.869 | 489 | 989 |
|  |  | 97.869 | 3,915 | 7,915 |
| 42 CFR |  |  |  |  |
| 488.845(b)(6) |  |  |  |  |
|  |  | 97.869 | 979 | 1,979 |
|  |  | 97.869 | 9,787 | 19,787 |
|  |  | 97.869 | 9,787 | 19,787 |
|  | 42 CFR | 97.869 | 9,787 | 19,787 |
|  | 488.845(d)(1)(ii) |  |  |  |
| 1396b(m)(5)(B) | 42 CFR 460.46 |  |  |  |
|  |  | 47.177 | 7,077 | 22,077 |
|  |  | 47.177 | 47,177 | 147,177 |
|  |  | 47.177 | 11,794 | 36,794 |
|  |  | 47.177 | 47,177 | 147,177 |
|  |  | 47.177 | 11,794 | 36,794 |
|  |  | 47.177 | 11,794 | 36,794 |
|  |  | 47.177 | 11,794 | 36,794 |
| 1396r(h)(3)(C) | 42 CFR 488.408 |  |  |  |
| (ii)(I) | (d)(1)(iii) |  |  |  |
|  |  | 106.278 | 53 | 103 |
|  |  | 106.278 | 3,188 | 6,188 |
|  | 42 CFR |  |  |  |
|  | 488.408(d)(1)(iv) |  |  |  |
|  |  | 106.278 | 1,063 | 2,063 |
|  |  | 106.278 | 10,628 | 20,628 |
|  | 42 CFR 488.408 |  |  |  |
|  | (e)(1)(iii) |  |  |  |
|  |  | 106.278 | 3,241 | 6,291 |
|  |  | 106.278 | 10,628 | 20,628 |
|  | 42 CFR |  |  |  |
|  | 488.408(e)(1)(iv) |  |  |  |
|  |  | 106.278 | 1,063 | 2,063 |
|  |  | 106.278 | 10,628 | 20,628 |
|  | 42 CFR |  |  |  |
|  | 488.408(e)(2)(ii) |  |  |  |
|  |  | 106.278 | 1,063 | 2,063 |
|  |  | 106.278 | 10,628 | 20,628 |
|  | 42 CFR |  |  |  |
|  | 488.438(a)(1)(i) |  |  |  |
|  |  | 106.278 | 3,241 | 6,291 |
|  |  | 106.278 | 10,628 | 20,628 |
|  | 42 CFR |  |  |  |
|  | 488.438(a)(1)(ii) |  |  |  |
|  |  | 106.278 | 53 | 103 |
|  |  | 106.278 | 3,188 | 6,188 |
|  | 42 CFR |  |  |  |
|  | 488.438(a)(2) |  |  |  |
|  |  | 106.278 | 1,063 | 2,063 |
|  |  | 106.278 | 10,628 | 20,628 |
| 1396r(f)(2)(B) | 42 CFR | 106.278 | 5,314 | 10,314 |
| (iii)(I)(c) | 483.151(b)(2)(iv) |  |  |  |
|  | and (b)(3)(iii) |  |  |  |
| 1396r(h)(3)(C) | 42 CFR | 106.278 | 5,314 | 10,314 |
| (ii)(I) | 483.151(c)(2) |  |  |  |
| 1396t(j)(2)(C) |  |  |  |  |
|  |  | 78.156 | 1 | 2 |
|  |  | 78.156 | 7,816 | 17,816 |
| 1396u- | 42 CFR 438.704 | 47.177 | 11,794 | 36,794 |
| 2(e)(2)(A)(i) |  |  |  |  |
|  |  | 47.177 | 11,794 | 36,794 |
|  |  | 47.177 | 11,794 | 36,794 |
|  |  | 47.177 | 11,794 | 36,794 |
| 1396u- | 42 CFR 438.704 | 47.177 | 47,177 | 147,177 |
| 2(e)(2)(A)(ii) |  |  |  |  |
|  |  | 47.177 | 47,177 | 147,177 |
| 1396u- | 42 CFR 438.704 | 47.177 | 7,077 | 22,077 |
| 2(e)(2)(A)(iv) |  |  |  |  |
| 1396u(h)(2) | 42 CFR 441, | 106.278 | 10,628 | 20,628 |
|  | Subpart I |  |  |  |
| 1396w-2(c)(1) |  | 10.02 | 1,002 | 11,002 |
| 1903(m)(5)(B) | 42 CFR 460.46 |  |  |  |
|  |  | 47.177 | 7,077 | 22,077 |
|  |  | 47.177 | 47,177 | 147,177 |
|  |  | 47.177 | 11,794 | 36,794 |
|  |  | 47.177 | 47,177 | 147,177 |
|  |  | 47.177 | 11,794 | 36,794 |
|  |  | 47.177 | 11,794 | 36,794 |
|  |  | 47.177 | 11,794 | 36,794 |
| 18041(c)(2) | 45 CFR 150.315 | 50.245 | 50 | 150 |
|  | and 45 CFR |  |  |  |
|  | 156.805(c) |  |  |  |
| 18081(h)(1)(A)(i) | 42 CFR 155.285 | 8.745 | 2,186 | 27,186 |
| (II) |  |  |  |  |
| 18081(h)(1)(B) | 42 CFR 155.285 | 8.745 | 21,862 | 271,862 |
| 18081(h)(2) | 42 CFR 155.260 | 8.745 | 2,186 | 27,186 |
| 31 U.S.C. (HHS): |  |  |  |  |
| 1352 | 45 CFR 93.400(e) | 89.361 | 8,936 | 18,936 |
|  |  |  |  |  |
|  |  | 89.361 | 8,936 | 18,936 |
|  |  | 89.361 | 89,361 | 189,361 |
|  |  | 89.361 | 8,936 | 18,936 |
|  |  |  |  |  |
|  |  | 89.361 | 8,936 | 18,936 |
|  |  | 89.361 | 89,361 | 189,361 |
|  | 45 CFR 93, |  |  |  |
|  | Appendix A |  |  |  |
|  |  | 89.361 | 8,936 | 18,936 |
|  |  | 89.361 | 89,361 | 189,361 |
|  |  |  |  |  |
|  |  | 89.361 | 8,936 | 18,936 |
|  |  | 89.361 | 89,361 | 189,361 |
| 3801-3812 | 45 CFR | 97.869 | 4,894 | 9,894 |
|  | 79.3(a)(1(iv) |  |  |  |
|  | 45 CFR | 97.869 | 4,894 | 9,894 |
|  | 79.3(b)(1)(ii) |  |  |  |

fn1 Some HHS components have not promulgated ***regulations*** regarding their civil monetary penalties-specific statutory authorities.

fn2 The description is not intended to be a comprehensive explanation of the underlying violation; the statute and corresponding ***regulation***, if applicable, should be consulted.

fn3 Statutory, or non-Inflation Act Adjustment.

fn4 Based on the lesser of the CPI-U multiplier for October 2015, or 150%.

fn5 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)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GWP1-NRF4-4368-00000-00&context=) 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 **[\*61560]** 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.

***Regulations***

**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:

1. **ice, Department of Health and Human Services**
2. **ZATIONS AND PATIENT SAFETY WORK PRODUCT**
3. The authority citation for part 3 continues to read as follows:

**Authority:** [*42 U.S.C. 216,*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GMD1-NRF4-440F-00000-00&context=) 299b-21 through 299b-26; [*42 U.S.C. 299c-6.*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSS1-NRF4-406W-00000-00&context=)

1. Section 3.404 is revised to read as follows:
2. **y penalty.**
3. The amount of a civil money penalty will be determined in accordance with paragraph (b) of this section and § 3.408.
4. 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* **[\*61561]** updated, is published at 45 CFR part 102.
5. **ARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES**
6. **ES, ASSESSMENTS, AND EXCLUSIONS**
7. 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*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GM31-NRF4-40JV-00000-00&context=) and 1395hh).

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

1. **D PROJECTS**
2. The authority citation for part 403 continues to read as follows:

**Authority:** [*42 U.S.C. 1395b-3*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GRH1-NRF4-43VH-00000-00&context=) and Secs. 1102 and 1871 of the Social Security Act [*(42 U.S.C. 1302*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GM31-NRF4-40JV-00000-00&context=) and 1395hh).

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

1. **ICARE AND LIMITATIONS ON MEDICARE PAYMENT**
2. 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,*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GM31-NRF4-40JV-00000-00&context=) 1395w-101 through 1395w-152, 1395hh, and 1395nn).

1. **d]**
2. 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 **[\*61562]** the phrase indicated in the fourth column:

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

1. **SYSTEMS FOR INPATIENT HOSPITAL SERVICES**
2. 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*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GM31-NRF4-40JV-00000-00&context=) 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]*

1. Section 412.612 is amended as follows:
2. 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
3. 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".
4. **PROGRAM**
5. 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*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GM31-NRF4-40JV-00000-00&context=) and 1395hh).

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

1. **PRESCRIPTION DRUG BENEFIT**
2. 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,*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GM31-NRF4-40JV-00000-00&context=) 1306, 1395w-101 through 1395w-152, and 1395hh).

1. 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 | "enrollees--up to $ 25,000 as adjusted |
|  | $ 25,000 for each | annually under 45 CFR part 102 for |
|  | determination" | each determination". |
| (b)(2) | "of up to $ 25,000 | "of up to $ 25,000 as adjusted |
|  | for each Part D | annually under 45 CFR part 102 for |
|  | enrollee" | 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 | "$ 250 as adjusted annually under 45 |
|  | Medicare enrollee" | CFR part 102 per Medicare enrollee". |
| (b)(4) | "or $ 100,000, | "or $ 100,000 as adjusted annually |
|  | whichever is | under 45 CFR part 102, whichever is |
|  | greater" | greater". |
| (c)(1) | "of not more than | "of not more than $ 25,000 as adjusted |
|  | $ 25,000 for each" | annually under 45 CFR part 102 for |
|  |  | each". |
| (c)(2) | "not more than | "not more than $ 100,000 as adjusted |
|  | $ 100,000 for | annually under 45 CFR part 102 for |
|  | each" | each". |
| (c)(4) | "$ 15,000 for each | "$ 15,000 as adjusted annually under |
|  | individual" | 45 CFR part 102 for each individual". |

1. **ATES AND LONG TERM CARE FACILITIES**
2. 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,*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GM31-NRF4-40JV-00000-00&context=) 1320a-7, 1395i, 1395hh and 1396r).

1. Section 483.20 is amended as follows:
2. 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
3. In paragraph (j)(1)(ii), by removing the phrase "not more than $ 5,000 for" and adding it its place the phrase "not more than $ 5,000 as adjusted annually under 45 CFR part 102 for".
4. Section 483.151 is amended as follows:
5. 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";
6. 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
7. 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".
8. **ON, AND ENFORCEMENT PROCEDURES**
9. The authority citation for part 488 continues to read as follows:

**Authority:** Secs. 1102, 1128l, 1864, 1865, 1871 and 1875 of the Social Security Act, unless otherwise noted [*(42 U.S.C. 1302,*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GM31-NRF4-40JV-00000-00&context=) 1320a-7j, 1395aa, 1395bb, 1395hh) and 1395ll.**§§ 488.307, 488.408, 488.438, 488.446, 488.725, and 488.845 [Amended]**

1. 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 | "$ 1,000-$ 10,000 as |
|  |  | instance" | 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 | "$ 1,000-$ 10,000 as |
|  |  | instance" | adjusted annually under 45 |
|  |  |  | CFR part 102 per |
|  |  |  | instance". |
|  | (e)(2)(ii) | "3,050-$ 10,000 per day or | "3,050-$ 10,000 as |
|  |  | $ 1,000-$ 10,000 per | adjusted annually under 45 |
|  |  | instance" | 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- | "Upper range". |
|  |  | $ 10,000" |  |
|  | (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- | "Upper range". |
|  |  | $ 3,000" |  |
|  | (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 | "$ 1,000-$ 10,000 as |
|  |  | instance" | 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 | "will exceed $ 10,000 as |
|  |  | for" | adjusted under 45 CFR part |
|  |  |  | 102 for". |
|  | (b)(3) | "upper range of $ 8,500 to | "upper range of $ 8,500 to |
|  | introductory | $ 10,000 per day" | $ 10,000 as adjusted |
|  | text |  | 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". |
|  | (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 | "range of $ 1,500-$ 8,500 |
|  |  | per day" | as adjusted annually under |
|  |  |  | 45 CFR part 102 per day". |
|  | (b)(5) | "range of $ 500-$ 4,000 | "range of $ 500-$ 4,000 as |
|  |  | are imposed" | adjusted annually under 45 |
|  |  |  | CFR part 102 are imposed". |
|  | (b)(6) | "range of $ 1,000 to | "range of $ 1,000 to |
|  |  | $ 10,000 per instance, not | $ 10,000 as adjusted |
|  |  | to exceed $ 10,000 each | annually under 45 CFR part |
|  |  | day" | 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 | "maximum of $ 10,000 as |
|  |  | day" | adjusted annually under 45 |
|  |  |  | CFR part 102 per day". |

1. **ENTS**
2. 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,*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSM1-NRF4-449F-00000-00&context=) 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.*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSM1-NRF4-449F-00000-00&context=)

1. Section 493.1834 is amended as follows:
2. 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
3. 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".
4. **R GENERAL--HEALTH CARE, DEPARTMENT OF HEALTH AND HUMAN SERVICES**
5. **IES, ASSESSMENTS AND EXCLUSIONS**
6. The authority citation for part 1003 continues to read as follows:

**Authority:** [*42 U.S.C. 262a,*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSX1-NRF4-41V3-00000-00&context=) 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).

1. Section 1003.103 is amended:
2. In paragraph (c)--
3. By removing the footnote in paragraph (c); and
4. 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
5. 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 | "3. This penalty amount is adjusted |
|  | $ 15,000" | annually for inflation, and is |
|  |  | published at 45 CFR part 102." |
|  | "not more than | "4. This penalty amount is adjusted |
|  | $ 100,000" | annually for inflation, and is |
|  |  | published at 45 CFR part 102." |
| (c) | "not more than | "5. This penalty amount is adjusted |
|  | $ 10,000" | annually for inflation, and is |
|  |  | published at 45 CFR part 102." |
| (d)(1) | "not more than | "6. This penalty amount is adjusted |
|  | $ 5,000" | annually for inflation, and is |
|  |  | published at 45 CFR part 102." |
|  | "not more than | "7. This penalty amount is adjusted |
|  | $ 25,000" | annually for inflation, and is |
|  |  | published at 45 CFR part 102." |
| (e)(1) | "not more than | "8. This penalty amount is adjusted |
|  | $ 50,000" | annually for inflation, and is |
|  |  | published at 45 CFR part 102." |
|  | "will not exceed | "9. This penalty amount is adjusted |
|  | $ 25,000;" | annually for inflation, and is |
|  |  | published at 45 CFR part 102." |
| (e)(2) | "not more than | "10. This penalty amount is adjusted |
|  | $ 50,000" | annually for inflation, and is |
|  |  | published at 45 CFR part 102." |
| (f)(1) | "up to $ 25,000" | "11. This penalty amount is adjusted |
| introductory text |  | annually for inflation, and is |
|  |  | published at 45 CFR part 102." |
| (f)(2) | "up to $ 25,000" | "12. This penalty amount is adjusted |
| introductory text |  | annually for inflation, and is |
|  |  | published at 45 CFR part 102." |
| (f)(3) | "up to $ 100,000" | "13. This penalty amount is adjusted |
| introductory text |  | annually for inflation, and is |
|  |  | published at 45 CFR part 102." |
| (f)(5) | "an additional | "14. This penalty amount is adjusted |
|  | $ 15,000" | annually for inflation, and is |
|  |  | published at 45 CFR part 102." |
| (g) | "not more than | "15. This penalty amount is adjusted |
|  | $ 25,000" | annually for inflation, and is |
|  |  | published at 45 CFR part 102." |
| (h)(1) | "not more than | "16. This penalty amount is adjusted |
|  | $ 50,000" | 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 | "18. This penalty amount is adjusted |
|  | $ 10,000" | annually for inflation, and is |
|  |  | published at 45 CFR part 102." |
| (k) | "not more than | "19. This penalty amount is adjusted |
|  | $ 2,000" | annually for inflation, and is |
|  |  | published at 45 CFR part 102." |
| (l) | "not more than | "20. This penalty amount is adjusted |
|  | $ 250,000" | annually for inflation, and is |
|  |  | published at 45 CFR part 102." |
| (l) | "and not more than | "21. This penalty amount is adjusted |
|  | $ 500,000" | annually for inflation, and is |
|  |  | published at 45 CFR part 102." |
| (m) | "not more than | "22. This penalty amount is adjusted |
|  | $ 10,000" | annually for inflation, and is |
|  |  | published at 45 CFR part 102." |

1. **lth and Human Services**
2. **PENALTIES**
3. The authority for part 79 continues to read as follows:

**Authority:** [*31 U.S.C. 3801*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GTG1-NRF4-42DD-00000-00&context=)-3812.

