February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. Because this rule authorizes pre-existing state rules which are at least equivalent to, and no less stringent than existing federal requirements, and impose no additional requirements beyond those imposed by state law, and there are no anticipated significant adverse human health or environmental effects, the rule is not subject to Executive Order 12898. The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this document and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This action nevertheless will be effective 60 days after the final approval is published in the **Federal Register**.

List of Subjects in 40 CFR Part 271

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Incorporation by reference, Indian—lands, Hazardous waste transportation, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Water pollution control, Water supply.

Authority: This action is issued under the authority of sections 2002(a), 3006, and 7004(b) of the Solid Waste Disposal Act as amended, 42 U.S.C. 6912(a), 6926, and 6974(b).

Dated: June 8, 2018.

Deborah Jordan,

Acting Regional Administrator, Region 9.

[FR Doc. 2018–13573 Filed 6–22–18; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 411

[CMS–1720–NC]

RIN 0938–AT64

Medicare Program; Request for Information Regarding the Physician Self-Referral Law

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Request for information.

SUMMARY: This request for information seeks input from the public on how to address any undue regulatory impact and burden of the physician self-referral law.

DATES: *Comment Date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 24, 2018.

ADDRESSES: In commenting, refer to file code CMS–1720–NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1720–NC, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1720–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Lisa O. Wilson, (410) 786–8852.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

I. Introduction

The Department of Health and Human Services (HHS) is working to transform the healthcare system into one that pays for value. Care coordination is a key aspect of systems that deliver value. Removing unnecessary government obstacles to care coordination is a key priority for HHS. To help accelerate the transformation to a value-based system that includes care coordination, HHS has launched a Regulatory Sprint to Coordinated Care, led by the Deputy Secretary. This Regulatory Sprint is focused on identifying regulatory requirements or prohibitions that may act as barriers to coordinated care, assessing whether those regulatory provisions are unnecessary obstacles to coordinated care, and issuing guidance or revising regulations to address such obstacles and, as appropriate, encouraging and incentivizing coordinated care.

The Centers for Medicare & Medicaid Services (CMS) has made facilitating coordinated care a top priority and seeks to identify ways in which its regulations may impose undue burdens on the healthcare industry and serve as obstacles to coordinated care and its efforts to deliver better value and care for patients. Through internal discussion and input from external stakeholders, CMS has identified some aspects of the physician self-referral law as a potential barrier to coordinated care. Addressing unnecessary obstacles to coordinated care, real or perceived, caused by the physician self-referral law is one of CMS's goals in this Regulatory Sprint. To inform our efforts to assess and address the impact and burden of the physician self-referral law, including whether and, if so, how it may prevent or inhibit care coordination, we welcome public comment on the physician self-referral law and, in particular, comment on the questions presented in this Request for Information (RFI).

II. Background

When enacted in 1989, the physician self-referral law (section 1877 of the Social Security Act), also known as the

''Stark Law,'' addressed the concern that health care decision making can be unduly influenced by a profit motive. When physicians have a financial incentive to refer patients for health care services, this incentive may affect utilization, patient choice, and competition. Overutilization may occur when items and services are ordered that would not have been ordered absent a profit motive. A patient's choice can be affected when he or she is steered to less convenient, lower quality, or more expensive providers of health care that are sharing profits with, or providing other remuneration to, the referring practitioner. Where referrals are controlled by those sharing profits or receiving other remuneration, the medical marketplace suffers since new competitors may have more difficulty generating business on superior quality, service, or price alone.

By design, the physician self-referral law is intended to disconnect a physician's health care decision making from his or her financial interests in other health care providers and suppliers. Specifically, the law: (1) Prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services. The prohibitions are absolute unless the physician's referral is permitted under an enumerated exception. The statute establishes a number of specific exceptions, and grants the Secretary the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse. For more information, please refer to the CMS physician self-referral website at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html?redirect=/PhysicianSelfReferral/.*

