medicine, public health, biological and physical sciences, epidemiology and biostatistics, clinical trial design, health care data management and analysis, patient advocacy, health care economics, medical ethics or other relevant professions.

The MEDCAC works from an agenda provided by the Designated Federal Official. The MEDCAC reviews and evaluates medical literature and technology assessments, and hears public testimony on the evidence available to address the impact of medical items and services on health outcomes of Medicare beneficiaries. The MEDCAC may also advise the Centers for Medicare & Medicaid Services (CMS) as part of Medicare's ''coverage with evidence development'' initiative.

**II. Provisions of the Notice**

As of June 2015, there will be 16 membership terms expiring. Of the 16 memberships expiring, 2 are industry representatives, 1 is a patient advocate, and the remaining 13 membership openings are for the at-large standing MEDCAC membership.

We wish to ensure adequate representation of the interests of both women and men, members of all ethnic groups and physically challenged individuals. Therefore, we encourage nominations of qualified candidates from these groups.

All nominations must be accompanied by curricula vitae. Nomination packages should be sent to Maria Ellis at the address listed in the **ADDRESSES** section of this notice. Nominees are selected based upon their individual qualifications. Nominees for membership must have expertise and experience in one or more of the following fields:

- Clinical medicine including subspecialties
- Administrative medicine
- Public health
- Biological and physical sciences
- Epidemiology and biostatistics
- Clinical trial design
- Health care data management and analysis
- Patient advocacy
- Health care economics
- Medical ethics
- Other relevant professions

We are looking particularly for experts in a number of fields. These include cancer screening, genetic testing, clinical epidemiology, psychopharmacology, screening and diagnostic testing analysis, and vascular surgery. We also need experts in biostatistics in clinical settings, dementia treatment, minority health, observational research design, stroke epidemiology, and women's health.

The nomination letter must include a statement that the nominee is willing to serve as a member of the MEDCAC and appears to have no conflict of interest that would preclude membership. We are requesting that all curricula vitae include the following:

- Date of birth
- Place of birth
- Social security number
- Title and current position
- Professional affiliation
- Home and business address
- Telephone and fax numbers
- Email address
- List of areas of expertise

In the nomination letter, we are requesting that nominees specify whether they are applying for a patient advocate position, for an at-large standing position, or as an industry representative. Potential candidates will be asked to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts in order to permit evaluation of possible sources of financial conflict of interest. Department policy prohibits multiple committee memberships. A federal advisory committee member may not serve on more than one committee within an agency at the same time.

Members are invited to serve for overlapping 2-year terms. A member may continue to serve after the expiration of the member's term until a successor is named. Any interested person may nominate one or more qualified persons. Self-nominations are also accepted. Individuals interested in the representative positions must include a letter of support from the organization or interest group they would represent. The current Secretary's Charter for the MEDCAC is available on the CMS Web site at: *http://www.cms.hhs.gov/FACA/Downloads/medcaccharter.pdf,* or you may obtain a copy of the charter by submitting a request to the contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

**Authority:** 5 U.S.C. App. 2, section 10(a)(1) and (a)(2).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program.)

Dated: November 4, 2014.

**Patrick Conway,**

*Deputy Administrator for Innovation and Quality and CMS Chief Medical Officer, Centers for Medicare & Medicaid Services.*

[FR Doc. 2014–26699 Filed 11–7–14; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–N–0362]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the current good manufacturing practice (CGMP) regulations for finished pharmaceuticals.

**DATES:** Submit either electronic or written comments on the collection of information by January 9, 2015.

**ADDRESSES:** Submit electronic comments on the collection of information to: *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA 305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of

information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals—21 CFR Parts 210 and 211 (OMB Control Number 0910–0139)—Extension**

Under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 351(a)(2)(B)), a drug is adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with CGMPs to ensure that such drug meets the requirements of the FD&C Act as to safety, and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

The FDA has the authority under section 701(a) of the FD&C Act (21 U.S.C. 371(a)) to issue regulations for the efficient enforcement of the FD&C Act regarding CGMP procedures for manufacturing, processing, and holding drugs and drug products. The CGMP regulations help ensure that drug products meet the statutory requirements for safety and have their purported or represented identity, strength, quality, and purity characteristics. The information collection requirements in the CGMP regulations provide FDA with the necessary information to perform its duty to protect public health and safety. CGMP requirements establish accountability in the manufacturing and processing of drug products, provide for meaningful FDA inspections, and enable manufacturers to improve the quality of drug products over time. The CGMP recordkeeping requirements also serve preventive and remedial purposes and provide crucial information if it is necessary to recall a drug product.