1. 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:
2. **es and assessments.**
3. \* \* \*
4. \* \* \*
5. \* \* \*

<1> 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.*

   \*    \*    \*    \*    \*

1. \* \* \*
2. \* \* \*
3. \* \* \*

<2> 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.*

   \*    \*    \*    \*    \*

1. **LOBBYING**
2. The authority for part 93 continues to read as follows:

**Authority:** Section 319, *Public Law 101-121* [*(31 U.S.C. 1352);*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GMN1-NRF4-417K-00000-00&context=) [*(5 U.S.C. 301).*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GMK1-NRF4-409K-00000-00&context=)

1. 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:
2. \* \* \*

<1> 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.*

   \*    \*    \*    \*    \*

1. 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:
2. **arding Lobbying**

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

   \*    \*    \*    \*    \*

1. \* \* \*

<1> 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.*

   \*    \*    \*    \*    \*

1. Part 102 is added to subchapter A to read as follows:
2. **MONETARY PENALTIES FOR INFLATION**

Sec.

1. **able.**

**Authority:** *Public Law 101-410, Sec. 701 of*  *Public Law 114-74,* [*31 U.S.C. 3801*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GTG1-NRF4-42DD-00000-00&context=)-3812.

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.

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.

1. **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. **[\*61566]**

| **Civil Monetary Penalty Authorities Administered by HHS Agencies and Penalty** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Amounts** | | | | | | |
| **[Effective September 6, 2016]** | | | | | | |
|  |  |  |  |  |  |  |
| **Citation** |  | **HHS** | **Description fn2** | **Date of** | **Pre-** | **Maximum** |
|  |  | **agency** |  | **last** | **inflation** | **adjusted** |
|  |  |  |  | **penalty** | **penalty** | **penalty** |
|  |  |  |  | **figure or** | **(]** | **(]** |
|  |  |  |  | **adjust-** |  |  |
|  |  |  |  | **ment fn3** |  |  |
| **U.S.C.** | **CFR fn1** |  |  |  |  |  |
| 21 |  |  |  |  |  |  |
| U.S.C.: |  |  |  |  |  |  |
| 333(b)(2) |  | FDA | Penalty for | 1988 | 50,000 | 98,935 |
| (A) |  |  | violations |  |  |  |
|  |  |  | related to drug |  |  |  |
|  |  |  | samples resulting |  |  |  |
|  |  |  | in a conviction |  |  |  |
|  |  |  | of any |  |  |  |
|  |  |  | representative of |  |  |  |
|  |  |  | manufacturer or |  |  |  |
|  |  |  | distributor in |  |  |  |
|  |  |  | any 10-year |  |  |  |
|  |  |  | period |  |  |  |
| 333(b)(2) |  | FDA | Penalty for | 1988 | 1,000,000 | 1,978,690 |
| (B) |  |  | 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 |  |  |  |
| 333(b)(3) |  | FDA | Penalty for | 1988 | 100,000 | 197,869 |
|  |  |  | failure to make a |  |  |  |
|  |  |  | report required |  |  |  |
|  |  |  | by 21 U.S.C. |  |  |  |
|  |  |  | 353(d)(3)(E) |  |  |  |
|  |  |  | relating to drug |  |  |  |
|  |  |  | samples |  |  |  |
| 333(f)(1) |  | FDA | Penalty for any | 1990 | 15,000 | 26,723 |
| (A) |  |  | person who |  |  |  |
|  |  |  | violates a |  |  |  |
|  |  |  | requirement |  |  |  |
|  |  |  | related to |  |  |  |
|  |  |  | devices for each |  |  |  |
|  |  |  | such violation |  |  |  |
|  |  |  | Penalty for | 1990 | 1,000,000 | 1,781,560 |
|  |  |  | aggregate of all |  |  |  |
|  |  |  | violations |  |  |  |
|  |  |  | related to |  |  |  |
|  |  |  | devices in a |  |  |  |
|  |  |  | single proceeding |  |  |  |
| 333(f)(2) |  | FDA | Penalty for any | 1996 | 50,000 | 75,123 |
| (A) |  |  | 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 |  |  |  |
|  |  |  | Penalty in the | 1996 | 250,000 | 375,613 |
|  |  |  | case of any other |  |  |  |
|  |  |  | person other than |  |  |  |
|  |  |  | an individual) |  |  |  |
|  |  |  | for such |  |  |  |
|  |  |  | introduction or |  |  |  |
|  |  |  | delivery of |  |  |  |
|  |  |  | adulterated food |  |  |  |
|  |  |  | Penalty for | 1996 | 500,000 | 751,225 |
|  |  |  | aggregate of all |  |  |  |
|  |  |  | such violations |  |  |  |
|  |  |  | related to |  |  |  |
|  |  |  | adulterated food |  |  |  |
|  |  |  | adjudicated in a |  |  |  |
|  |  |  | single proceeding |  |  |  |
| 333(f)(3) |  | FDA | Penalty for all | 2007 | 10,000 | 11,383 |
| (A) |  |  | 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 |  |  |  |
| 333(f)(3) |  | FDA | Penalty for each | 2007 | 10,000 | 11,383 |
| (B) |  |  | day the above |  |  |  |
|  |  |  | violation is not |  |  |  |
|  |  |  | corrected after a |  |  |  |
|  |  |  | 30-day period |  |  |  |
|  |  |  | following |  |  |  |
|  |  |  | notification |  |  |  |
|  |  |  | until the |  |  |  |
|  |  |  | violation is |  |  |  |
|  |  |  | corrected |  |  |  |
| 333(f)(4) |  | FDA | Penalty for any | 2007 | 250,000 | 284,583 |
| (A)(i) |  |  | responsible |  |  |  |
|  |  |  | person that |  |  |  |
|  |  |  | violates a |  |  |  |
|  |  |  | requirement of 21 |  |  |  |
|  |  |  | U.S.C. 355(o) |  |  |  |
|  |  |  | (post-marketing |  |  |  |
|  |  |  | studies, clinical |  |  |  |
|  |  |  | trials, |  |  |  |
|  |  |  | labeling), 21 |  |  |  |
|  |  |  | U.S.C. 355(p) |  |  |  |
|  |  |  | (risk evaluation |  |  |  |
|  |  |  | and mitigation |  |  |  |
|  |  |  | (REMS)), or 21 |  |  |  |
|  |  |  | U.S.C. 355-1 |  |  |  |
|  |  |  | (REMS) |  |  |  |
|  |  |  | Penalty for | 2007 | 1,000,000 | 1,138,330 |
|  |  |  | aggregate of all |  |  |  |
|  |  |  | such above |  |  |  |
|  |  |  | violations in a |  |  |  |
|  |  |  | single proceeding |  |  |  |
| 333(f)(4) |  | FDA | Penalty for REMS | 2007 | 250,000 | 284,583 |
| (A)(ii) |  |  | violation that |  |  |  |
|  |  |  | continues after |  |  |  |
|  |  |  | written notice to |  |  |  |
|  |  |  | the responsible |  |  |  |
|  |  |  | person for the |  |  |  |
|  |  |  | first 30-day |  |  |  |
|  |  |  | period (or any |  |  |  |
|  |  |  | portion thereof) |  |  |  |
|  |  |  | the responsible |  |  |  |
|  |  |  | person continues |  |  |  |
|  |  |  | to be in |  |  |  |
|  |  |  | violation |  |  |  |
|  |  |  | Penalty for REMS | 2007 | 1,000,000 | 1,138,330 |
|  |  |  | violation that |  |  |  |
|  |  |  | continues after |  |  |  |
|  |  |  | written notice to |  |  |  |
|  |  |  | responsible |  |  |  |
|  |  |  | person doubles |  |  |  |
|  |  |  | for every 30-day |  |  |  |
|  |  |  | period thereafter |  |  |  |
|  |  |  | the violation |  |  |  |
|  |  |  | continues, but |  |  |  |
|  |  |  | may not exceed |  |  |  |
|  |  |  | penalty amount |  |  |  |
|  |  |  | for any 30-day |  |  |  |
|  |  |  | period |  |  |  |
|  |  |  | Penalty for | 2007 | 10,000,00 | 11,383,30 |
|  |  |  | aggregate of all |  | 0 | 0 |
|  |  |  | such above |  |  |  |
|  |  |  | violations |  |  |  |
|  |  |  | adjudicated in a |  |  |  |
|  |  |  | single proceeding |  |  |  |
| 333(f)(9) |  | FDA | Penalty for any | 2009 | 15,000 | 16,503 |
| (A) |  |  | person who |  |  |  |
|  |  |  | violates a |  |  |  |
|  |  |  | requirement which |  |  |  |
|  |  |  | relates to |  |  |  |
|  |  |  | tobacco products |  |  |  |
|  |  |  | for each such |  |  |  |
|  |  |  | violation |  |  |  |
|  |  |  | Penalty for | 2009 | 1,000,000 | 1,100,200 |
|  |  |  | aggregate of all |  |  |  |
|  |  |  | such violations |  |  |  |
|  |  |  | of tobacco |  |  |  |
|  |  |  | product |  |  |  |
|  |  |  | requirement |  |  |  |
|  |  |  | adjudicated in a |  |  |  |
|  |  |  | single proceeding |  |  |  |
| 333(f)(9) |  | FDA | Penalty per | 2009 | 250,000 | 275,050 |
| (B)(i)(I) |  |  | violation related |  |  |  |
|  |  |  | to violations of |  |  |  |
|  |  |  | tobacco |  |  |  |
|  |  |  | requirements |  |  |  |
|  |  |  | Penalty for | 2009 | 1,000,000 | 1,100,200 |
|  |  |  | aggregate of all |  |  |  |
|  |  |  | such violations |  |  |  |
|  |  |  | of tobacco |  |  |  |
|  |  |  | product |  |  |  |
|  |  |  | requirements |  |  |  |
|  |  |  | adjudicated in a |  |  |  |
|  |  |  | single proceeding |  |  |  |
| 333(f)(9) |  | FDA | Penalty in the | 2009 | 250,000 | 275,050 |
| (B)(i) |  |  | case of a |  |  |  |
| (II) |  |  | violation of |  |  |  |
|  |  |  | tobacco product |  |  |  |
|  |  |  | requirements that |  |  |  |
|  |  |  | continues after |  |  |  |
|  |  |  | written notice to |  |  |  |
|  |  |  | such person, for |  |  |  |
|  |  |  | the first 30-day |  |  |  |
|  |  |  | period (or any |  |  |  |
|  |  |  | portion thereof) |  |  |  |
|  |  |  | the person |  |  |  |
|  |  |  | continues to be |  |  |  |
|  |  |  | in violation |  |  |  |
|  |  |  | Penalty for | 2009 | 1,000,000 | 1,100,200 |
|  |  |  | violation of |  |  |  |
|  |  |  | tobacco product |  |  |  |
|  |  |  | requirements that |  |  |  |
|  |  |  | continues after |  |  |  |
|  |  |  | written notice to |  |  |  |
|  |  |  | such person shall |  |  |  |
|  |  |  | double for every |  |  |  |
|  |  |  | 30-day period |  |  |  |
|  |  |  | thereafter the |  |  |  |
|  |  |  | violation |  |  |  |
|  |  |  | continues, but |  |  |  |
|  |  |  | may not exceed |  |  |  |
|  |  |  | penalty amount |  |  |  |
|  |  |  | for any 30-day |  |  |  |
|  |  |  | period |  |  |  |
|  |  |  | Penalty for | 2009 | 10,000,00 | 11,002,00 |
|  |  |  | aggregate of all |  | 0 | 0 |
|  |  |  | such violations |  |  |  |
|  |  |  | related to |  |  |  |
|  |  |  | tobacco product |  |  |  |
|  |  |  | requirements |  |  |  |
|  |  |  | adjudicated in a |  |  |  |
|  |  |  | single proceeding |  |  |  |
| 333(f)(9) |  | FDA | Penalty for any | 2009 | 250,000 | 275,050 |
| (B)(ii) |  |  | person who either |  |  |  |
| (I) |  |  | 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 |  |  |  |
|  |  |  | Penalty for | 2009 | 1,000,000 | 1,100,200 |
|  |  |  | aggregate of for |  |  |  |
|  |  |  | all such above |  |  |  |
|  |  |  | violations |  |  |  |
|  |  |  | adjudicated in a |  |  |  |
|  |  |  | single proceeding |  |  |  |
| 333(f)(9) |  | FDA | Penalty for | 2009 | 250,000 | 275,050 |
| (B)(ii) |  |  | violation of |  |  |  |
| (II) |  |  | 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 |  |  |  |
|  |  |  | Penalty for post- | 2009 | 1,000,000 | 1,100,200 |
|  |  |  | 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 |  |  |  |
|  |  |  | Penalty for | 2009 | 10,000,00 | 11,002,00 |
|  |  |  | aggregate above |  | 0 | 0 |
|  |  |  | tobacco product |  |  |  |
|  |  |  | requirement |  |  |  |
|  |  |  | violations |  |  |  |
|  |  |  | adjudicated in a |  |  |  |
|  |  |  | single proceeding |  |  |  |
| 333(g)(1) |  | FDA | Penalty for any | 2007 | 250,000 | 284,583 |
|  |  |  | person who |  |  |  |
|  |  |  | disseminates or |  |  |  |
|  |  |  | causes another |  |  |  |
|  |  |  | party to |  |  |  |
|  |  |  | disseminate a |  |  |  |
|  |  |  | direct-to- |  |  |  |
|  |  |  | consumer |  |  |  |
|  |  |  | advertisement |  |  |  |
|  |  |  | that is false or |  |  |  |
|  |  |  | misleading for |  |  |  |
|  |  |  | the first such |  |  |  |
|  |  |  | violation in any |  |  |  |
|  |  |  | 3-year period |  |  |  |
|  |  |  | Penalty for each | 2007 | 500,000 | 569,165 |
|  |  |  | subsequent above |  |  |  |
|  |  |  | violation in any |  |  |  |
|  |  |  | 3-year period |  |  |  |
| 333 note |  | FDA | Penalty to be | 2009 | 250 | 275 |
|  |  |  | applied for |  |  |  |
|  |  |  | violations of |  |  |  |
|  |  |  | restrictions on |  |  |  |
|  |  |  | the sale or |  |  |  |
|  |  |  | distribution of |  |  |  |
|  |  |  | tobacco products |  |  |  |
|  |  |  | promulgated under |  |  |  |
|  |  |  | [*21 U.S.C. 387f*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GMD1-NRF4-446N-00000-00&context=)(d) |  |  |  |
|  |  |  | (e.g., violations |  |  |  |
|  |  |  | of ***regulations*** in |  |  |  |
|  |  |  | 21 CFR Part 1140) |  |  |  |
|  |  |  | with respect to a |  |  |  |
|  |  |  | retailer with an |  |  |  |
|  |  |  | approved training |  |  |  |
|  |  |  | program in the |  |  |  |
|  |  |  | case of a second |  |  |  |
|  |  |  | ***regulation*** |  |  |  |
|  |  |  | violation within |  |  |  |
|  |  |  | a 12-month period |  |  |  |
|  |  |  | Penalty in the | 2009 | 500 | 550 |
|  |  |  | case of a third |  |  |  |
|  |  |  | tobacco product |  |  |  |
|  |  |  | ***regulation*** |  |  |  |
|  |  |  | violation within |  |  |  |
|  |  |  | a 24-month period |  |  |  |
|  |  |  | Penalty in the | 2009 | 2,000 | 2,200 |
|  |  |  | case of a fourth |  |  |  |
|  |  |  | tobacco product |  |  |  |
|  |  |  | ***regulation*** |  |  |  |
|  |  |  | violation within |  |  |  |
|  |  |  | a 24-month period |  |  |  |
|  |  |  | Penalty in the | 2009 | 5,000 | 5,501 |
|  |  |  | case of a fifth |  |  |  |
|  |  |  | tobacco product |  |  |  |
|  |  |  | ***regulation*** |  |  |  |
|  |  |  | violation within |  |  |  |
|  |  |  | a 36-month period |  |  |  |
|  |  |  | Penalty in the | 2009 | 10,000 | 11,002 |
|  |  |  | case of a sixth |  |  |  |
|  |  |  | or subsequent |  |  |  |
|  |  |  | tobacco product |  |  |  |
|  |  |  | ***regulation*** |  |  |  |
|  |  |  | violation within |  |  |  |
|  |  |  | a 48-month period |  |  |  |
|  |  |  | as determined on |  |  |  |
|  |  |  | a case-by-case |  |  |  |
|  |  |  | basis |  |  |  |
|  |  |  | Penalty to be | 2009 | 250 | 275 |
|  |  |  | applied for |  |  |  |
|  |  |  | violations of |  |  |  |
|  |  |  | restrictions on |  |  |  |
|  |  |  | the sale or |  |  |  |
|  |  |  | distribution of |  |  |  |
|  |  |  | tobacco products |  |  |  |
|  |  |  | promulgated under |  |  |  |