CMS is aware of the effect the physician self-referral law may have on parties participating or considering participation in integrated delivery models, alternative payment models, and arrangements to incent improvements in outcomes and reductions in cost. The President's Budget for fiscal year (FY) 2019 included a legislative proposal to establish a new exception to the physician self-referral law for arrangements that arise due to participation in alternative payment models. In addition to this legislative proposal, CMS has engaged stakeholders through comment solicitations in several recent rulemakings. In 2017, through the annual payment rules, CMS asked for comments on improvements that can be made to the health care delivery system that reduce unnecessary burdens for clinicians, other providers, and patients and their families. In response, commenters shared additional information regarding the barriers to participation in health care delivery and payment reform efforts, both public and private, as well as the burdens of compliance with the physician self-referral law and our regulations as they exist today. As a result of our review of these comments, and with a goal of reducing regulatory burden and dismantling barriers to value-based care transformation, while also protecting the integrity of the Medicare program, we are requesting additional information in this RFI. We are particularly interested in your thoughts on issues that include, but are not limited to, the structure of arrangements between parties that participate in alternative payment models or other novel financial arrangements, the need for revisions or additions to exceptions to the physician self-referral law, and terminology related to alternative payment models and the physician self-referral law. We look forward to receiving your input on this RFI.

III. Request for Information

We are requesting public input on the following areas:

1. Please tell us about either existing or potential arrangements that involve DHS entities and referring physicians that participate in alternative payment models or other novel financial arrangements, whether or not such models and financial arrangements are sponsored by CMS. Please include a description of the alternative payment model(s) and novel financial arrangements if not sponsored by CMS. We recommend that you identify concerns regarding the applicability of existing exceptions to the physician self-referral law and/or the ability of the arrangements to satisfy the requirements of an existing exception, as well as the extent to which the physician self-referral law may be impacting commercial alternative payment models and novel financial arrangements. Please be specific regarding the terms of the arrangements with respect to the following:

- The categories/types of parties (for example, the parties are a hospital and physician group with downstream payments to individual physicians in the group).
- Which parties bear risk (and how and to what extent) under the arrangement (for example, per capita payments from a payor are paid to a hospital with downstream payments on a discounted fee schedule to individual physicians; a bundled payment from a payor for all hospital and physician services is split between a hospital and physicians based on a predetermined percentage; hospital-sponsored gainsharing program where participating physicians share in cost savings; physician incentive payments are available for achieving predetermined metrics; etc.).
- The scope of the arrangement (for example, non-Medicare beneficiaries only, Medicare beneficiaries only, or all patients regardless of payor).
- The timeframe of the arrangement (for example, ongoing or for a duration that aligns with a payor-specific initiative).
- Items and services provided under the arrangement and by whom (for example, infrastructure, such as electronic health records technology; physician services; care coordination services; etc.).
- How the arrangement furthers the purpose of the alternative payment model or novel financial arrangement.
- Whether and, if so, how the arrangement mitigates the financial incentives for inappropriate self-referrals, and/or overutilization of items and services, and patient choice.

2. What, if any, additional exceptions to the physician self-referral law are necessary to protect financial arrangements between DHS entities and referring physicians who participate in the same alternative payment model? Specifically—

- What additional exceptions are necessary to protect accountable care organization models?
- What additional exceptions are necessary to protect bundled payment models?
- What additional exceptions are necessary to protect two-sided risk models in a FFS environment?
- What additional exceptions are necessary to protect other payment models (please explain the nature and design of such models)?
- How (if at all) should a new exception (or exceptions) protect individual DHS referrals (see 42 CFR 411.355), ownership or investment interests (see 42 CFR 411.356), or compensation arrangements (see 42 CFR 411.357)?

3. What, if any, additional exceptions to the physician self-referral law are necessary to protect financial arrangements that involve integrating

and coordinating care outside of an alternative payment model? Specifically, what types of financial arrangements and/or remuneration related to care integration and coordination should be protected and why? How (if at all) should a new exception (or exceptions) protect individual DHS referrals (see 42 CFR 411.355), ownership or investment interests (see 42 CFR 411.356), or compensation arrangements (see 42 CFR 411.357)?

4. Please share your thoughts on the utility of the current exception at 42 CFR 411.357(n) for risk-sharing arrangements.

5. Please share your thoughts on the utility of the special rule for compensation under a physician incentive plan within the exception at 42 CFR 411.357(d) for personal service arrangements.