The general requirements for recordkeeping under part 211 (21 CFR part 211) are set forth in § 211.180. Any production, control, or distribution record associated with a batch and required to be maintained in compliance with part 211 must be retained for at least 1 year after the expiration date of the batch and, for certain over-the-counter (OTC) drugs, 3 years after distribution of the batch (§ 211.180(a)). Records for all components, drug product containers, closures, and labeling are required to be maintained for at least 1 year after the expiration date and 3 years for certain OTC products (§ 211.180(b)).

All part 211 records must be readily available for authorized inspections during the retention period (§ 211.180(c)), and such records may be retained either as original records or as true copies (§ 211.180(d)). In addition, 21 CFR 11.2(a) provides that ''for records required to be maintained but not submitted to the Agency, persons may use electronic records in lieu of paper records or electronic signatures in lieu of traditional signatures, in whole or in part, provided that the requirements of this part are met.'' To the extent this electronic option is used, the burden of maintaining paper records should be substantially reduced, as should any review of such records.

In order to facilitate improvements and corrective actions, records must be maintained so that data can be used for evaluating, at least annually, the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures (§ 211.180(e)). Written procedures for these evaluations are to be established and include provisions for a review of a representative number of batches and, where applicable, records associated with the batch; provisions for a review of complaints, recalls, returned, or salvaged drug products; and investigations conducted under § 211.192 for each drug product.

The specific recordkeeping requirements provided in table 1 are as follows:

Section 211.34—Consultants advising on the manufacture, processing, packing, or holding of drug products must have sufficient education, training, and experience to advise on the subject for which they are retained. Records must be maintained stating the name, address, and qualifications of any consultants and the type of service they provide.

Section 211.67(c)—Records must be kept of maintenance, cleaning, sanitizing, and inspection as specified in §§ 211.180 and 211.182.

Section 211.68—Appropriate controls must be exercised over computer or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Section 211.68(a)—Records must be maintained of calibration checks, inspections, and computer or related system programs for automatic, mechanical, and electronic equipment.

Section 211.68(b)—All appropriate controls must be exercised over all computers or related systems and control data systems to assure that changes in master production and control records or other records are instituted only by authorized persons.

Section 211.72—Filters for liquid filtration used in the manufacture, processing, or packing of injectable drug products intended for human use must not release fibers into such products.

Section 211.80(d)—Each container or grouping of containers for components or drug product containers or closures must be identified with a distinctive code for each lot in each shipment received. This code must be used in recording the disposition of each lot. Each lot must be appropriately identified as to its status.

Section 211.100(b)—Written production and process control procedures must be followed in the execution of the various production and process control functions and must be documented at the time of performance. Any deviation from the written procedures must be recorded and justified.

Section 211.105(b)—Major equipment must be identified by a distinctive identification number or code that must be recorded in the batch production record to show the specific equipment used in the manufacture of each batch of a drug product. In cases where only one of a particular type of equipment exists in a manufacturing facility, the

name of the equipment may be used in lieu of a distinctive identification number or code.

Section 211.122(c)—Records must be maintained for each shipment received of each different labeling and packaging material indicating receipt, examination, or testing.

Section 211.130(e)—Inspection of packaging and labeling facilities must be made immediately before use to assure that all drug products have been removed from previous operations. Inspection must also be made to assure that packaging and labeling materials not suitable for subsequent operations have been removed. Results of inspection must be documented in the batch production records.

Section 211.132(c)—Certain retail packages of OTC drug products must bear a statement that is prominently placed so consumers are alerted to the specific tamper-evident feature of the package. The labeling statement is required to be so placed that it will be unaffected if the tamper-resistant feature of the package is breached or missing. If the tamper-evident feature chosen is one that uses an identifying characteristic, that characteristic is required to be referred to in the labeling statement.

Section 211.132(d)—A request for an exemption from packaging and labeling requirements by a manufacturer or packer is required to be submitted in the form of a citizen petition under 21 CFR 10.30.

Section 211.137—Requirements regarding product expiration dating and compliance with 21 CFR 201.17.

Section 211.160(a)—The establishment of any specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, including any change in such specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, must be drafted by the appropriate organizational unit and reviewed and approved by the quality control unit. These requirements must be followed and documented at the time of performance. Any deviation from the written specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms must be recorded and justified.

Section 211.165(e)—The accuracy, sensitivity, specificity, and reproducibility of test methods employed by a firm must be established and documented. Such validation and documentation may be accomplished in accordance with § 211.194(a)(2).