|  |  |  | [*21 U.S.C. 387f*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GMD1-NRF4-446N-00000-00&context=)(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 |  |  |  |
|  |  |  | Penalty in the | 2009 | 500 | 550 |
|  |  |  | case of a second |  |  |  |
|  |  |  | tobacco product |  |  |  |
|  |  |  | ***regulation*** |  |  |  |
|  |  |  | violation within |  |  |  |
|  |  |  | a 12-month period |  |  |  |
|  |  |  | Penalty in the | 2009 | 1,000 | 1,100 |
|  |  |  | case of a third |  |  |  |
|  |  |  | tobacco product |  |  |  |
|  |  |  | ***regulation*** |  |  |  |
|  |  |  | violation within |  |  |  |
|  |  |  | a 24-month period |  |  |  |
|  |  |  | Penalty in the | 2009 | 2,000 | 2,200 |
|  |  |  | case of a fourth |  |  |  |
|  |  |  | tobacco product |  |  |  |
|  |  |  | ***regulation*** |  |  |  |
|  |  |  | violation within |  |  |  |
|  |  |  | a 24-month period |  |  |  |
|  |  |  | Penalty in the | 2009 | 5,000 | 5,501 |
|  |  |  | case of a fifth |  |  |  |
|  |  |  | tobacco product |  |  |  |
|  |  |  | ***regulation*** |  |  |  |
|  |  |  | violation within |  |  |  |
|  |  |  | a 36-month period |  |  |  |
|  |  |  | Penalty in the | 2009 | 10,000 | 11,002 |
|  |  |  | case of a sixth |  |  |  |
|  |  |  | or subsequent |  |  |  |
|  |  |  | tobacco product |  |  |  |
|  |  |  | ***regulation*** |  |  |  |
|  |  |  | violation within |  |  |  |
|  |  |  | a 48-month period |  |  |  |
|  |  |  | as determined on |  |  |  |
|  |  |  | a case-by-case |  |  |  |
|  |  |  | basis |  |  |  |
| 335b(a) |  | FDA | Penalty for each | 1992 | 250,000 | 419,320 |
|  |  |  | 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 |  |  |  |
|  |  |  | Penalty in the | 1992 | 1,000,000 | 1,677,280 |
|  |  |  | case of any other |  |  |  |
|  |  |  | person (other |  |  |  |
|  |  |  | than an |  |  |  |
|  |  |  | individual) per |  |  |  |
|  |  |  | above violation |  |  |  |
| 360pp(b) |  | FDA | Penalty for any | 1968 | 1,100 | 2,750 |
| (1) |  |  | person who |  |  |  |
|  |  |  | violates any such |  |  |  |
|  |  |  | requirements for |  |  |  |
|  |  |  | electronic |  |  |  |
|  |  |  | products, with |  |  |  |
|  |  |  | each unlawful act |  |  |  |
|  |  |  | or omission |  |  |  |
|  |  |  | constituting a |  |  |  |
|  |  |  | separate |  |  |  |
|  |  |  | violation |  |  |  |
|  |  |  | Penalty imposed | 1968 | 375,000 | 937,500 |
|  |  |  | for any related |  |  |  |
|  |  |  | series of |  |  |  |
|  |  |  | violations of |  |  |  |
|  |  |  | requirements |  |  |  |
|  |  |  | relating to |  |  |  |
|  |  |  | electronic |  |  |  |
|  |  |  | products |  |  |  |
| 42 |  |  |  |  |  |  |
| U.S.C.: |  |  |  |  |  |  |
| 262(d) |  | FDA | Penalty per day | 1986 | 100,000 | 215,628 |
|  |  |  | for violation of |  |  |  |
|  |  |  | order of recall |  |  |  |
|  |  |  | of biological |  |  |  |
|  |  |  | product |  |  |  |
|  |  |  | presenting |  |  |  |
|  |  |  | imminent or |  |  |  |
|  |  |  | substantial |  |  |  |
|  |  |  | hazard |  |  |  |
| 263b(h) |  | FDA | Penalty for | 1992 | 10,000 | 16,773 |
| (3) |  |  | failure to obtain |  |  |  |
|  |  |  | a mammography |  |  |  |
|  |  |  | certificate as |  |  |  |
|  |  |  | required |  |  |  |
| 300aa- |  | FDA | Penalty per | 1986 | 100,000 | 215,628 |
| 28(b)(1) |  |  | occurrence for |  |  |  |
|  |  |  | any vaccine |  |  |  |
|  |  |  | manufacturer that |  |  |  |
|  |  |  | intentionally |  |  |  |
|  |  |  | destroys, alters, |  |  |  |
|  |  |  | falsifies, or |  |  |  |
|  |  |  | conceals any |  |  |  |
|  |  |  | record or report |  |  |  |
|  |  |  | required |  |  |  |
| 256b(d) |  | HRSA | Penalty for each | 2010 | 5,000 | 5,437 |
| (1)(B) |  |  | instance of |  |  |  |
| (vi) |  |  | overcharging a |  |  |  |
|  |  |  | 340B covered |  |  |  |
|  |  |  | entity |  |  |  |
| 299c- |  | AHRQ | Penalty for an | 1999 | 10,000 | 14,140 |
| (3)(d) |  |  | establishment or |  |  |  |
|  |  |  | person supplying |  |  |  |
|  |  |  | information |  |  |  |
|  |  |  | obtained in the |  |  |  |
|  |  |  | course of |  |  |  |
|  |  |  | activities for |  |  |  |
|  |  |  | any purpose other |  |  |  |
|  |  |  | than the purpose |  |  |  |
|  |  |  | for which it was |  |  |  |
|  |  |  | supplied |  |  |  |
| 653(l)(2) | 45 CFR | ACF | Penalty for | 1998 | 1,000 | 1,450 |
|  | 303.21(f) |  | Misuse of |  |  |  |
|  |  |  | Information in |  |  |  |
|  |  |  | the National |  |  |  |
|  |  |  | Directory of New |  |  |  |
|  |  |  | Hires |  |  |  |
| 262a(i) | 42 CFR | OIG | Penalty for each | 2002 | 250,000 | 327,962 |
| (1) | Part 1003 |  | individual who |  |  |  |
|  |  |  | violates safety |  |  |  |
|  |  |  | and security |  |  |  |
|  |  |  | procedures |  |  |  |
|  |  |  | related to |  |  |  |
|  |  |  | handling |  |  |  |
|  |  |  | dangerous |  |  |  |
|  |  |  | biological agents |  |  |  |
|  |  |  | and toxins |  |  |  |
|  |  |  | Penalty for any | 2002 | 500,000 | 655,925 |
|  |  |  | other person who |  |  |  |
|  |  |  | violates safety |  |  |  |
|  |  |  | and security |  |  |  |
|  |  |  | procedures |  |  |  |
|  |  |  | related to |  |  |  |
|  |  |  | handling |  |  |  |
|  |  |  | dangerous |  |  |  |
|  |  |  | biological agents |  |  |  |
|  |  |  | and toxins. |  |  |  |
| 1320a- | 42 CFR | OIG | Penalty for | 1996 | 10,000 | 15,024 |
| 7a(a) | Part 1003 |  | knowingly |  |  |  |
|  |  |  | presenting or |  |  |  |
|  |  |  | causing to be |  |  |  |
|  |  |  | presented to an |  |  |  |
|  |  |  | officer, |  |  |  |
|  |  |  | employee, or |  |  |  |
|  |  |  | agent of the |  |  |  |
|  |  |  | United States a |  |  |  |
|  |  |  | false claim |  |  |  |
|  |  |  | Penalty for | 1996 | 10,000 | 15,024 |
|  |  |  | knowingly |  |  |  |
|  |  |  | presenting or |  |  |  |
|  |  |  | causing to be |  |  |  |
|  |  |  | presented a |  |  |  |
|  |  |  | request for |  |  |  |
|  |  |  | payment which |  |  |  |
|  |  |  | violates the |  |  |  |
|  |  |  | terms of an |  |  |  |
|  |  |  | assignment, |  |  |  |
|  |  |  | agreement, or PPS |  |  |  |
|  |  |  | agreement |  |  |  |
|  |  |  | Penalty for | 1996 | 15,000 | 22,537 |
|  |  |  | 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 |  |  |  |
|  |  |  | Penalty for an | 1996 | 10,000 | 15,024 |
|  |  |  | excluded party |  |  |  |
|  |  |  | retaining |  |  |  |
|  |  |  | ownership or |  |  |  |
|  |  |  | control interest |  |  |  |
|  |  |  | in a |  |  |  |
|  |  |  | participating |  |  |  |
|  |  |  | entity |  |  |  |
|  |  |  | Penalty for | 1996 | 10,000 | 15,024 |
|  |  |  | remuneration |  |  |  |
|  |  |  | offered to induce |  |  |  |
|  |  |  | program |  |  |  |
|  |  |  | beneficiaries to |  |  |  |
|  |  |  | use particular |  |  |  |
|  |  |  | providers, |  |  |  |
|  |  |  | practitioners, or |  |  |  |
|  |  |  | suppliers |  |  |  |
|  |  |  | Penalty for | 1997 | 10,000 | 14,718 |
|  |  |  | employing or |  |  |  |
|  |  |  | contracting with |  |  |  |
|  |  |  | an excluded |  |  |  |
|  |  |  | individual |  |  |  |
|  |  |  | Penalty for | 1997 | 50,000 | 73,588 |
|  |  |  | 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 |  |  |  |
|  |  |  | Penalty for | 2010 | 10,000 | 10,874 |
|  |  |  | ordering or |  |  |  |
|  |  |  | prescribing |  |  |  |
|  |  |  | medical or other |  |  |  |
|  |  |  | item or service |  |  |  |
|  |  |  | during a period |  |  |  |
|  |  |  | in which the |  |  |  |
|  |  |  | person was |  |  |  |
|  |  |  | excluded |  |  |  |
|  |  |  | Penalty for | 2010 | 50,000 | 54,372 |
|  |  |  | 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 |  |  |  |
|  |  |  | Penalty for | 2010 | 10,000 | 10,874 |
|  |  |  | knowing of an |  |  |  |
|  |  |  | overpayment and |  |  |  |
|  |  |  | failing to report |  |  |  |
|  |  |  | and return |  |  |  |
|  |  |  | Penalty for | 2010 | 50,000 | 54,372 |
|  |  |  | making or using a |  |  |  |
|  |  |  | false record or |  |  |  |
|  |  |  | statement that is |  |  |  |
|  |  |  | material to a |  |  |  |
|  |  |  | false or |  |  |  |
|  |  |  | fraudulent claim |  |  |  |
|  |  |  | Penalty for | 2010 | 15,000 | 16,312 |
|  |  |  | failure to grant |  |  |  |
|  |  |  | timely access to |  |  |  |
|  |  |  | HHS OIG for |  |  |  |
|  |  |  | audits, |  |  |  |
|  |  |  | investigations, |  |  |  |
|  |  |  | evaluations, and |  |  |  |
|  |  |  | other statutory |  |  |  |
|  |  |  | functions of HHS |  |  |  |
|  |  |  | OIG |  |  |  |
| 1320a- | 42 CFR | OIG | Penalty for | 1986 | 2,000 | 4,313 |
| 7a(b) | Part 1003 |  | payments by a |  |  |  |
|  |  |  | hospital or |  |  |  |
|  |  |  | critical access |  |  |  |
|  |  |  | hospital to |  |  |  |
|  |  |  | induce a |  |  |  |
|  |  |  | physician to |  |  |  |
|  |  |  | reduce or limit |  |  |  |
|  |  |  | services to |  |  |  |
|  |  |  | individuals under |  |  |  |
|  |  |  | direct care of |  |  |  |
|  |  |  | physician or who |  |  |  |
|  |  |  | are entitled to |  |  |  |
|  |  |  | certain medical |  |  |  |
|  |  |  | assistance |  |  |  |
|  |  |  | benefits |  |  |  |
|  |  |  | Penalty for | 1986 | 2,000 | 4,313 |
|  |  |  | 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 |  |  |  |
|  |  |  | Penalty for a | 1996 | 5,000 | 7,512 |
|  |  |  | physician who |  |  |  |
|  |  |  | executes a |  |  |  |
|  |  |  | document that |  |  |  |
|  |  |  | falsely certifies |  |  |  |
|  |  |  | home health needs |  |  |  |
|  |  |  | for Medicare |  |  |  |
|  |  |  | beneficiaries |  |  |  |
| 1320a- | 42 CFR | OIG | Penalty for | 1997 | 25,000 | 36,794 |
| 7e(b)(6) | Part 1003 |  | failure to report |  |  |  |
| (A) |  |  | any final adverse |  |  |  |
|  |  |  | action taken |  |  |  |
|  |  |  | against a health |  |  |  |
|  |  |  | care provider, |  |  |  |
|  |  |  | supplier, or |  |  |  |
|  |  |  | practitioner |  |  |  |
| 1320b- | 42 CFR | OIG | Penalty for the | 1988 | 5,000 | 9,893 |
| 10(b)(1) | Part 1003 |  | 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 |  |  |  |
| 1320b- | 42 CFR | OIG | Penalty for the | 1988 | 25,000 | 49,467 |
| 10(b)(2) | Part 1003 |  | 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 |  |  |  |
| 1395i- |  | OIG | Penalty for | 1987 | 1,000 | 2,063 |
| 3(b)(3) |  |  | certification of |  |  |  |
| (B)(ii) |  |  | a false statement |  |  |  |
| (1) |  |  | in assessment of |  |  |  |
|  |  |  | functional |  |  |  |
|  |  |  | capacity of a |  |  |  |
|  |  |  | Skilled Nursing |  |  |  |
|  |  |  | Facility resident |  |  |  |
|  |  |  | assessment |  |  |  |
| 1395i- |  | OIG | Penalty for | 1987 | 5,000 | 10,314 |
| 3(b)(3) |  |  | causing another |  |  |  |
| (B)(ii) |  |  | to certify or |  |  |  |
| (2) |  |  | make a false |  |  |  |
|  |  |  | statement in |  |  |  |
|  |  |  | assessment of |  |  |  |
|  |  |  | functional |  |  |  |
|  |  |  | capacity of a |  |  |  |
|  |  |  | Skilled Nursing |  |  |  |
|  |  |  | Facility resident |  |  |  |
|  |  |  | assessment |  |  |  |
| 1395i- |  | OIG | Penalty for any | 1987 | 2,000 | 4,126 |
| 3(g)(2) |  |  | individual who |  |  |  |
| (A) |  |  | notifies or |  |  |  |
|  |  |  | causes to be |  |  |  |
|  |  |  | notified a |  |  |  |
|  |  |  | Skilled Nursing |  |  |  |
|  |  |  | Facility of the |  |  |  |
|  |  |  | time or date on |  |  |  |
|  |  |  | which a survey is |  |  |  |
|  |  |  | to be conducted |  |  |  |
| 1395w- | 42 CFR | OIG | Penalty for a | 1996 | 25,000 | 37,561 |
| 27(g)(2) | 422.752; |  | Medicare |  |  |  |
| (A) | 42 CFR |  | Advantage |  |  |  |
|  | Part 1003 |  | organization that |  |  |  |
|  |  |  | substantially |  |  |  |
|  |  |  | fails to provide |  |  |  |
|  |  |  | medically |  |  |  |
|  |  |  | necessary, |  |  |  |
|  |  |  | required items |  |  |  |
|  |  |  | and services |  |  |  |
|  |  |  | Penalty for a | 1997 | 25,000 | 36,794 |
|  |  |  | Medicare |  |  |  |
|  |  |  | Advantage |  |  |  |
|  |  |  | organization that |  |  |  |
|  |  |  | charges excessive |  |  |  |
|  |  |  | premiums |  |  |  |
|  |  |  | Penalty for a | 1997 | 25,000 | 36,794 |
|  |  |  | Medicare |  |  |  |
|  |  |  | Advantage |  |  |  |
|  |  |  | organization that |  |  |  |
|  |  |  | improperly expels |  |  |  |
|  |  |  | or refuses to |  |  |  |
|  |  |  | reenroll a |  |  |  |
|  |  |  | beneficiary |  |  |  |
|  |  |  | Penalty for a | 1997 | 100,000 | 147,177 |
|  |  |  | Medicare |  |  |  |
|  |  |  | Advantage |  |  |  |
|  |  |  | organization that |  |  |  |
|  |  |  | engages in |  |  |  |
|  |  |  | practice that |  |  |  |
|  |  |  | would reasonably |  |  |  |
|  |  |  | be expected to |  |  |  |
|  |  |  | have the effect |  |  |  |
|  |  |  | of denying or |  |  |  |
|  |  |  | discouraging |  |  |  |
|  |  |  | enrollment |  |  |  |
|  |  |  | Penalty per | 1997 | 15,000 | 22,077 |
|  |  |  | 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 |  |  |  |
|  |  |  | Penalty for a | 1997 | 100,000 | 147,177 |
|  |  |  | Medicare |  |  |  |
|  |  |  | Advantage |  |  |  |
|  |  |  | organization |  |  |  |
|  |  |  | misrepresenting |  |  |  |
|  |  |  | or falsifying |  |  |  |
|  |  |  | information to |  |  |  |
|  |  |  | Secretary |  |  |  |
|  |  |  | Penalty for a | 1997 | 25,000 | 36,794 |
|  |  |  | Medicare |  |  |  |
|  |  |  | Advantage |  |  |  |
|  |  |  | organization |  |  |  |
|  |  |  | misrepresenting |  |  |  |
|  |  |  | or falsifying |  |  |  |
|  |  |  | information to |  |  |  |
|  |  |  | individual or |  |  |  |
|  |  |  | other entity |  |  |  |
|  |  |  | Penalty for | 1997 | 25,000 | 36,794 |
|  |  |  | Medicare |  |  |  |
|  |  |  | Advantage |  |  |  |
|  |  |  | organization |  |  |  |
|  |  |  | interfering with |  |  |  |
