

We are not using notice and comment rulemaking in this notification of Medicare Part A premiums for CY 2017 as that procedure is unnecessary because of the lack of discretion in the statutory formula that is used to calculate the premium and the solely ministerial function that this notice serves. The APA permits agencies to waive notice and comment rulemaking when notice and public comment thereon are unnecessary. On this basis, we waive publication of a proposed notice and a solicitation of public comments.

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

VII. Regulatory Impact Analysis

A. Statement of Need

Section 1818(d) of the Act requires the Secretary of the Department of Health and Human Services (the Secretary) during September of each year to determine and publish the amount to be paid, on an average per capita basis, from the Federal Hospital Insurance Trust Fund for services incurred in the impending CY (including the associated administrative costs) on behalf of individuals aged 65 and over who will be entitled to benefits under Medicare Part A.

B. Overall Impact

We have examined the impact of this notice as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. Part I, Ch. 8).

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). A regulatory impact analysis (RIA) must be prepared for major notices with economically significant effects (\$100 million or more in any 1 year). As stated in section IV of this notice, we estimate that the overall effect of the changes in the Part A premium will be a cost to voluntary enrollees (section 1818 and section 1818A of the Act) of about \$17 million. As a result, this notice is non-economically significant under section 3(f)(1) of Executive Order 12866 and is not a major action under the Congressional Review Act. In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than \$7.5 million to \$38.5 million in any 1 year (for details, see the Small Business Administration's Web site at http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf).

Individuals and states are not included in the definition of a small entity. As discussed above, this annual notice announces Medicare's Hospital Insurance (Part A) premium for uninsured enrollees in CY 2017. As a result, we are not preparing an analysis for the RFA because the Secretary has determined that this notice will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. As discussed above, we are not preparing an analysis for section 1102(b) of the Act, because the Secretary has determined that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also

requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold is approximately \$146 million. This notice does not impose mandates that will have a consequential effect of \$146 million or more on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this notice does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Dated: September 23, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: November 8, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1311]

Paul S. Singh: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The U.S. Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debaring Paul S. Singh from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Dr. Singh was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Dr. Singh was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Singh failed to request a hearing. Dr. Singh's failure to request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective November 15, 2016.

ADDRESSES: Submit applications for special 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 (ELEM-4144), Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 301-796-4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act. On July 31, 2015, the U.S. District Court for the Eastern District of California entered judgment against Dr. Singh for one count of mail fraud, in violation of 18 U.S.C. 1341.

FDA's finding that the debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: Dr. Singh was the President and Secretary of Paul S. Singh, DO, Inc., and provided obstetric and gynecological services to women. Beginning on or about May 2008, and continuing to at least on or about June 2012, within the Eastern District of California and elsewhere, Dr. Singh devised a scheme and artifice to defraud health care benefit programs, patients, and others of money and property by means of materially false and fraudulent pretenses, representations, and promises.

During the time period described, Dr. Singh provided his patients forms of birth control, including the insertion of an intrauterine device ("IUD"). IUDs are regulated by FDA. At the relevant time, FDA had only approved one IUD, which used copper as its active ingredient, the ParaGard T-380A IUD. ParaGard T-380A was sold only by its manufacturer and was not available on third-party Web sites.

The insertion of a non-FDA approved copper IUD risks a patient's health and safety. Dr. Singh knew of this risk and knew that inserting a non-FDA approved copper IUD was prohibited by FDA. Despite this, Dr. Singh obtained non-FDA approved copper IUDs by purchasing them on the Internet and inserted them in his patients. Dr. Singh

failed to inform his patients that he had inserted a non-FDA approved copper IUD, and none of his patients consented to the insertion of one. On or about August 17, 2010, FDA agents met with Dr. Singh and warned him that he could not insert non-FDA approved copper IUDs, and he agreed that he would stop doing so. Notwithstanding this warning, Dr. Singh continued to insert non-FDA approved copper IUDs in his patients and falsely claimed to his patients that he was inserting FDA-approved copper IUDs.

Dr. Singh billed at least 10 different health care benefit programs for payment for the insertion of non-FDA approved copper IUDs in his patients. In submitting these claims, Dr. Singh knowingly misrepresented the type of IUD he had inserted. Dr. Singh caused the U.S. mails to be used to carry out an essential part of his scheme. At all relevant times, Dr. Singh acted with the intent to defraud. As a result of Dr. Singh's conduct, he made false claims of over \$83,000 to health care benefit programs, his patients, and others.

As a result of this conviction, FDA sent Dr. Singh by certified mail on August 17, 2016, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(B) of the FD&C Act, that Dr. Singh was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. FDA determined that Dr. Singh's felony conviction was related to the regulation of drug products because the conduct underlying his conviction undermined FDA's regulatory oversight over drug products marketed in the United States—it involved using and misrepresenting as approved unapproved IUDs that presented health risks to patients. The proposal also offered Dr. Singh an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. The proposal was received on August 23, 2016. Dr. Singh did not request a hearing and has, therefore, waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs, under sections 306(a)(2)(B) of the FD&C Act,

under authority delegated to him (Staff Manual Guide 1410.35), finds that Paul S. Singh has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Section 306(c)(2)(A)(ii) of the FD&C Act requires that Dr. Singh's debarment be permanent.

As a result of the foregoing finding, Paul S. Singh is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**) (see sections 201(dd) (21 U.S.C. 321(dd)), 306(c)(1)(B), and 306(c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Paul S. Singh, in any capacity during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Dr. Singh provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications from Paul S. Singh during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Dr. Singh for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2016-N-1311 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket, and will be viewable at <http://www.regulations.gov> or at the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 9, 2016.

Armando Zamora,

Deputy Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs.

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