Section 211.166—Stability testing program for drug products.

Section 211.173—Animals used in testing components, in-process materials, or drug products for compliance with established specifications must be maintained and controlled in a manner that assures their suitability for their intended use. They must be identified, and adequate records must be maintained showing the history of their use.

Section 211.180(e)—Written records required by part 211 must be maintained so that data can be used for evaluating, at least annually, the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures. Written procedures must be established and followed for such evaluations and must include provisions for a representative number of batches, whether approved or unapproved or rejected, and a review of complaints, recalls, returned, or salvaged drug products, and investigations conducted under § 211.192 for each drug product.

Section 211.180(f)—Procedures must be established to assure that the responsible officials of the firm, if they are not personally involved in or immediately aware of such actions, are notified in writing of any investigations, conducted under § 211.198, 211.204, or 211.208, any recalls, reports of inspectional observations issued, or any regulatory actions relating to good manufacturing practices brought by FDA.

Section 211.182—Specifies requirements for equipment cleaning records and the use log.

Section 211.184—Specifies requirements for component, drug product container, closure, and labeling records.

Section 211.186—Specifies master production and control records requirements.

Section 211.188—Specifies batch production and control records requirement.

Section 211.192—Specifies the information that must be maintained on the investigation of discrepancies found in the review of all drug product production and control records by the quality control staff.

Section 211.194—Explains and describes laboratory records that must be retained.

Section 211.196—Specifies the information that must be included in records on the distribution of the drug.

Section 211.198—Specifies and describes the handling of all complaint files received by the applicant.

Section 211.204—Specifies that records be maintained of returned and salvaged drug products and describes the procedures involved.

Written procedures, referred to here as standard operating procedures (SOPs), are required for many part 211 records. The current SOP requirements were initially provided in a final rule published in the **Federal Register** of September 29, 1978 (43 FR 45014), and are now an integral and familiar part of the drug manufacturing process. The major information collection impact of SOPs results from their creation. Thereafter, SOPs need to be periodically updated. A combined estimate for routine maintenance of SOPs is provided in table 1. The 25 SOP provisions under part 211 in the combined maintenance estimate include:

Section 211.22(d)—Responsibilities and procedures of the quality control unit;

Section 211.56(b)—Sanitation procedures;

Section 211.56(c)—Use of suitable rodenticides, insecticides, fungicides, fumigating agents, and cleaning and sanitizing agents;

Section 211.67(b)—Cleaning and maintenance of equipment;

Section 211.68(a)—Proper performance of automatic, mechanical, and electronic equipment;

Section 211.80(a)—Receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers or closures;

Section 211.94(d)—Standards or specifications, methods of testing, and methods of cleaning, sterilizing, and processing to remove pyrogenic properties for drug product containers and closures;

Section 211.100(a)—Production and process control;

Section 211.110(a)—Sampling and testing of in-process materials and drug products;

Section 211.113(a)—Prevention of objectionable microorganisms in drug products not required to be sterile;

Section 211.113(b)—Prevention of microbiological contamination of drug products purporting to be sterile, including validation of any sterilization process;

Section 211.115(a)—System for reprocessing batches that do not conform to standards or specifications, to insure that reprocessed batches conform with all established standards, specifications, and characteristics;

Section 211.122(a)—Receipt, identification, storage, handling, sampling, examination and/or testing of labeling and packaging materials;

Section 211.125(f)—Control procedures for the issuance of labeling;

Section 211.130—Packaging and label operations, prevention of mixup and cross contamination, identification and handling of filed drug product containers that are set aside and held in unlabeled condition, and identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch;

Section 211.142—Warehousing;

Section 211.150—Distribution of drug products;

Section 211.160—Laboratory controls;

Section 211.165(c)—Testing and release for distribution;

Section 211.166(a)—Stability testing;

Section 211.167—Special testing requirements;

Section 211.180(f)—Notification of responsible officials of investigations, recalls, reports of inspectional observations, and any regulatory actions relating to good manufacturing practice;

Section 211.198(a)—Written and oral complaint procedures, including quality control unit review of any complaint involving specifications failures, and serious and unexpected adverse drug experiences;

Section 211.204—Holding, testing, and reprocessing of returned drug products; and

Section 211.208—Drug product salvaging.

In addition, the following regulations in parts 610 and 680 (21 CFR parts 610 and 680) reference certain CGMP regulations in part 211: §§ 610.12(g), 610.13(a)(2), 610.18(d), 680.2(f), and 680.3(f). In table 1, the burden associated with the information collection requirements in these regulations is included in the burden estimates under §§ 211.165, 211.167, 211.188, and 211.194, as appropriate.