|  |  |  | provider's advice |  |  |  |
|  |  |  | to enrollee and |  |  |  |
|  |  |  | non-MCO |  |  |  |
|  |  |  | affiliated |  |  |  |
|  |  |  | providers that |  |  |  |
|  |  |  | balance bill |  |  |  |
|  |  |  | enrollees |  |  |  |
|  |  |  | Penalty for a | 1997 | 25,000 | 36,794 |
|  |  |  | Medicare |  |  |  |
|  |  |  | Advantage |  |  |  |
|  |  |  | organization that |  |  |  |
|  |  |  | employs or |  |  |  |
|  |  |  | contracts with |  |  |  |
|  |  |  | excluded |  |  |  |
|  |  |  | individual or |  |  |  |
|  |  |  | entity |  |  |  |
|  |  |  | Penalty for a | 2010 | 25,000 | 36,794 |
|  |  |  | Medicare |  |  |  |
|  |  |  | Advantage |  |  |  |
|  |  |  | organization |  |  |  |
|  |  |  | enrolling an |  |  |  |
|  |  |  | individual in |  |  |  |
|  |  |  | without prior |  |  |  |
|  |  |  | written consent |  |  |  |
|  |  |  | Penalty for a | 2010 | 25,000 | 36,794 |
|  |  |  | Medicare |  |  |  |
|  |  |  | Advantage |  |  |  |
|  |  |  | organization |  |  |  |
|  |  |  | transferring an |  |  |  |
|  |  |  | enrollee to |  |  |  |
|  |  |  | another plan |  |  |  |
|  |  |  | without consent |  |  |  |
|  |  |  | or solely for the |  |  |  |
|  |  |  | purpose of |  |  |  |
|  |  |  | earning a |  |  |  |
|  |  |  | commission |  |  |  |
|  |  |  | Penalty for a | 2010 | 25,000 | 36,794 |
|  |  |  | Medicare |  |  |  |
|  |  |  | Advantage |  |  |  |
|  |  |  | organization |  |  |  |
|  |  |  | failing to comply |  |  |  |
|  |  |  | with marketing |  |  |  |
|  |  |  | restrictions or |  |  |  |
|  |  |  | applicable |  |  |  |
|  |  |  | implementing |  |  |  |
|  |  |  | ***regulations*** or |  |  |  |
|  |  |  | guidance |  |  |  |
|  |  |  | Penalty for a | 2010 | 25,000 | 36,794 |
|  |  |  | Medicare |  |  |  |
|  |  |  | Advantage |  |  |  |
|  |  |  | organization |  |  |  |
|  |  |  | employing or |  |  |  |
|  |  |  | contracting with |  |  |  |
|  |  |  | an individual or |  |  |  |
|  |  |  | entity who |  |  |  |
|  |  |  | violates 1395w- |  |  |  |
|  |  |  | 27(g)(1)(A)-(J) |  |  |  |
| 1395w- | 42 CFR | OIG | Penalty for a | 2003 | 10,000 | 12,856 |
| 141(i)(3) | Part 1003 |  | prescription drug |  |  |  |
|  |  |  | card sponsor that |  |  |  |
|  |  |  | falsifies or |  |  |  |
|  |  |  | misrepresents |  |  |  |
|  |  |  | marketing |  |  |  |
|  |  |  | materials, |  |  |  |
|  |  |  | overcharges |  |  |  |
|  |  |  | program |  |  |  |
|  |  |  | enrollees, or |  |  |  |
|  |  |  | misuse |  |  |  |
|  |  |  | transitional |  |  |  |
|  |  |  | assistance funds |  |  |  |
| 1395cc(g) | 42 CFR | OIG | Penalty for | 1972 | 2,000 | 5,000 |
|  | Part 1003 |  | improper billing |  |  |  |
|  |  |  | by Hospitals, |  |  |  |
|  |  |  | Critical Access |  |  |  |
|  |  |  | Hospitals, or |  |  |  |
|  |  |  | Skilled Nursing |  |  |  |
|  |  |  | Facilities |  |  |  |
| 1395dd(d) | 42 CFR | OIG | Penalty for a | 1987 | 50,000 | 103,139 |
| (1) | Part 1003 |  | hospital or |  |  |  |
|  |  |  | responsible |  |  |  |
|  |  |  | physician dumping |  |  |  |
|  |  |  | patients needing |  |  |  |
|  |  |  | emergency medical |  |  |  |
|  |  |  | care, if the |  |  |  |
|  |  |  | hospital has 100 |  |  |  |
|  |  |  | beds or more |  |  |  |
|  |  |  | Penalty for a | 1987 | 25,000 | 51,570 |
|  |  |  | hospital or |  |  |  |
|  |  |  | responsible |  |  |  |
|  |  |  | physician dumping |  |  |  |
|  |  |  | patients needing |  |  |  |
|  |  |  | emergency medical |  |  |  |
|  |  |  | care, if the |  |  |  |
|  |  |  | hospital has less |  |  |  |
|  |  |  | than 100 beds |  |  |  |
| 1395mm(i) | 42 CFR | OIG | Penalty for a HMO | 1987 | 25,000 | 51,570 |
| (6)(B)(i) | Part 1003 |  | or ***competitive*** |  |  |  |
|  |  |  | plan is such plan |  |  |  |
|  |  |  | substantially |  |  |  |
|  |  |  | fails to provide |  |  |  |
|  |  |  | medically |  |  |  |
|  |  |  | necessary, |  |  |  |
|  |  |  | required items or |  |  |  |
|  |  |  | services |  |  |  |
|  |  |  | Penalty for | 1987 | 25,000 | 51,570 |
|  |  |  | HMOs/***competitive*** |  |  |  |
|  |  |  | medical plans |  |  |  |
|  |  |  | that charge |  |  |  |
|  |  |  | premiums in |  |  |  |
|  |  |  | excess of |  |  |  |
|  |  |  | permitted amounts |  |  |  |
|  |  |  | Penalty for a HMO | 1987 | 25,000 | 51,570 |
|  |  |  | or ***competitive*** |  |  |  |
|  |  |  | medical plan that |  |  |  |
|  |  |  | expels or refuses |  |  |  |
|  |  |  | to reenroll an |  |  |  |
|  |  |  | individual per |  |  |  |
|  |  |  | prescribed |  |  |  |
|  |  |  | conditions |  |  |  |
|  |  |  | Penalty for a HMO | 1987 | 100,000 | 206,278 |
|  |  |  | or ***competitive*** |  |  |  |
|  |  |  | medical plan that |  |  |  |
|  |  |  | implements |  |  |  |
|  |  |  | practices to |  |  |  |
|  |  |  | discourage |  |  |  |
|  |  |  | enrollment of |  |  |  |
|  |  |  | individuals |  |  |  |
|  |  |  | needing services |  |  |  |
|  |  |  | in future |  |  |  |
|  |  |  | Penalty per | 1988 | 15,000 | 29,680 |
|  |  |  | individual not |  |  |  |
|  |  |  | enrolled in a |  |  |  |
|  |  |  | plan as a result |  |  |  |
|  |  |  | of a HMO or |  |  |  |
|  |  |  | ***competitive*** |  |  |  |
|  |  |  | medical plan that |  |  |  |
|  |  |  | implements |  |  |  |
|  |  |  | practices to |  |  |  |
|  |  |  | discourage |  |  |  |
|  |  |  | enrollment of |  |  |  |
|  |  |  | individuals |  |  |  |
|  |  |  | needing services |  |  |  |
|  |  |  | in the future |  |  |  |
|  |  |  | Penalty for a HMO | 1987 | 100,000 | 206,278 |
|  |  |  | or ***competitive*** |  |  |  |
|  |  |  | medical plan that |  |  |  |
|  |  |  | misrepresents or |  |  |  |
|  |  |  | falsifies |  |  |  |
|  |  |  | information to |  |  |  |
|  |  |  | the Secretary |  |  |  |
|  |  |  | Penalty for a HMO | 1987 | 25,000 | 51,570 |
|  |  |  | or ***competitive*** |  |  |  |
|  |  |  | medical plan that |  |  |  |
|  |  |  | misrepresents or |  |  |  |
|  |  |  | falsifies |  |  |  |
|  |  |  | information to an |  |  |  |
|  |  |  | individual or any |  |  |  |
|  |  |  | other entity |  |  |  |
|  |  |  | Penalty for | 1987 | 25,000 | 51,570 |
|  |  |  | failure by HMO or |  |  |  |
|  |  |  | ***competitive*** |  |  |  |
|  |  |  | medical plan to |  |  |  |
|  |  |  | assure prompt |  |  |  |
|  |  |  | payment of |  |  |  |
|  |  |  | Medicare risk |  |  |  |
|  |  |  | sharing contracts |  |  |  |
|  |  |  | or incentive plan |  |  |  |
|  |  |  | provisions |  |  |  |
|  |  |  | Penalty for HMO | 1989 | 25,000 | 47,340 |
|  |  |  | that employs or |  |  |  |
|  |  |  | contracts with |  |  |  |
|  |  |  | excluded |  |  |  |
|  |  |  | individual or |  |  |  |
|  |  |  | entity |  |  |  |
| 1395nn(g) | 42 CFR | OIG | Penalty for | 1994 | 15,000 | 23,863 |
| (3) | Part 1003 |  | submitting or |  |  |  |
|  |  |  | causing to be |  |  |  |
|  |  |  | submitted claims |  |  |  |
|  |  |  | in violation of |  |  |  |
|  |  |  | the Stark Law's |  |  |  |
|  |  |  | restrictions on |  |  |  |
|  |  |  | physician self- |  |  |  |
|  |  |  | referrals |  |  |  |
| 1395nn(g) | 42 CFR | OIG | Penalty for | 1994 | 100,000 | 159,089 |
| (4) | Part 1003 |  | circumventing |  |  |  |
|  |  |  | Stark Law's |  |  |  |
|  |  |  | restrictions on |  |  |  |
|  |  |  | physician self- |  |  |  |
|  |  |  | referrals |  |  |  |
| 1395ss(d) | 42 CFR | OIG | Penalty for a | 1988 | 5,000 | 9,893 |
| (1) | Part 1003 |  | material |  |  |  |
|  |  |  | misrepresentation |  |  |  |
|  |  |  | regarding Medigap |  |  |  |
|  |  |  | compliance |  |  |  |
|  |  |  | policies |  |  |  |
| 1395ss(d) | 42 CFR | OIG | Penalty for | 1988 | 5,000 | 9,893 |
| (2) | Part 1003 |  | selling Medigap |  |  |  |
|  |  |  | policy under |  |  |  |
|  |  |  | false pretense |  |  |  |
| 1395ss(d) | 42 CFR | OIG | Penalty for an | 1990 | 25,000 | 44,539 |
| (3)(A) | Part 1003 |  | issuer that sells |  |  |  |
| (ii) |  |  | health insurance |  |  |  |
|  |  |  | policy that |  |  |  |
|  |  |  | duplicates |  |  |  |
|  |  |  | benefits |  |  |  |
|  |  |  | Penalty for | 1990 | 15,000 | 26,723 |
|  |  |  | someone other |  |  |  |
|  |  |  | than issuer that |  |  |  |
|  |  |  | sells health |  |  |  |
|  |  |  | insurance that |  |  |  |
|  |  |  | duplicates |  |  |  |
|  |  |  | benefits |  |  |  |
| 1395ss(d) | 42 CFR | OIG | Penalty for using | 1988 | 5,000 | 9,893 |
| (4)(A) | Part 1003 |  | mail to sell a |  |  |  |
|  |  |  | non-approved |  |  |  |
|  |  |  | Medigap insurance |  |  |  |
|  |  |  | policy |  |  |  |
| 1396b(m) | 42 CFR | OIG | Penalty for a | 1988 | 25,000 | 49,467 |
| (5)(B)(i) | Part 1003 |  | Medicaid MCO that |  |  |  |
|  |  |  | substantially |  |  |  |
|  |  |  | fails to provide |  |  |  |
|  |  |  | medically |  |  |  |
|  |  |  | necessary, |  |  |  |
|  |  |  | required items or |  |  |  |
|  |  |  | services |  |  |  |
|  |  |  | Penalty for a | 1988 | 25,000 | 49,467 |
|  |  |  | Medicaid MCO that |  |  |  |
|  |  |  | charges excessive |  |  |  |
|  |  |  | premiums |  |  |  |
|  |  |  | Penalty for a | 1988 | 100,000 | 197,869 |
|  |  |  | Medicaid MCO that |  |  |  |
|  |  |  | improperly expels |  |  |  |
|  |  |  | or refuses to |  |  |  |
|  |  |  | reenroll a |  |  |  |
|  |  |  | beneficiary |  |  |  |
|  |  |  | Penalty per | 1988 | 15,000 | 29,680 |
|  |  |  | 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 |  |  |  |
|  |  |  | Penalty for a | 1988 | 100,000 | 197,869 |
|  |  |  | Medicaid MCO |  |  |  |
|  |  |  | misrepresenting |  |  |  |
|  |  |  | or falsifying |  |  |  |
|  |  |  | information to |  |  |  |
|  |  |  | the Secretary |  |  |  |
|  |  |  | Penalty for a | 1988 | 25,000 | 49,467 |
|  |  |  | Medicaid MCO |  |  |  |
|  |  |  | misrepresenting |  |  |  |
|  |  |  | or falsifying |  |  |  |
|  |  |  | information to an |  |  |  |
|  |  |  | individual or |  |  |  |
|  |  |  | another entity |  |  |  |
|  |  |  | Penalty for a | 1990 | 25,000 | 44,539 |
|  |  |  | Medicaid MCO that |  |  |  |
|  |  |  | fails to comply |  |  |  |
|  |  |  | with contract |  |  |  |
|  |  |  | requirements with |  |  |  |
|  |  |  | respect to |  |  |  |
|  |  |  | physician |  |  |  |
|  |  |  | incentive plans |  |  |  |
| 1396r(b) | 42 CFR | OIG | Penalty for | 1987 | 1,000 | 2,063 |
| (3)(B) | Part 1003 |  | willfully and |  |  |  |
| (ii)(I) |  |  | knowingly |  |  |  |
|  |  |  | certifying a |  |  |  |
|  |  |  | material and |  |  |  |
|  |  |  | false statement |  |  |  |
|  |  |  | in a Skilled |  |  |  |
|  |  |  | Nursing Facility |  |  |  |
|  |  |  | resident |  |  |  |
|  |  |  | assessment |  |  |  |
| 1396r(b) | 42 CFR | OIG | Penalty for | 1987 | 5,000 | 10,314 |
| (3)(B) | Part 1003 |  | willfully and |  |  |  |
| (ii)(II) |  |  | knowingly causing |  |  |  |
|  |  |  | another |  |  |  |
|  |  |  | individual to |  |  |  |
|  |  |  | certify a |  |  |  |
|  |  |  | material and |  |  |  |
|  |  |  | false statement |  |  |  |
|  |  |  | in a Skilled |  |  |  |
|  |  |  | Nursing Facility |  |  |  |
|  |  |  | resident |  |  |  |
|  |  |  | assessment |  |  |  |
| 1396r(g) | 42 CFR | OIG | Penalty for | 1987 | 2,000 | 4,126 |
| (2)(A)(i) | Part 1003 |  | notifying or |  |  |  |
|  |  |  | causing to be |  |  |  |
|  |  |  | notified a |  |  |  |
|  |  |  | Skilled Nursing |  |  |  |
|  |  |  | Facility of the |  |  |  |
|  |  |  | time or date on |  |  |  |
|  |  |  | which a survey is |  |  |  |
|  |  |  | to be conducted |  |  |  |
| 1396r-8 | 42 CFR | OIG | Penalty for the | 1990 | 100,000 | 178,156 |
| (b)(3)(B) | Part 1003 |  | knowing provision |  |  |  |
|  |  |  | of false |  |  |  |
|  |  |  | information or |  |  |  |
|  |  |  | refusing to |  |  |  |
|  |  |  | provide |  |  |  |
|  |  |  | information about |  |  |  |
|  |  |  | charges or prices |  |  |  |
|  |  |  | of a covered |  |  |  |
|  |  |  | outpatient drug |  |  |  |
| 1396r- | 42 CFR |  | Penalty per day | 1990 | 10,000 | 17,816 |
| 8(b)(3) | Part 1003 |  | for failure to |  |  |  |
| (C)(i) |  |  | timely provide |  |  |  |
|  |  |  | information by |  |  |  |
|  |  |  | drug manufacturer |  |  |  |
|  |  |  | with rebate |  |  |  |
|  |  |  | agreement |  |  |  |
| 1396r- | 42 CFR |  | Penalty for | 1990 | 100,000 | 178,156 |
| 8(b)(3) | Part 1003 |  | knowing provision |  |  |  |
| (C)(ii) |  |  | of false |  |  |  |
|  |  |  | information by |  |  |  |
|  |  |  | drug manufacturer |  |  |  |
|  |  |  | with rebate |  |  |  |
|  |  |  | agreement |  |  |  |
| 1396t(i) | 42 CFR | OIG | Penalty for | 1990 | 2,000 | 3,563 |
| (3)(A) | Part 1003 |  | notifying home |  |  |  |
|  |  |  | and community- |  |  |  |
|  |  |  | based providers |  |  |  |
|  |  |  | or settings of |  |  |  |
|  |  |  | survey |  |  |  |
| 11131(c) | 42 CFR | OIG | Penalty for | 1986 | 10,000 | 21,563 |
|  | Part 1003 |  | failing to report |  |  |  |
|  |  |  | a medical |  |  |  |
|  |  |  | malpractice claim |  |  |  |
|  |  |  | to National |  |  |  |
|  |  |  | Practitioner Data |  |  |  |
|  |  |  | Bank |  |  |  |
| 11137(b) | 42 CFR | OIG | Penalty for | 1986 | 10,000 | 21,563 |
| (2) | Part 1003 |  | breaching |  |  |  |
|  |  |  | confidentiality |  |  |  |
|  |  |  | of information |  |  |  |
|  |  |  | reported to |  |  |  |
|  |  |  | National |  |  |  |
|  |  |  | Practitioner Data |  |  |  |
|  |  |  | Bank |  |  |  |
| 299b- | 42 CFR | OCR | Penalty for | 2005 | 10,000 | 11,940 |
| 22(f)(1) | 3.404 |  | violation of |  |  |  |
|  |  |  | confidentiality |  |  |  |
|  |  |  | provision of the |  |  |  |
|  |  |  | Patient Safety |  |  |  |
|  |  |  | and Quality |  |  |  |
|  |  |  | Improvement Act |  |  |  |
| 1320(d)- | 45 CFR | OCR | Penalty for each | 1996 | 100 | 150 |