6. Please share your thoughts on possible approaches to address the application of the physician self-referral law to financial arrangements among participants in alternative payment models and other novel financial arrangements. Consider the following:

- Would a single exception provide sufficient protection for all types of financial arrangements?
- Would a multifaceted approach that amends existing exceptions and/or establishes new exceptions be preferable?
- Would such a multifaceted approach sufficiently allow parties to identify and satisfy the requirements of one (or more) applicable exceptions in order to protect individual DHS referrals, ownership or investment interests, and/or compensation arrangements?

7. In the context of health care delivery, payment reform, and the physician self-referral law, please share your thoughts on definitions for critical terminology such as—

- Alternative payment model
- Care coordination
- Clinical integration
- Financial integration
- Risk
- Risk-sharing
- Physician incentive program
- Gainsharing
- Health plan
- Health system
- Integrated delivery system
- Enrollee

8. Please identify and suggest definitions for other terminology relevant to the comments requested in this RFI.

9. Please share your thoughts on possible approaches to defining ''commercial reasonableness'' in the context of the exceptions to the physician self-referral law.

10. Please share your thoughts on possible approaches to modifying the definition of ''fair market value'' consistent with the statute and in the context of the exceptions to the physician self-referral law.

11. Please share your thoughts on when, *in the context of the physician self-referral law,* compensation should be considered to ''take into account the volume or value of referrals'' by a physician or ''take into account other business generated'' between parties to an arrangement. Please share with us, by way of example or otherwise, compensation formulas that do *not* take into account the volume or value of referrals by a physician or other business generated between parties.

12. Please share your thoughts on when, *in the context of alternative payment models and other novel financial arrangements,* compensation should be considered to ''take into account the volume or value of referrals'' by a physician or ''take into account other business generated'' between parties to an arrangement. Please share with us, by way of example or otherwise, compensation formulas that do *not* take into account the volume or value of referrals by a physician or other business generated between parties.

13. Please share your thoughts regarding whether and, if so, what barriers exist to qualifying as a ''group practice'' under the regulations at 42 CFR 411.352.

14. Please share your thoughts on the application and utility of the current exception at 42 CFR 411.357(g) for remuneration unrelated to DHS. Specifically, how could CMS interpret this exception to cover a broader array of arrangements?

15. Please identify any provisions, definitions, and/or exceptions in the regulations at 42 CFR 411.351 through 411.357 for which additional clarification would be useful.

16. Please share your thoughts on the role of transparency in the context of the physician self-referral law. For example, if provided by the referring physician to a beneficiary, would transparency about physician's financial relationships, price transparency, or the availability of other data necessary for informed consumer purchasing (such as data about quality of services provided) reduce or eliminate the harms to the Medicare program and its beneficiaries that the physician self-referral law is intended to address?

17. Please share your thoughts on whether and how CMS could design a model to test whether transparency safeguards other than those currently contained in the physician self-referral law could effectively address the impact of financial self-interest on physician medical decision-making.

18. Please share your thoughts on the compliance costs for regulated entities.

19. Please identify any recent studies assessing the positive or negative effects of the physician self-referral law on the healthcare industry. To the extent publicly available, please provide a copy of the study(ies).

20. Please share your thoughts regarding whether CMS should measure the effectiveness of the physician self-referral law in preventing unnecessary utilization and other forms of program abuse relative to the cost burden on the regulated industry and, if so, how CMS could estimate this.

Respondents are encouraged to provide complete but concise and organized responses, including any relevant data and specific examples. However, respondents are not required to address every issue or respond to every question discussed in this RFI to have their responses considered. In accordance with the implementing regulations of the Paperwork Reduction Act at 5 CFR 1320.3(h)(4), all responses will be considered provided they contain information CMS can use to identify and contact the commenter, if needed.

Please note, this is a request for information only. As previously stated, respondents are encouraged to provide complete but concise responses. This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), application, proposal abstract, or quotation. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through this RFI and will not accept unsolicited proposals. Respondents are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. Not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. Please note that CMS will not respond to questions about the policy issues raised in this RFI. CMS may or may not

choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses.

Responses to this RFI are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the U.S. Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur costs for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. CMS may publicly post the comments received, or a summary thereof.

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. However, section III. of this document does contain a general solicitation of comments in the form of a request for information. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA. 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.*).

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we may respond to the comments in the preamble to that document.

Dated: June 19, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2018–13529 Filed 6–20–18; 4:15 pm]

BILLING CODE 4120–01–P