Although most of the CGMP provisions covered in this document were created many years ago, there will be some existing firms expanding into new manufacturing areas and startup firms that will need to create SOPs. As provided in table 1, FDA is assuming that approximately 100 firms will have to create up to 25 SOPs for a total of 2,500 records, and the Agency estimates that it will take 20 hours per recordkeeper to create 25 new SOPs for a total of 50,000 hours.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| 21 CFR Section | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| SOP Maintenance | 4,360 | 1 | 4,360 | 25 | 109,000 |
| New startup SOPs | 100 | 25 | 2500 | 20 | 50,000 |
| 211.34—Consultants | 4,360 | .25 | 1,090 | 0.50 (30 minutes) | 545 |
| 211.67(c)—Equipment cleaning and maintenance | 4,360 | 50 | 218,000 | .25 (15 minutes) | 54,500 |
| 211.68—Changes in master production and control records or other records. | 4,360 | 2 | 8,720 | 1 | 8,720 |
| 211.68(a)—Automatic, mechanical, and electronic equipment. | 4,360 | 10 | 43,600 | .50 (30 minutes) | 21,800 |
| 211.68(b)—Computer or related systems | 4,360 | 5 | 21,800 | .25 (15 minutes) | 5,450 |
| 211.72—Filters | 4,360 | .25 | 1,090 | 1 | 1,090 |
| 211.80(d)—Components and drug product containers or closures. | 4,360 | .25 | 1,090 | .10 (6 minutes) | 109 |
| 211.100(b)—Production and process controls | 4,360 | 3 | 13,080 | 2 | 26,160 |
| 211.105(b)—Equipment identification | 4,360 | .25 | 1,090 | .25 (15 minutes) | 273 |
| 211.122(c)—Labeling and packaging material | 4,360 | 50 | 218,000 | .25 (15 minutes) | 54,500 |
| 211.130(e)—Labeling and packaging facilities | 4,360 | 50 | 218,000 | .25 (15 minutes) | 54,500 |
| 211.132(c)—Tamper-evident packaging | 1,769 | 20 | 35,380 | .50 (30 minutes) | 17,690 |
| 211.132(d)—Tamper-evident packaging | 1,769 | .2 | 354 | .50 (30 minutes) | 177 |
| 211.137—Expiration dating | 4,360 | 5 | 21,800 | .50 (30 minutes) | 10,900 |
| 211.160(a)—Laboratory controls | 4,360 | 2 | 8,720 | 1 | 8,720 |
| 211.165(e)—Test methodology | 4,360 | 1 | 4,360 | 1 | 4,360 |
| 211.166—Stability testing | 4,360 | 2 | 8,720 | .50 (30 minutes) | 4,360 |
| 211.173—Laboratory animals | 1,077 | 1 | 1,077 | .25 (15 minutes) | 269 |
| 211.180(e)—Production, control, and distribution records. | 4,360 | .2 | 872 | .25 (15 minutes) | 218 |
| 211.180(f)—Procedures for notification of regulatory actions. | 4,360 | .2 | 872 | 1 | 872 |
| 211.182—Equipment cleaning and use log | 4,360 | 2 | 8,720 | .25 (15 minutes) | 2,180 |
| 211.184—Component, drug product container, closure, and labeling records. | 4,360 | 3 | 13,080 | .50 (30 minutes) | 6,540 |
| 211.186—Master production and control records | 4,360 | 10 | 43,600 | 2 | 87,200 |
| 211.188—Batch production and control records | 4,360 | 25 | 109,000 | 2 | 218,000 |
| 211.192—Discrepancies in drug product production and control records. | 4,360 | 2 | 8,720 | 1 | 8,720 |
| 211.194—Laboratory records | 4,360 | 25 | 109,000 | .50 (30 minutes) | 54,500 |
| 211.196—Distribution records | 4,360 | 25 | 109,000 | .25 (15 minutes) | 27,250 |
| 211.198—Compliant files | 4,360 | 5 | 21,800 | 1 | 21,800 |
| 211.204—Returned drug products | 4,360 | 10 | 43,600 | .50 (30 minutes) | 21,800 |
| Total | | | | | 882,203 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: November 4, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–26596 Filed 11–7–14; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2013–N–1106]**

### Armando Santos: Debarment Order

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring Armando Santos from providing services in any capacity to a person that has an approved or pending drug product application for a period of 12 years. FDA bases this order on a finding that Mr. Santos was convicted of seven felony counts under Federal law for conduct involving health care fraud, conspiracy to commit health care fraud, and false statements related to health care matters and that this pattern of conduct is sufficient to find that there is reason to believe he may violate requirements under the FD&C Act relating to drug products. Mr. Santos was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Mr. Santos failed to respond. Mr. Santos's failure to respond constitutes a waiver of his right to a hearing concerning this action.