| 5(a) | 160.404(b |  | pre-February 18, |  |  |  |
|  | )(1)(i),( |  | 2009 violation of |  |  |  |
|  | ii) |  | the HIPAA |  |  |  |
|  |  |  | administrative |  |  |  |
|  |  |  | simplification |  |  |  |
|  |  |  | provisions |  |  |  |
|  |  |  | Calendar Year Cap | 1996 | 25,000 | 37,561 |
| 1320(d)- | 45 CFR | OCR | Penalty for each |  |  |  |
| 5(a) | 160.404(b |  | February 18, 2009 |  |  |  |
|  | )(2)(i)(A |  | or later |  |  |  |
|  | ), (B) |  | 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 | 2009 | 100 | 110 |
|  |  |  | Maximum | 2009 | 50,000 | 55,010 |
|  |  |  | Calendar Year Cap | 2009 | 1,500,000 | 1,650,300 |
|  | 45 CFR | OCR | Penalty for each |  |  |  |
|  | 160.404 |  | February 18, 2009 |  |  |  |
|  | (b)(2) |  | or later |  |  |  |
|  | (ii)(A), |  | violation of a |  |  |  |
|  | (B) |  | HIPAA |  |  |  |
|  |  |  | administrative |  |  |  |
|  |  |  | simplification |  |  |  |
|  |  |  | provision in |  |  |  |
|  |  |  | which it is |  |  |  |
|  |  |  | established that |  |  |  |
|  |  |  | the violation was |  |  |  |
|  |  |  | due to reasonable |  |  |  |
|  |  |  | cause and not to |  |  |  |
|  |  |  | willful neglect: |  |  |  |
|  |  |  | Minimum | 2009 | 1,000 | 1,100 |
|  |  |  | Maximum | 2009 | 50,000 | 55,010 |
|  |  |  | Calendar Year Cap | 2009 | 1,500,000 | 1,650,300 |
|  | 45 CFR | OCR | Penalty for each |  |  |  |
|  | 160.404 |  | February 18, 2009 |  |  |  |
|  | (b)(2) |  | or later |  |  |  |
|  | (iii)(A), |  | violation of a |  |  |  |
|  | (B) |  | 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 | 2009 | 10,000 | 11,002 |
|  |  |  | Maximum | 2009 | 50,000 | 55,010 |
|  |  |  | Calendar Year Cap | 2009 | 1,500,000 | 1,650,300 |
|  | 45 CFR | OCR | Penalty for each |  |  |  |
|  | 160.404 |  | February 18, 2009 |  |  |  |
|  | (b)(2) |  | or later |  |  |  |
|  | (iv)(A), |  | violation of a |  |  |  |
|  | (B) |  | 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 | 2009 | 50,000 | 55,010 |
|  |  |  | Maximum | 2009 | 1,500,000 | 1,650,300 |
|  |  |  | Calendar Year Cap | 2009 | 1,500,000 | 1,650,300 |
| 263a(h) | 42 CFR | CMS | Penalty for a |  |  |  |
| (2)(B) & | 493.1834 |  | clinical |  |  |  |
| 1395w- | (d)(2)(i) |  | laboratory's |  |  |  |
| 2(b)(2) |  |  | failure to meet |  |  |  |
| (A)(ii) |  |  | participation and |  |  |  |
|  |  |  | certification |  |  |  |
|  |  |  | requirements and |  |  |  |
|  |  |  | poses immediate |  |  |  |
|  |  |  | jeopardy: |  |  |  |
|  |  |  | Minimum | 1988 | 3,050 | 6,035 |
|  |  |  | Maximum | 1988 | 10,000 | 19,787 |
|  | 42 CFR | CMS | Penalty for a |  |  |  |
|  | 493.1834 |  | clinical |  |  |  |
|  | (d)(2) |  | laboratory's |  |  |  |
|  | (ii) |  | failure to meet |  |  |  |
|  |  |  | participation and |  |  |  |
|  |  |  | certification |  |  |  |
|  |  |  | requirements and |  |  |  |
|  |  |  | the failure does |  |  |  |
|  |  |  | not pose |  |  |  |
|  |  |  | immediate |  |  |  |
|  |  |  | jeopardy: |  |  |  |
|  |  |  | Minimum | 1988 | 50 | 99 |
|  |  |  | Maximum | 1988 | 3,000 | 5,936 |
| 300gg- | 45 CFR | CMS | Failure to | 2010 | 1,000 | 1,087 |
| 15(f) | 147.200 |  | provide the |  |  |  |
|  | (e) |  | Summary of |  |  |  |
|  |  |  | Benefits and |  |  |  |
|  |  |  | Coverage |  |  |  |
| 300gg-18 | 45 CFR | CMS | Penalty for | 2010 | 100 | 109 |
|  | 158.606 |  | violations of |  |  |  |
|  |  |  | ***regulations*** |  |  |  |
|  |  |  | related to the |  |  |  |
|  |  |  | medical loss |  |  |  |
|  |  |  | ratio reporting |  |  |  |
|  |  |  | and rebating |  |  |  |
| 1320a- | 42 CFR | CMS | Penalty for |  |  |  |
| 7h(b)(1) | 402.105 |  | manufacturer or |  |  |  |
|  | (d)(5); |  | group purchasing |  |  |  |
|  | 42 CFR |  | organization |  |  |  |
|  | 403.912 |  | failing to report |  |  |  |
|  | (a) & (c) |  | information |  |  |  |
|  |  |  | required under 42 |  |  |  |
|  |  |  | U.S.C. 1320a- |  |  |  |
|  |  |  | 7h(a), relating |  |  |  |
|  |  |  | to physician |  |  |  |
|  |  |  | ownership or |  |  |  |
|  |  |  | investment |  |  |  |
|  |  |  | interests: |  |  |  |
|  |  |  | Minimum | 2010 | 1,000 | 1,087 |
|  |  |  | Maximum | 2010 | 10,000 | 10,874 |
|  |  |  | Calendar Year Cap | 2010 | 150,000 | 163,117 |
| 1320a- | 42 CFR | CMS | Penalty for |  |  |  |
| 7h(b)(2) | 402.105 |  | manufacturer or |  |  |  |
|  | (h); 42 |  | group purchasing |  |  |  |
|  | CFR 403 |  | organization |  |  |  |
|  | 912(b) & |  | knowingly failing |  |  |  |
|  | (c) |  | to report |  |  |  |
|  |  |  | information |  |  |  |
|  |  |  | required under 42 |  |  |  |
|  |  |  | U.S.C. 1320a- |  |  |  |
|  |  |  | 7h(a), relating |  |  |  |
|  |  |  | to physician |  |  |  |
|  |  |  | ownership or |  |  |  |
|  |  |  | investment |  |  |  |
|  |  |  | interests: |  |  |  |
|  |  |  | Minimum | 2010 | 10,000 | 10,874 |
|  |  |  | Maximum | 2010 | 100,000 | 108,745 |
|  |  |  | Calendar Year Cap | 2010 | 1,000,000 | 1,087,450 |
| 1320a- |  | CMS | Penalty for an | 2010 | 100,000 | 108,745 |
| 7j(h)(3) |  |  | administrator of |  |  |  |
| (A) |  |  | a facility that |  |  |  |
|  |  |  | fails to comply |  |  |  |
|  |  |  | with notice |  |  |  |
|  |  |  | requirements for |  |  |  |
|  |  |  | the closure of a |  |  |  |
|  |  |  | facility |  |  |  |
|  | 42 CFR | CMS | Minimum penalty | 2010 | 500 | 544 |
|  | 488.446 |  | for the first |  |  |  |
|  | (a)(1), |  | offense of an |  |  |  |
|  | (2), & |  | administrator who |  |  |  |
|  | (3) |  | fails to provide |  |  |  |
|  |  |  | notice of |  |  |  |
|  |  |  | facility closure |  |  |  |
|  |  |  | Minimum penalty | 2010 | 1,500 | 1,631 |
|  |  |  | for the second |  |  |  |
|  |  |  | offense of an |  |  |  |
|  |  |  | administrator who |  |  |  |
|  |  |  | fails to provide |  |  |  |
|  |  |  | notice of |  |  |  |
|  |  |  | facility closure |  |  |  |
|  |  |  | Minimum penalty | 2010 | 3,000 | 3,262 |
|  |  |  | for the third and |  |  |  |
|  |  |  | subsequent |  |  |  |
|  |  |  | offenses of an |  |  |  |
|  |  |  | administrator who |  |  |  |
|  |  |  | fails to provide |  |  |  |
|  |  |  | notice of |  |  |  |
|  |  |  | facility closure |  |  |  |
| 1320a- |  | CMS | Penalty for an | 1994 | 5,000 | 7,954 |
| 8(a)(1) |  |  | 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 |  |  |  |
|  |  |  | Penalty for | 2015 | 7,500 | 7,500 |
|  |  |  | 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 |  |  |  |
| 1320a- |  | CMS | Penalty for a | 2004 | 5,000 | 6,229 |
| 8(a)(3) |  |  | 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 |  |  |  |
| 1320b- |  | CMS | Penalty for | 2010 | 200,000 | 217,490 |
| 25(c)(1) |  |  | failure of |  |  |  |
| (A) |  |  | 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 |  |  |  |
| 1320b- |  | CMS | Penalty for | 2010 | 300,000 | 326,235 |
| 25(c)(2) |  |  | failure of |  |  |  |
| (A) |  |  | 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 |  |  |  |
| 1320b- |  | CMS | Penalty for a | 2010 | 200,000 | 217,490 |
| 25(d)(2) |  |  | 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 |  |  |  |
| 1395b- | 42 CFR | CMS | Penalty for any | 1997 | 100 | 147 |
| 7(b)(2) | 402.105 |  | person who |  |  |  |
| (B) | (g) |  | knowingly and |  |  |  |
|  |  |  | willfully fails |  |  |  |
|  |  |  | to furnish a |  |  |  |
|  |  |  | beneficiary with |  |  |  |
|  |  |  | an itemized |  |  |  |
|  |  |  | statement of |  |  |  |
|  |  |  | items or services |  |  |  |
|  |  |  | within 30 days of |  |  |  |
|  |  |  | the beneficiary's |  |  |  |
|  |  |  | request |  |  |  |
| 1395i- | 42 CFR | CMS | Penalty per day |  |  |  |
| 3(h)(2) | 488.408 |  | for a Skilled |  |  |  |
| (B)(ii) | (d)(1) |  | Nursing Facility |  |  |  |
| (I) | (iii) |  | that has a |  |  |  |
|  |  |  | Category 2 |  |  |  |
|  |  |  | violation of |  |  |  |
|  |  |  | certification |  |  |  |
|  |  |  | requirements: |  |  |  |
|  |  |  | Minimum | 1987 | 50 | 103 |
|  |  |  | Maximum | 1987 | 3,000 | 6,188 |
|  | 42 CFR | CMS | Penalty per |  |  |  |
|  | 488.408 |  | instance of |  |  |  |
|  | (d)(1) |  | Category 2 |  |  |  |
|  | (iv) |  | noncompliance by |  |  |  |
|  |  |  | a Skilled Nursing |  |  |  |
|  |  |  | Facility: |  |  |  |
|  |  |  | Minimum | 1987 | 1,000 | 2,063 |
|  |  |  | Maximum | 1987 | 10,000 | 20,628 |
|  | 42 CFR | CMS | Penalty per day |  |  |  |
|  | 488.408 |  | for a Skilled |  |  |  |
|  | (e)(1) |  | Nursing Facility |  |  |  |
|  | (iii) |  | that has a |  |  |  |
|  |  |  | Category 3 |  |  |  |
|  |  |  | violation of |  |  |  |
|  |  |  | certification |  |  |  |
|  |  |  | requirements: |  |  |  |
|  |  |  | Minimum | 1987 | 3,050 | 6,291 |
|  |  |  | Maximum | 1987 | 10,000 | 20,628 |
|  | 42 CFR | CMS | Penalty per |  |  |  |
|  | 488.408 |  | instance of |  |  |  |
|  | (e)(1) |  | Category 3 |  |  |  |
|  | (iv) |  | noncompliance by |  |  |  |
|  |  |  | a Skilled Nursing |  |  |  |
|  |  |  | Facility: |  |  |  |
|  |  |  | Minimum | 1987 | 1,000 | 2,063 |
|  |  |  | Maximum | 1987 | 10,000 | 20,628 |
|  | 42 CFR | CMS | Penalty per day |  |  |  |
|  | 488.408 |  | and per instance |  |  |  |
|  | (e)(2) |  | for a Skilled |  |  |  |
|  | (ii) |  | Nursing Facility |  |  |  |
|  |  |  | that has Category |  |  |  |
|  |  |  | 3 noncompliance |  |  |  |
|  |  |  | with Immediate |  |  |  |
|  |  |  | Jeopardy: |  |  |  |
|  |  |  | Per Day (Minimum) | 1987 | 3,050 | 6,291 |
|  |  |  | Per Day (Maximum) | 1987 | 10,000 | 20,628 |
|  |  |  | Per Instance | 1987 | 1,000 | 2,063 |
|  |  |  | (Minimum) |  |  |  |
|  |  |  | Per Instance | 1987 | 10,000 | 20,628 |
|  |  |  | (Maximum) |  |  |  |
|  | 42 CFR | CMS | Penalty per day |  |  |  |
|  | 488.438 |  | of a Skilled |  |  |  |
|  | (a)(1)(i) |  | Nursing Facility |  |  |  |
|  |  |  | that fails to |  |  |  |
|  |  |  | meet |  |  |  |
|  |  |  | certification |  |  |  |
|  |  |  | requirements. |  |  |  |
|  |  |  | These amounts |  |  |  |
|  |  |  | represent the |  |  |  |
|  |  |  | upper range per |  |  |  |
|  |  |  | day: |  |  |  |
|  |  |  | Minimum | 1987 | 3,050 | 6,291 |
|  |  |  | Maximum | 1987 | 10,000 | 20,628 |
|  | 42 CFR | CMS | Penalty per day |  |  |  |
|  | 488.438 |  | of a Skilled |  |  |  |
|  | (a)(1) |  | Nursing Facility |  |  |  |
|  | (ii) |  | that fails to |  |  |  |
|  |  |  | meet |  |  |  |
|  |  |  | certification |  |  |  |
|  |  |  | requirements. |  |  |  |
|  |  |  | These amounts |  |  |  |
|  |  |  | represent the |  |  |  |
|  |  |  | lower range per |  |  |  |
|  |  |  | day: |  |  |  |
|  |  |  | Minimum | 1987 | 50 | 103 |
|  |  |  | Maximum | 1987 | 3,000 | 6,188 |
|  | 42 CFR | CMS | Penalty per |  |  |  |
|  | 488.438 |  | instance of a |  |  |  |
|  | (a)(2) |  | Skilled Nursing |  |  |  |
|  |  |  | Facility that |  |  |  |
|  |  |  | fails to meet |  |  |  |
|  |  |  | certification |  |  |  |
|  |  |  | requirements: |  |  |  |
|  |  |  | Minimum | 1987 | 1,000 | 2,063 |
|  |  |  | Maximum | 1987 | 10,000 | 20,628 |
| 1395l(h) | 42 CFR | CMS | Penalty for | 1996 | 10,000 | 15,024 |
| (5)(D) | 402.105 |  | knowingly, |  |  |  |
|  | (d)(2)(i) |  | 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)) |  |  |  |
| 1395l(i) |  | CMS | Penalty for | 1988 | 2,000 | 3,957 |
| (6) |  |  | 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 |  |  |  |
| 1395l(q) | 42 CFR | CMS | Penalty for | 1989 | 2,000 | 3,787 |
| (2)(B)(i) | 402.105 |  | knowingly and |  |  |  |
|  | (a) |  | willfully failing |  |  |  |
|  |  |  | to provide |  |  |  |
|  |  |  | information about |  |  |  |
|  |  |  | a referring |  |  |  |
|  |  |  | physician when |  |  |  |
|  |  |  | seeking payment |  |  |  |
|  |  |  | on an unassigned |  |  |  |
|  |  |  | basis |  |  |  |
| 1395m(a) | 42 CFR | CMS | Penalty for any | 1996 | 10,000 | 15,024 |
| (11)(A) | 402.1(c) |  | durable medical |  |  |  |
|  | (4), |  | equipment |  |  |  |
|  | 402.105 |  | supplier that |  |  |  |
|  | (d)(2) |  | knowingly and |  |  |  |
|  | (ii) |  | 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)) |  |  |  |
| 1395m(a) | 42 CFR | CMS | Penalty for any | 1996 | 10,000 | 15,024 |
| (18)(B) | 402.1(c) |  | nonparticipating |  |  |  |
|  | (5), |  | durable medical |  |  |  |
|  | 402.105 |  | equipment |  |  |  |
|  | (d)(2) |  | supplier that |  |  |  |
|  | (iii) |  | 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)) |  |  |  |
| 1395m(b) | 42 CFR | CMS | Penalty for any | 1996 | 10,000 | 15,024 |
| (5)(C) | 402.1(c) |  | nonparticipating |  |  |  |
|  | (6), |  | physician or |  |  |  |
|  | 402.105 |  | supplier that |  |  |  |
|  | (d)(2) |  | knowingly and |  |  |  |
|  | (iv) |  | 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)) |  |  |  |
| 1395m(h) | 42 CFR | CMS | Penalty for any | 1996 | 10,000 | 15,024 |
| (3) | 402.1(c) |  | supplier of |  |  |  |
|  | (8), |  | prosthetic |  |  |  |
|  | 402.105 |  | devices, |  |  |  |
|  | (d)(2) |  | orthotics, and |  |  |  |
|  | (vi) |  | prosthetics that |  |  |  |
|  |  |  | knowing 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)) |  |  |  |
| 1395m(j) |  | CMS | Penalty for any | 1994 | 1,000 | 1,591 |
| (2)(A) |  |  | supplier of |  |  |  |
| (iii) |  |  | 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 |  |  |  |
| 1395m(j) | 42 CFR | CMS | Penalty for any | 1996 | 10,000 | 15,024 |
| (4) | 402.1(c) |  | supplier of |  |  |  |
|  | (10), |  | durable medical |  |  |  |
|  | 402.105 |  | equipment, |  |  |  |
|  | (d)(2) |  | including a |  |  |  |
|  | (vii) |  | 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 as |  |  |  |
|  |  |  | 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)) |  |  |  |
| 1395m(k) | 42 CFR | CMS | Penalty for any | 1996 | 10,000 | 15,024 |
| (6) | 402.1(c) |  | person or entity |  |  |  |
|  | (31), |  | who knowingly and |  |  |  |
|  | 402.105 |  | willfully bills |  |  |  |
|  | (d)(3) |  | 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)) |  |  |  |
| 1395m(l) | 42 CFR | CMS | Penalty for any | 1996 | 10,000 | 15,024 |
| (6) | 402.1(c) |  | supplier of |  |  |  |
|  | (32), |  | ambulance |  |  |  |
|  | 402.105 |  | services who |  |  |  |
|  | (d)(4) |  | 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)) |  |  |  |
| 1395u(b) | 42 CFR | CMS | Penalty for any | 1996 | 10,000 | 15,024 |
| (18)(B) | 402.1(c) |  | practitioner |  |  |  |
|  | (11), |  | specified in |  |  |  |
|  | 402.105 |  | Section |  |  |  |
|  | (d)(2) |  | 1842(b)(18)(C) of |  |  |  |
|  | (viii) |  | 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)) |  |  |  |
| 1395u(j) | 42 CFR | CMS | Penalty for any | 1996 | 10,000 | 15,024 |
| (2)(B) | 402.1(c) |  | 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)) |  |  |  |
| 1395u(k) | 42 CFR | CMS | Penalty for any | 1996 | 10,000 | 15,024 |
|  | 402.1(c) |  | physician who |  |  |  |
|  | (12), |  | knowingly and |  |  |  |
|  | 402.105 |  | willfully |  |  |  |
|  | (d)(2) |  | presents or |  |  |  |
|  | (ix) |  | 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)) |  |  |  |
| 1395u(l) | 42 CFR | CMS | Penalty for any | 1996 | 10,000 | 15,024 |
| (3) | 402.1(c) |  | nonparticipating |  |  |  |
|  | (13), |  | physician who |  |  |  |
|  | 402.105 |  | does not accept |  |  |  |
|  | (d)(2)(x) |  | 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)) |  |  |  |
| 1395u(m) | 42 CFR | CMS | Penalty for any | 1996 | 10,000 | 15,024 |
| (3) | 402.1(c) |  | nonparticipating |  |  |  |
|  | (14), |  | physician |  |  |  |
|  | 402.105 |  | charging more |  |  |  |
|  | (d)(2) |  | than $ 500 who |  |  |  |
|  | (xi) |  | 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)) |  |  |  |
|  | 42 CFR | CMS | Penalty for any | 1996 | 10,000 | 15,024 |
| 1395u(n) | 402.1(c) |  | physician who |  |  |  |
| (3) | (15), |  | knowingly, |  |  |  |
|  | 402.105 |  | willfully, and |  |  |  |
|  | (d)(2) |  | repeatedly bills |  |  |  |
|  | (xii) |  | 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)) |  |  |  |
| 1395u(o) | 42 CFR | CMS | Penalty for any | 1996 | 10,000 | 15,024 |
| (3)(B) | 414.707 |  | practitioner |  |  |  |
|  | (b) |  | 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)) |  |  |  |
| 1395u(p) |  | CMS | Penalty for any | 1988 | 2,000 | 3,957 |
| (3)(A) |  |  | 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 |  |  |  |
| 1395w- | 42 CFR | CMS | Penalty for a | 2003 | 10,000 | 12,856 |
| 3a(d)(4) | 414.806 |  | pharmaceutical |  |  |  |
| (A) |  |  | manufacturer's |  |  |  |
|  |  |  | misrepresentation |  |  |  |
|  |  |  | of average sales |  |  |  |
|  |  |  | price of a drug, |  |  |  |
|  |  |  | or biologic |  |  |  |
| 1395w- | 42 CFR | CMS | Penalty for any | 1996 | 10,000 | 15,024 |
| 4(g)(1) | 402.1(c) |  | nonparticipating |  |  |  |
| (B) | (17), |  | physician, |  |  |  |
|  | 402.105 |  | supplier, or |  |  |  |
|  | (d)(2) |  | other person that |  |  |  |
|  | (xiii) |  | 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)) |  |  |  |
| 1395w- | 42 CFR | CMS | Penalty for any | 1996 | 10,000 | 15,024 |
| 4(g)(3) | 402.1(c) |  | person that |  |  |  |
| (B) | (18), |  | knowingly and |  |  |  |
|  | 402.105 |  | willfully bills |  |  |  |
|  | (d)(2) |  | for statutorily |  |  |  |
|  | (xiv) |  | 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)) |  |  |  |
| 1395w- | 42 CFR | CMS | Penalty for each | 1997 | 25,000 | 36,794 |
| 27(g)(3) | 422.760 |  | termination |  |  |  |
| (A); | (b); 42 |  | determination the |  |  |  |
| 1857(g) | CFR |  | Secretary makes |  |  |  |
| (3) | 423.760 |  | that is the |  |  |  |
|  | (b) |  | result of actions |  |  |  |
|  |  |  | by a Medicare |  |  |  |
|  |  |  | Advantage |  |  |  |
|  |  |  | organization or |  |  |  |
|  |  |  | Part D sponsor |  |  |  |
|  |  |  | that has |  |  |  |
|  |  |  | adversely |  |  |  |
|  |  |  | affected an |  |  |  |
|  |  |  | individual |  |  |  |
|  |  |  | covered under the |  |  |  |
|  |  |  | organization's |  |  |  |
|  |  |  | contract |  |  |  |
| 1395w- |  | CMS | Penalty for each | 1997 | 10,000 | 14,718 |
| 27(g)(3) |  |  | week beginning |  |  |  |
| (B); |  |  | after the |  |  |  |
| 1857(g) |  |  | initiation of |  |  |  |
| (3) |  |  | 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*** |  |  |  |
| 1395w- |  | CMS | Penalty for a | 2000 | 100,000 | 136,689 |
| 27(g)(3) |  |  | Medicare |  |  |  |
| (D); |  |  | Advantage |  |  |  |
| 1857(g) |  |  | organization's or |  |  |  |
| (3) |  |  | Part D sponsor's |  |  |  |
|  |  |  | early termination |  |  |  |
|  |  |  | of its contract |  |  |  |
| 1395y(b) | 42 CFR | CMS | Penalty for an | 1990 | 5,000 | 8,908 |
| (3)(C) | 411.103 |  | employer or other |  |  |  |
|  | (b) |  | 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 |  |  |  |
| 1395y(b) | 42 CFR | CMS | Penalty for any | 1998 | 1,000 | 1,450 |
| (5)(C) | 402.1(c) |  | non-governmental |  |  |  |
| (ii) | (20); 42 |  | employer that, |  |  |  |
|  | CFR |  | before October 1, |  |  |  |
|  | 402.105 |  | 1998, willfully |  |  |  |
|  | (b)(2) |  | or repeatedly |  |  |  |
|  |  |  | failed to provide |  |  |  |
|  |  |  | timely and |  |  |  |
|  |  |  | accurate |  |  |  |
|  |  |  | information |  |  |  |
|  |  |  | requested |  |  |  |
|  |  |  | relating to an |  |  |  |
|  |  |  | employee's group |  |  |  |
|  |  |  | health insurance |  |  |  |
|  |  |  | coverage |  |  |  |
| 1395y(b) | 42 CFR | CMS | Penalty for any | 1994 | 2,000 | 3,182 |
| (6)(B) | 402.1(c) |  | entity that |  |  |  |
|  | (21), |  | knowingly, |  |  |  |
|  | 402.105 |  | willfully, and |  |  |  |
|  | (a) |  | 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 |  |  |  |
| 1395y(b) |  | CMS | Penalty for any | 2007 | 1,000 | 1,138 |
| (7)(B)(i) |  |  | 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 |  |  |  |
| 1395y(b) |  | CMS | Penalty for any | 2007 | 1,000 | 1,138 |
| (8)(E) |  |  | 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 |  |  |  |
| 1395nn(g) | 42 CFR | CMS | Penalty for any | 1989 | 10,000 | 18,936 |
| (5) | 411.361 |  | person that fails |  |  |  |
|  |  |  | to report |  |  |  |
|  |  |  | information |  |  |  |
|  |  |  | required by HHS |  |  |  |
|  |  |  | under Section |  |  |  |
|  |  |  | 1877(f) |  |  |  |
|  |  |  | concerning |  |  |  |
|  |  |  | ownership, |  |  |  |
|  |  |  | investment, and |  |  |  |
|  |  |  | compensation |  |  |  |
|  |  |  | arrangements |  |  |  |
| 1395pp(h) | 42 CFR | CMS | Penalty for any | 1996 | 10,000 | 15,024 |
|  | 402.1(c) |  | durable medical |  |  |  |
|  | (23), |  | equipment |  |  |  |
|  | 402.105 |  | supplier, |  |  |  |
|  | (d)(2) |  | including a |  |  |  |
|  | (xv) |  | 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)) |  |  |  |
| 1395ss(a) | 42 CFR | CMS | Penalty for any | 1987 | 25,000 | 51,569 |
| (2) | 402.1(c) |  | person that |  |  |  |
|  | (24), |  | issues a Medicare |  |  |  |
|  | 405.105 |  | supplemental |  |  |  |
|  | (f)(1) |  | policy that has |  |  |  |
|  |  |  | not been approved |  |  |  |
|  |  |  | by the State |  |  |  |
|  |  |  | regulatory |  |  |  |
|  |  |  | program or does |  |  |  |
|  |  |  | not meet Federal |  |  |  |
|  |  |  | standards after a |  |  |  |
|  |  |  | statutorily |  |  |  |
|  |  |  | defined effective |  |  |  |
|  |  |  | date |  |  |  |
| 1395ss(d) |  | CMS | Penalty for | 1990 | 15,000 | 26,723 |
| (3)(A) |  |  | someone other |  |  |  |
| (vi)(II) |  |  | than issuer that |  |  |  |
|  |  |  | sells or issues a |  |  |  |
|  |  |  | Medicare |  |  |  |
|  |  |  | supplemental |  |  |  |
|  |  |  | policy to |  |  |  |
|  |  |  | beneficiary |  |  |  |
|  |  |  | without a |  |  |  |
|  |  |  | disclosure |  |  |  |
|  |  |  | statement |  |  |  |
|  |  |  | Penalty for an | 1990 | 25,000 | 44,539 |
|  |  |  | issuer that sells |  |  |  |
|  |  |  | or issues a |  |  |  |
|  |  |  | Medicare |  |  |  |
|  |  |  | supplemental |  |  |  |
|  |  |  | policy without |  |  |  |
|  |  |  | disclosure |  |  |  |
|  |  |  | statement |  |  |  |
| 1395ss(d) |  | CMS | Penalty for | 1990 | 15,000 | 26,723 |
| (3)(B) |  |  | someone other |  |  |  |
| (iv) |  |  | than issuer that |  |  |  |
|  |  |  | sells or issues a |  |  |  |
|  |  |  | Medicare |  |  |  |
|  |  |  | supplemental |  |  |  |
|  |  |  | policy without |  |  |  |
|  |  |  | acknowledgement |  |  |  |
|  |  |  | form |  |  |  |
|  |  |  | Penalty for | 1990 | 25,000 | 44,539 |
|  |  |  | issuer that sells |  |  |  |
|  |  |  | or issues a |  |  |  |
|  |  |  | Medicare |  |  |  |
|  |  |  | supplemental |  |  |  |
|  |  |  | policy without an |  |  |  |
|  |  |  | acknowledgement |  |  |  |
|  |  |  | form |  |  |  |
| 1395ss(p) | 42 CFR | CMS | Penalty for any | 1990 | 15,000 | 26,723 |
| (8) | 402.1(c) |  | person that sells |  |  |  |
|  | (25), |  | or issues |  |  |  |
|  | 402.105 |  | Medicare |  |  |  |
|  | (e) |  | supplemental |  |  |  |
|  |  |  | polices after a |  |  |  |
|  |  |  | given date that |  |  |  |
|  |  |  | fail to conform |  |  |  |
|  |  |  | to the NAIC or |  |  |  |
|  |  |  | Federal standards |  |  |  |
|  |  |  | established by |  |  |  |
|  |  |  | statute |  |  |  |
|  | 42 CFR | CMS | Penalty for any | 1990 | 25,000 | 44,539 |
|  | 402.1(c) |  | person that sells |  |  |  |
|  | (25), |  | or issues |  |  |  |
|  | 405.105 |  | Medicare |  |  |  |
|  | (f)(2) |  | supplemental |  |  |  |
|  |  |  | polices after a |  |  |  |
|  |  |  | given date that |  |  |  |
|  |  |  | fail to conform |  |  |  |
|  |  |  | to the NAIC or |  |  |  |
|  |  |  | Federal standards |  |  |  |
|  |  |  | established by |  |  |  |
|  |  |  | statute |  |  |  |
| 1395ss(p) | 42 CFR | CMS | Penalty for any | 1990 | 15,000 | 26,723 |
| (9)(C) | 402.1(c) |  | person that sells |  |  |  |
|  | (26), |  | a Medicare |  |  |  |
|  | 402.105 |  | supplemental |  |  |  |
|  | (e) |  | 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 |  |  |  |
|  | 42 CFR |  | Penalty for any | 1990 | 25,000 | 44,539 |
|  | 402.1(c) |  | person that sells |  |  |  |
|  | (26), |  | a Medicare |  |  |  |
|  | 405.105 |  | supplemental |  |  |  |
|  | (f)(3), |  | policy and fails |  |  |  |
|  | (4) |  | 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 |  |  |  |
| 1395ss(q) | 42 CFR | CMS | Penalty for any | 1990 | 25,000 | 44,539 |
| (5)(C) | 402.1(c) |  | person that fails |  |  |  |
|  | (27), |  | to suspend the |  |  |  |
|  | 405.105 |  | policy of a |  |  |  |
|  | (f)(5) |  | policyholder made |  |  |  |
|  |  |  | eligible for |  |  |  |
|  |  |  | medical |  |  |  |
|  |  |  | assistance or |  |  |  |
|  |  |  | automatically |  |  |  |
|  |  |  | reinstates the |  |  |  |
|  |  |  | policy of a |  |  |  |
|  |  |  | policyholder who |  |  |  |
|  |  |  | has lost |  |  |  |
|  |  |  | eligibility for |  |  |  |
|  |  |  | medical |  |  |  |
|  |  |  | assistance, under |  |  |  |
|  |  |  | certain |  |  |  |
|  |  |  | circumstances |  |  |  |
| 1395ss(r) | 42 CFR | CMS | Penalty for any | 1990 | 25,000 | 44,539 |
| (6)(A) | 402.1(c) |  | person that fails |  |  |  |
|  | (28), |  | to provide |  |  |  |
|  | 405.105 |  | refunds or |  |  |  |
|  | (f)(6) |  | credits as |  |  |  |
|  |  |  | required by |  |  |  |
|  |  |  | section |  |  |  |
|  |  |  | 1882(r)(1)(B) |  |  |  |
| 1395ss(s) | 42 CFR | CMS | Penalty for any | 1990 | 5,000 | 18,908 |
| (4) | 402.1(c) |  | issuer of a |  |  |  |
|  | (29), |  | Medicare |  |  |  |
|  | 405.105 |  | supplemental |  |  |  |
|  | (c) |  | 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 |  |  |  |
| 1395ss(t) | 42 CFR | CMS | Penalty for any | 1990 | 25,000 | 44,539 |
| (2) | 402.1(c) |  | issuer of a |  |  |  |
|  | (30), |  | Medicare |  |  |  |
|  | 405.105 |  | supplemental |  |  |  |
|  | (f)(7) |  | policy that fails |  |  |  |
|  |  |  | to fulfill listed |  |  |  |
|  |  |  | responsibilities |  |  |  |
| 1395ss(v) |  | CMS | Penalty someone | 2003 | 15,000 | 19,284 |
| (4)(A) |  |  | other than issuer |  |  |  |
|  |  |  | who sells, |  |  |  |
|  |  |  | issues, or renews |  |  |  |
|  |  |  | a medigap Rx |  |  |  |
|  |  |  | policy to an |  |  |  |
|  |  |  | individual who is |  |  |  |
|  |  |  | a Part D enrollee |  |  |  |
|  |  |  | Penalty for an | 2003 | 25,000 | 32,140 |
|  |  |  | issuer who sells, |  |  |  |
|  |  |  | issues, or renews |  |  |  |
|  |  |  | a Medigap Rx |  |  |  |
|  |  |  | policy who is a |  |  |  |
|  |  |  | Part D enrollee |  |  |  |
| 1395bbb | 42 CFR | CMS | Penalty for any | 1987 | 2,000 | 4,126 |
| (c)(1) | 488.725 |  | individual who |  |  |  |
|  | (c) |  | 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 |  |  |  |
| 1395bbb | 42 CFR | CMS | Maximum daily | 1988 | 10,000 | 19,787 |
| (f)(2)(A) | 488.845 |  | penalty amount |  |  |  |
| (i) | (b)(2) |  | for each day a |  |  |  |
|  | (iii); 42 |  | home health |  |  |  |
|  | CFR |  | agency is not in |  |  |  |
|  | 488.845 |  | compliance with |  |  |  |
|  | (b)(3)- |  | statutory |  |  |  |
|  | (6); and |  | requirements |  |  |  |
|  | 42 CFR |  |  |  |  |  |
|  | 488.845 |  |  |  |  |  |
|  | (d)(1) |  |  |  |  |  |
|  | (ii) |  |  |  |  |  |
|  | 42 CFR |  | Penalty per day |  |  |  |
|  | 488.845 |  | for home health |  |  |  |
|  | (b)(3) |  | agency's |  |  |  |
|  |  |  | noncompliance |  |  |  |
|  |  |  | (Upper Range): |  |  |  |