**DATES:** This order is effective November 10, 2014.

**ADDRESSES:** Submit applications for termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Kenny Shade, Division of Enforcement, Office of Enforcement and Import Operations, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rm. 4144, Rockville, MD 20857, 301–796–4640.

**SUPPLEMENTARY INFORMATION:**

### I. Background

Section 306(b)(2)(B)(ii)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(ii)(I)) permits debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct that involves bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records, or interference with, obstruction of an investigation into, or prosecution of any criminal offense, and it finds, on the basis of the conviction and other information, that such individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe the individual may violate requirements under the FD&C Act relating to drug products.

On August 15, 2011, the U.S. District Court for the Southern District of Florida entered judgment against Mr. Santos after a jury found him guilty of four counts of health care fraud in violation of 18 U.S.C. 1347, one count of conspiracy to commit health care fraud in violation of 18 U.S.C. 1349, and two counts of false statements related to health care matters in violation of 18 U.S.C. 1035(a)(2).

The FDA's finding that debarment is appropriate is based on the felony convictions referenced herein. The factual basis for these convictions is as follows: Mr. Santos was a registered nurse working for a home health agency located in the Southern District of Florida. As a registered nurse in the home health field, it was Mr. Santos's duty to provide skilled nursing services to patients and maintain proper documentation of all treatments provided to patients.

From on or about June 29, 2007, through on or about March 13, 2009, Mr. Santos conspired with others to defraud Medicare. Mr. Santos and his coconspirators, among other things, submitted and caused the submission of false and fraudulent claims to Medicare, and paid kickbacks and bribes to Medicare beneficiaries in exchange for the use of their Medicare beneficiary numbers as the bases of claims filed for home health care. Mr. Santos and his co-conspirators signed patient assessment forms falsely certifying that Medicare beneficiaries were in need of home health services that were medically unnecessary.

Mr. Santos created false weekly visit/time records in which he claimed to be providing skilled nursing services to two separate Medicare beneficiaries at the same time. On four separate occasions, Mr. Santos submitted and caused the submission of false and fraudulent claims to Medicare, representing that he had provided various home health services to beneficiaries pursuant to physicians' plans of care. He caused a home health agency to submit approximately $230,315 in false and fraudulent claims to Medicare for home health services allegedly rendered to Medicare beneficiaries, when such home health services were not medically necessary and had not been provided. As a result of these fraudulent claims, Mr. Santos caused Medicare to make payments of approximately $152,664 to a Miami-Dade County home health agency.

In addition, Mr. Santos knowingly and willfully made materially false statements and representations, in connection with the delivery of and payment for health care benefits, items, and services. Specifically, Mr. Santos prepared documents entitled ''Skilled Nursing Progress Note[s]'' which falsely stated that he had injected Medicare beneficiaries with insulin on two occasions, when he knew he had not performed these services.

As a result of his convictions, on April 9, 2014, FDA sent Mr. Santos a notice by certified mail proposing to debar him for 12 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on the finding, under section 306(b)(2)(B)(ii)(I) of the FD&C Act, that Mr. Santos was convicted of seven felonies under Federal law for conduct involving health care fraud, conspiracy to commit health care fraud, and false statements related to health care matters, and that the Agency found, on the basis of these convictions and other information, that Mr. Santos had demonstrated a pattern of conduct sufficient to find that there is reason to believe he may violate requirements under the FD&C Act relating to drug products. This conclusion was based on the fact that Mr. Santos had legal and professional obligations to ensure that he kept accurate medical records for each patient and that he submitted accurate medical claims for services he provided. Instead, Mr. Santos signed patient assessment forms falsely certifying that Medicare beneficiaries were in need of home health services that were medically unnecessary, and he submitted false weekly visit/time records. Mr. Santos additionally prepared false ''Skilled Nursing Progress Note[s]'' stating that he had injected two Medicare beneficiaries with insulin when he had not done so. He submitted and caused the submission of false and fraudulent claims to Medicare. He engaged in this conduct repeatedly over a period of almost 2 years. His convictions indicate that he knowingly and willfully disregarded his legal and professional obligations to keep accurate medical records and to submit accurate claims for the services he provided.