|  |  |  | Minimum | 1988 | 8,500 | 16,819 |
|  |  |  | Maximum | 1988 | 10,000 | 19,787 |
|  | 42 CFR |  | Penalty for a | 1988 | 10,000 | 19,787 |
|  | 488.845 |  | home health |  |  |  |
|  | (b)(3)(i) |  | agency's |  |  |  |
|  |  |  | deficiency or |  |  |  |
|  |  |  | deficiencies that |  |  |  |
|  |  |  | cause immediate |  |  |  |
|  |  |  | jeopardy and |  |  |  |
|  |  |  | result in actual |  |  |  |
|  |  |  | harm |  |  |  |
|  | 42 CFR |  | Penalty for a | 1988 | 9,000 | 17,808 |
|  | 488.845 |  | home health |  |  |  |
|  | (b)(3) |  | agency's |  |  |  |
|  | (ii) |  | deficiency or |  |  |  |
|  |  |  | deficiencies that |  |  |  |
|  |  |  | cause immediate |  |  |  |
|  |  |  | jeopardy and |  |  |  |
|  |  |  | result in |  |  |  |
|  |  |  | potential for |  |  |  |
|  |  |  | harm |  |  |  |
|  | 42 CFR |  | Penalty for an | 1988 | 8,500 | 16,819 |
|  | 488.845 |  | isolated incident |  |  |  |
|  | (b)(3) |  | of noncompliance |  |  |  |
|  | (iii) |  | in violation of |  |  |  |
|  |  |  | established HHA |  |  |  |
|  |  |  | policy |  |  |  |
|  | 42 CFR |  | Penalty for a |  |  |  |
|  | 488.845 |  | repeat and/or |  |  |  |
|  | (b)(4) |  | 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 |  | Penalty for a |  |  |  |
|  | 488.845 |  | repeat and/or |  |  |  |
|  | (b)(5) |  | condition-level |  |  |  |
|  |  |  | deficiency that |  |  |  |
|  |  |  | does not |  |  |  |
|  |  |  | constitute |  |  |  |
|  |  |  | immediate |  |  |  |
|  |  |  | jeopardy and that |  |  |  |
|  |  |  | is related |  |  |  |
|  |  |  | predominately to |  |  |  |
|  |  |  | structure or |  |  |  |
|  |  |  | process-oriented |  |  |  |
|  |  |  | conditions (Lower |  |  |  |
|  |  |  | Range): |  |  |  |
|  |  |  | Minimum | 1988 | 500 | 989 |
|  |  |  | Maximum | 1988 | 4,000 | 7,915 |
|  | 42 CFR |  | Penalty imposed |  |  |  |
|  | 488.845 |  | for instance of |  |  |  |
|  | (b)(6) |  | 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 | 1988 | 1,000 | 1,979 |
|  |  |  | Maximum | 1988 | 10,000 | 19,787 |
|  |  |  | Penalty for each | 1988 | 10,000 | 19,787 |
|  |  |  | day of |  |  |  |
|  |  |  | noncompliance |  |  |  |
|  |  |  | (Maximum) |  |  |  |
|  | 42 CFR |  | Penalty for each | 1988 | 10,000 | 19,787 |
|  | 488.845 |  | day of |  |  |  |
|  | (d)(1) |  | noncompliance |  |  |  |
|  | (ii) |  | (Maximum) |  |  |  |
| 1396b(m)( | 42 CFR | CMS | Penalty for PACE |  |  |  |
| 5)(B) | 460.46 |  | 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 | 1997 | 25,000 | 36,794 |
|  |  |  | PACE organization |  |  |  |
|  |  |  | that charges |  |  |  |
|  |  |  | excessive |  |  |  |
|  |  |  | premiums |  |  |  |
|  |  |  | Penalty for a | 1997 | 100,000 | 147,177 |
|  |  |  | PACE organization |  |  |  |
|  |  |  | misrepresenting |  |  |  |
|  |  |  | or falsifying |  |  |  |
|  |  |  | information to |  |  |  |
|  |  |  | CMS, the State, |  |  |  |
|  |  |  | or an individual |  |  |  |
|  |  |  | or other entity |  |  |  |
|  |  |  | Penalty for each | 1997 | 25,000 | 36,794 |
|  |  |  | 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 | 1997 | 25,000 | 36,794 |
|  |  |  | involuntarily |  |  |  |
|  |  |  | disenrolling a |  |  |  |
|  |  |  | participant |  |  |  |
|  |  |  | Penalty for | 1997 | 25,000 | 36,794 |
|  |  |  | discriminating or |  |  |  |
|  |  |  | discouraging |  |  |  |
|  |  |  | enrollment or |  |  |  |
|  |  |  | disenrollment of |  |  |  |
|  |  |  | participants on |  |  |  |
|  |  |  | the basis of an |  |  |  |
|  |  |  | individual's |  |  |  |
|  |  |  | health status or |  |  |  |
|  |  |  | need for health |  |  |  |
|  |  |  | care services |  |  |  |
| 1396r(h) | 42 CFR | CMS | Penalty per day |  |  |  |
| (3)(C) | 488.408 |  | for a nursing |  |  |  |
| (ii)(I) | (d)(1) |  | facility's |  |  |  |
|  | (iii) |  | failure to meet a |  |  |  |
|  |  |  | Category 2 |  |  |  |
|  |  |  | Certification: |  |  |  |
|  |  |  | Minimum | 1987 | 50 | 103 |
|  |  |  | Maximum | 1987 | 3,000 | 6,188 |
|  | 42 CFR | CMS | Penalty per |  |  |  |
|  | 488.408 |  | instance for a |  |  |  |
|  | (d)(1) |  | nursing |  |  |  |
|  | (iv) |  | facility's |  |  |  |
|  |  |  | failure to meet |  |  |  |
|  |  |  | Category 2 |  |  |  |
|  |  |  | certification: |  |  |  |
|  |  |  | Minimum | 1987 | 1,000 | 2,063 |
|  |  |  | Maximum | 1987 | 10,000 | 20,628 |
|  | 42 CFR | CMS | Penalty per day |  |  |  |
|  | 488.408 |  | for a nursing |  |  |  |
|  | (e)(1) |  | facility's |  |  |  |
|  | (iii) |  | failure to meet |  |  |  |
|  |  |  | Category 3 |  |  |  |
|  |  |  | certification: |  |  |  |
|  |  |  | Minimum | 1987 | 3,050 | 6,291 |
|  |  |  | Maximum | 1987 | 10,000 | 20,628 |
|  | 42 CFR | CMS | Penalty per |  |  | 2,063 |
|  | 488.408 |  | instance for a |  |  |  |
|  | (e)(1) |  | nursing |  |  |  |
|  | (iv) |  | facility's |  |  |  |
|  |  |  | failure to meet |  |  |  |
|  |  |  | Category 3 |  |  |  |
|  |  |  | certification: |  |  |  |
|  |  |  | Minimum | 1987 | 1,000 | 20,628 |
|  |  |  | Maximum | 1987 | 10,000 |  |
|  | 42 CFR | CMS | Penalty per |  |  | 2,063 |
|  | 488.408 |  | instance for a |  |  |  |
|  | (e)(2) |  | nursing |  |  |  |
|  | (ii) |  | facility's |  |  |  |
|  |  |  | failure to meet |  |  |  |
|  |  |  | Category 3 |  |  |  |
|  |  |  | certification, |  |  |  |
|  |  |  | which results in |  |  |  |
|  |  |  | immediate |  |  |  |
|  |  |  | jeopardy: |  |  |  |
|  |  |  | Minimum | 1987 | 1,000 | 20,628 |
|  |  |  | Maximum | 1987 | 10,000 |  |
|  | 42 CFR | CMS | Penalty per day |  |  | 6,291 |
|  | 488.438 |  | for nursing |  |  |  |
|  | (a)(1)(i) |  | facility's |  |  |  |
|  |  |  | failure to meet |  |  |  |
|  |  |  | certification |  |  |  |
|  |  |  | (Upper Range): |  |  |  |
|  |  |  | Minimum | 1987 | 3,050 | 20,628 |
|  |  |  | Maximum | 1987 | 10,000 | 2,063 |
|  | 42 CFR | CMS | Penalty per day |  |  |  |
|  | 488.438 |  | for nursing |  |  |  |
|  | (a)(1) |  | facility's |  |  |  |
|  | (ii) |  | failure to meet |  |  |  |
|  |  |  | certification |  |  |  |
|  |  |  | (Lower Range): |  |  |  |
|  |  |  | Minimum | 1987 | 50 | 103 |
|  |  |  | Maximum | 1987 | 3,000 | 6,188 |
|  | 42 CFR | CMS | Penalty per |  |  |  |
|  | 488.438 |  | instance for |  |  |  |
|  | (a)(2) |  | nursing |  |  |  |
|  |  |  | facility's |  |  |  |
|  |  |  | failure to meet |  |  |  |
|  |  |  | certification: |  |  |  |
|  |  |  | Minimum | 1987 | 1,000 | 2,063 |
|  |  |  | Maximum | 1987 | 10,000 | 20,628 |
| 1396r(f) | 42 CFR | CMS | Grounds to | 1987 | 5,000 | 10,314 |
| (2)(B) | 483.151 |  | prohibit approval |  |  |  |
| (iii)(I) | (b)(2) |  | of Nurse Aide |  |  |  |
| (c) | (iv) and |  | Training |  |  |  |
|  | (b)(3) |  | Program--if |  |  |  |
|  | (iii) |  | 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] |  |  |  |
| 1396r(h) | 42 CFR | CMS | Grounds to waive | 1987 | 5,000 | 10,314 |
| (3)(C) | 483.151 |  | disapproval of |  |  |  |
| (ii)(I) | (c)(2) |  | 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] |  |  |  |
| 1396t(j) |  | CMS | Penalty for each |  |  |  |
| (2)(C) |  |  | day of |  |  |  |
|  |  |  | noncompliance for |  |  |  |
|  |  |  | a home or |  |  |  |
|  |  |  | community care |  |  |  |
|  |  |  | provider that no |  |  |  |
|  |  |  | longer meets the |  |  |  |
|  |  |  | minimum |  |  |  |
|  |  |  | requirements for |  |  |  |
|  |  |  | home and |  |  |  |
|  |  |  | community care: |  |  |  |
|  |  |  | Minimum | 1990 | 1 | 2 |
|  |  |  | Maximum | 1990 | 10,000 | 17,816 |
| 1396u- | 42 CFR | CMS | Penalty for a | 1997 | 25,000 | 36,794 |
| 2(e)(2) | 438.704 |  | Medicaid managed |  |  |  |
| (A)(i) |  |  | care organization |  |  |  |
|  |  |  | that fails |  |  |  |
|  |  |  | substantially to |  |  |  |
|  |  |  | provide medically |  |  |  |
|  |  |  | necessary items |  |  |  |
|  |  |  | and services |  |  |  |
|  |  |  | Penalty for | 1997 | 25,000 | 36,794 |
|  |  |  | Medicaid managed |  |  |  |
|  |  |  | care organization |  |  |  |
|  |  |  | that imposes |  |  |  |
|  |  |  | premiums or |  |  |  |
|  |  |  | charges on |  |  |  |
|  |  |  | enrollees in |  |  |  |
|  |  |  | excess of the |  |  |  |
|  |  |  | premiums or |  |  |  |
|  |  |  | charges permitted |  |  |  |
|  |  |  | Penalty for a | 1997 | 25,000 | 36,794 |
|  |  |  | Medicaid managed |  |  |  |
|  |  |  | care organization |  |  |  |
|  |  |  | that |  |  |  |
|  |  |  | misrepresents or |  |  |  |
|  |  |  | falsifies |  |  |  |
|  |  |  | information to |  |  |  |
|  |  |  | another |  |  |  |
|  |  |  | individual or |  |  |  |
|  |  |  | entity |  |  |  |
|  |  |  | Penalty for a | 1997 | 25,000 | 36,794 |
|  |  |  | Medicaid managed |  |  |  |
|  |  |  | care organization |  |  |  |
|  |  |  | that fails to |  |  |  |
|  |  |  | comply with the |  |  |  |
|  |  |  | applicable |  |  |  |
|  |  |  | statutory |  |  |  |
|  |  |  | requirements for |  |  |  |
|  |  |  | such |  |  |  |
|  |  |  | organizations |  |  |  |
| 1396u- | 42 CFR | CMS | Penalty for a | 1997 | 100,000 | 147,177 |
| 2(e)(2) | 438.704 |  | Medicaid managed |  |  |  |
| (A)(ii) |  |  | care organization |  |  |  |
|  |  |  | that |  |  |  |
|  |  |  | misrepresents or |  |  |  |
|  |  |  | falsifies |  |  |  |
|  |  |  | information to |  |  |  |
|  |  |  | the HHS Secretary |  |  |  |
|  |  |  | Penalty for | 1997 | 100,000 | 147,177 |
|  |  |  | Medicaid managed |  |  |  |
|  |  |  | care organization |  |  |  |
|  |  |  | that acts to |  |  |  |
|  |  |  | discriminate |  |  |  |
|  |  |  | among enrollees |  |  |  |
|  |  |  | on the basis of |  |  |  |
|  |  |  | their health |  |  |  |
|  |  |  | status |  |  |  |
| 1396u- | 42 CFR | CMS | Penalty for each | 1997 | 15,000 | 22,077 |
| 2(e)(2) | 438.704 |  | individual that |  |  |  |
| (A)(iv) |  |  | 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 |  |  |  |
| 1396u(h) | 42 CFR | CMS | Penalty for a | 1990 | 10,000 | 20,628 |
| (2) | 441, |  | provider not |  |  |  |
|  | Subpart I |  | meeting one of |  |  |  |
|  |  |  | the requirements |  |  |  |
|  |  |  | relating to the |  |  |  |
|  |  |  | protection of the |  |  |  |
|  |  |  | health, safety, |  |  |  |
|  |  |  | and welfare of |  |  |  |
|  |  |  | individuals |  |  |  |
|  |  |  | receiving |  |  |  |
|  |  |  | community |  |  |  |
|  |  |  | supported living |  |  |  |
|  |  |  | arrangements |  |  |  |
|  |  |  | services |  |  |  |
| 1396w- |  | CMS | Penalty for | 2009 | 10,000 | 11,002 |
| 2(c)(1) |  |  | disclosing |  |  |  |
|  |  |  | information |  |  |  |
|  |  |  | related to |  |  |  |
|  |  |  | eligibility |  |  |  |
|  |  |  | determinations |  |  |  |
|  |  |  | for medical |  |  |  |
|  |  |  | assistance |  |  |  |
|  |  |  | programs |  |  |  |
| 18041(c) | 45 CFR | CMS | Failure to comply | 1996 | 100 | 150 |
| (2) | 150.315; |  | with requirements |  |  |  |
|  | 45 CFR |  | of the Public |  |  |  |
|  | 156.805 |  | Health Services |  |  |  |
|  | (c) |  | 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)) |  |  |  |
| 18081(h) | 42 CFR | CMS | Penalty for | 2010 | 25,000 | 27,186 |
| (1)(A)(i) | 155.285 |  | providing false |  |  |  |
| (II) |  |  | information on |  |  |  |
|  |  |  | Exchange |  |  |  |
|  |  |  | application |  |  |  |
| 18081(h) | 42 CFR | CMS | Penalty for | 2010 | 250,000 | 271,862 |
| (1)(B) | 155.285 |  | knowingly or |  |  |  |
|  |  |  | willfully |  |  |  |
|  |  |  | providing false |  |  |  |
|  |  |  | information on |  |  |  |
|  |  |  | Exchange |  |  |  |
|  |  |  | application |  |  |  |
| 18081(h) | 42 CFR | CMS | Penalty for | 2010 | 25,000 | 27,186 |
|  | 155.260 |  | knowingly or |  |  |  |
|  |  |  | willfully |  |  |  |
|  |  |  | disclosing |  |  |  |
|  |  |  | protected |  |  |  |
|  |  |  | information from |  |  |  |
|  |  |  | Exchange |  |  |  |
| 31 |  |  |  |  |  |  |
| U.S.C.: |  |  |  |  |  |  |
| 1352 | 45 CFR | HHS | Penalty for the | 1989 | 10,000 | 18,936 |
|  | 93.400(e) |  | 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 | 1989 | 10,000 | 18,936 |
|  |  |  | Maximum | 1989 | 100,000 | 189,361 |
|  |  |  | Penalty for the | 1989 | 10,000 | 18,936 |
|  |  |  | 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 | 1989 | 10,000 | 18,936 |
|  |  |  | Maximum | 1989 | 100,000 | 189,361 |
|  | 45 CFR | HHS | Penalty for |  |  |  |
|  | 93, |  | failure to |  |  |  |
|  | Appendix |  | provide |  |  |  |
|  | A |  | certification |  |  |  |
|  |  |  | regarding |  |  |  |
|  |  |  | lobbying in the |  |  |  |
|  |  |  | award documents |  |  |  |
|  |  |  | for all sub- |  |  |  |
|  |  |  | awards of all |  |  |  |
|  |  |  | tiers: |  |  |  |
|  |  |  | Minimum | 1989 | 10,000 | 18,936 |
|  |  |  | Maximum | 1989 | 100,000 | 189,361 |
|  |  |  | 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 |
| 3801-3812 | 45 CFR | HHS | Penalty against | 1988 | 5,000 | 9,894 |
|  | 79.3(a) |  | any individual |  |  |  |
|  | (1)(iv) |  | who--with |  |  |  |
|  |  |  | knowledge or |  |  |  |
|  |  |  | reason to know-- |  |  |  |
|  |  |  | makes, presents |  |  |  |
|  |  |  | or submits a |  |  |  |
|  |  |  | false, fictitious |  |  |  |
|  |  |  | or fraudulent |  |  |  |
|  |  |  | claim to the |  |  |  |
|  |  |  | Department |  |  |  |
|  | 45 CFR |  | Penalty against | 1988 | 5,000 | 9,894 |
|  | 79.3(b) |  | any individual |  |  |  |
|  | (1(ii) |  | who--with |  |  |  |
|  |  |  | knowledge or |  |  |  |
|  |  |  | reason to know-- |  |  |  |
|  |  |  | makes, presents |  |  |  |
|  |  |  | or submits a |  |  |  |
|  |  |  | false, fictitious |  |  |  |
|  |  |  | or fraudulent |  |  |  |
|  |  |  | claim to the |  |  |  |
|  |  |  | Department |  |  |  |

1. **FORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS**
2. 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*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GMV1-NRF4-431M-00000-00&context=) through 300gg-63, 300gg-91, and 300gg-92), as amended.

1. 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".
2. **GROUP AND INDIVIDUAL INSURANCE MARKETS**
3. 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*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GMV1-NRF4-431M-00000-00&context=) through 300gg-63, 300gg-91, and 300gg-92).

1. 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".
2. **ENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT**
3. 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*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YXM-BBK1-NRF4-4001-00000-00&context=)-18024, 18031-18033, 18041-18042, 18051, 18054, 18071, and 18081-18083).

1. 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".
2. Amend § 155.285 as follows:
3. 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";
4. 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
5. 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".
6. **SUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES**
7. 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*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YXM-BBK1-NRF4-4001-00000-00&context=)-18024, 18031-18032, 18041-18042, 18044, 18054, 18061, 18063, 18071, 18082, [*26 U.S.C. 36B,*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YXM-7BJ1-NRF4-4001-00000-00&context=) and [*31 U.S.C. 9701).*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GMX1-NRF4-4451-00000-00&context=)

1. 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".
2. **UM REVENUE: REPORTING AND REBATE REQUIREMENTS**
3. 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),*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YXM-BJD1-NRF4-4006-00000-00&context=) as amended.

1. 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".
2. **IVE REQUIREMENTS**
3. The authority for part 160 continues to read as follows:

**Authority:** [*42 U.S.C. 1302*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GM31-NRF4-40JV-00000-00&context=)(a); [*42 U.S.C. 1320d*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GWS1-NRF4-440D-00000-00&context=)-1320d-9; sec. 264, *Pub. L. 104-191,*  *110 Stat. 2033-2034* [*(42 U.S.C. 1320d-2*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GMS1-NRF4-4292-00000-00&context=) (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.*

1. Section 160.404 is amended by revising paragraph (a) to read as follows:
2. **ney penalty.**
3. 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 **[\*61582]** 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.*

   \*    \*    \*    \*    \*

1. ***ed to Public Welfare***
2. **Assistance (Assistance Programs), Administration for Children and Families, Department of Health and Human Services**
3. **AM OPERATIONS**
4. The authority citation for part 303 continues to read as follows:

**Authority:** [*42 U.S.C. 651*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GPV1-NRF4-423Y-00000-00&context=) through 658, 659a, 660, 663, 664, 666, 667, 1302, 1396a(a)(25), 1396b(d)(2), 1396b(o), 1396b(p), and 1396(k).

1. Section 303.21 is amended by revising paragraph (f) to read as follows:
2. **losure of confidential information.**

\*    \*    \*    \*    \*

1. Penalties for unauthorized disclosure. Any disclosure or use of confidential information in violation of [*42 U.S.C. 653*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GPD1-NRF4-43BS-00000-00&context=)(l)(2) and implementing ***regulations*** shall be subject to:
2. Any State and Federal statutes that impose legal sanctions for such disclosure; and
3. The maximum civil monetary penalties associated with the statutory provisions authorizing civil monetary penalties under [*42 U.S.C. 653*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GPD1-NRF4-43BS-00000-00&context=)(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.*

[FR Doc. 2016-18680 Filed 9-2-16; 8:45 am]

BILLING CODE 4150-24-P

**Dates**

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

**Contacts**

**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.

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