determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule 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 of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 5, 2022.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.555, amend the table in paragraph (a) by:

■ a. Adding in alphabetical order the entries for ''Caneberry, subgroup 13–07A''; ''Currant''; ''Pea and bean, succulent shelled, subgroup 6B''; ''Tropical and subtropical, small fruit, edible peel, subgroup 23A''; and ''Vegetable, legume, edible podded, subgroup 6A''.

■ b. Add footnote 4.

The additions read as follows:

§ 180.555 Trifloxystrobin; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * * * *	
Caneberry, subgroup 13–07A [4]	2
* * * * * * *	
Currant [4]	3
* * * * * * *	
Pea and bean, succulent shelled, subgroup 6B [4]	0.2
* * * * * * *	
Tropical and subtropical, small fruit, edible peel, subgroup 23A [4]	0.3
* * * * * * *	
Vegetable, legume, edible podded, subgroup 6A [4]	1.5
* * * * * * *	
[3] * * * * * * *	

[4] There are no U.S. registrations on this commodity as of January 11, 2022.

* * * * *

[FR Doc. 2022–00311 Filed 1–10–22; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1008

Medicare and State Health Care Programs: Fraud and Abuse; Procedures Regarding the Submission of Advisory Opinion Requests to, and the Issuance of Advisory Opinions by, OIG

AGENCY: Office of Inspector General (OIG), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: OIG is amending the regulations governing the procedures for the submission of advisory opinion requests to, and the issuance of advisory opinions by, OIG.

DATES: This final rule is effective February 10, 2022.

FOR FURTHER INFORMATION CONTACT: Christina Hinkle, Office of Counsel to the Inspector General, (202) 465–6245.

SUPPLEMENTARY INFORMATION:

I. Background

Pursuant to section 1128D of the Social Security Act (the Act),[1] HHS, through OIG, publishes advisory opinions regarding the application of the Federal anti-kickback statute [2] and the safe harbor provisions, as well as OIG's administrative sanction authorities, to parties' proposed or existing arrangements. More specifically, in consultation with the Department of Justice (DOJ) OIG issues written advisory opinions to requesting parties with regard to: (1) What constitutes prohibited remuneration under the Federal anti-kickback statute; (2) whether an arrangement or proposed arrangement satisfies the criteria in section 1128B(b)(3) of the Act, or established by regulation (*i.e.,* safe harbors),[3] for activities that do not result in prohibited remuneration; (3) what constitutes an inducement to reduce or

[1] 42 U.S.C. 1320a–7d.

[2] Section 1128B of the Act; 42 U.S.C. 1320a–7b(b).

[3] The safe harbor regulations are set forth at 42 CFR 1001.952.

limit services to Medicare or Medicaid program beneficiaries under section 1128A(b) of the Act; [4] and (4) whether an activity or proposed activity constitutes grounds for the imposition of sanctions under section 1128,[5] 1128A, or 1128B of the Act.

Section 1128D(b) required the issuance of regulations to carry out the advisory opinion process and specified that the regulations must provide for ''the procedure to be followed by the [OIG] in responding to a request for an advisory opinion.'' In response to this requirement, OIG issued an interim final rule with comment period in 1997.[6] In this interim final rule, OIG established a new 42 CFR part 1008, which contains the specific procedures for the submission of requests by individuals or entities for advisory opinions to and the issuance of advisory opinions by OIG, in consultation with DOJ. We revised and clarified our regulations in a final rule issued in 1998.[7] In 2008, we revised certain procedural requirements in 42 CFR part 1008 for submitting payments for advisory opinion costs.[8]

In the 1997 interim final rule, OIG established a procedural regulation—42 CFR 1008.15(c)—that describes the circumstances in which OIG will not accept a request or will not issue an opinion. Specifically, § 1008.15(c) provides that an advisory opinion request will not be accepted and/or an advisory opinion will not be issued when: (1) The request is not related to a named individual or entity; (2) the same or substantially the same course of action is under investigation, or is or has been the subject of a proceeding involving HHS or another governmental agency; or (3) an informed opinion cannot be made, or could be made only after extensive investigation, clinical study, testing, or collateral inquiry. Section 1008.15(c) has not been modified since it was promulgated in 1997.

II. Final Rule

This final rule removes the procedural provision at 42 CFR 1008.15(c)(2), which precludes the acceptance of an advisory opinion request and/or issuance of an advisory opinion when the same or substantially the same course of action is under investigation or has been the subject of a proceeding involving HHS or another governmental agency. In addition, this final rule corrects a grammatical error in § 1008.15(c).

Section 1008.15(c) is a procedural rule that was promulgated consistent with our statutory obligation under section 1128D(b) of the Act. The purpose of § 1008.15(c)(2) is to prevent the advisory opinion process from interfering with the investigatory or prosecutorial authority of OIG, DOJ, or any other governmental agency. Under the current regulation, no advisory opinion is issued if the same or substantially the same course of action is under investigation or is the subject of a proceeding involving HHS or another governmental agency.

We are removing § 1008.15(c)(2) for two reasons. First, removal of this provision will offer OIG more flexibility in responding to requests for advisory opinions. In particular, this final rule will afford OIG the flexibility to issue a favorable or unfavorable advisory opinion when an arrangement presented in an advisory opinion request involves conduct that is the same or substantially the same as conduct that is under investigation or subject to a proceeding. When OIG has rejected advisory opinion requests pursuant to the existing regulation, some requestors have expressed frustration with this regulatory provision because it prevents OIG from providing its legal opinion regarding the application of certain Federal fraud and abuse authorities. Second, removal of § 1008.15(c)(2) may provide industry stakeholders with greater transparency regarding factors the Government may consider in evaluating compliance with certain Federal fraud and abuse laws and distinguishing between similar arrangements.

In conjunction with issuing this rule, OIG is publishing on its website an enforcement policy statement announcing that, as of the effective date of this rule, if the arrangement for which an advisory opinion is sought is the same or similar to conduct that is currently under investigation or is the subject of a proceeding involving a governmental agency, that fact will weigh against the issuance of a favorable advisory opinion because such circumstances generally indicate that the arrangement does not present a sufficiently low risk of fraud and abuse. That said, consistent with current practices, OIG will carefully consider the facts and circumstances of each advisory opinion request in our legal assessment.

This rulemaking is separate and distinct from the Request for Information (RFI) entitled ''OIG Modernization Initiative To Improve Its Publicly Available Resources,'' published in the **Federal Register** on September 24, 2021.[9] OIG has not yet reviewed and considered comments made in response to the RFI, and this rulemaking is not connected to any feedback received in response to the RFI.

III. Regulatory Impact Statement

As set forth below, we have examined the impact of this final rule as required by Executive Order 12866, the Regulatory Flexibility Act (RFA) of 1980, the Unfunded Mandates Reform Act of 1995, Executive Order 13132, and Executive Order 13771.

A. Administrative Procedure Act

The advisory opinion process is an established OIG program. This final rule is limited to modifying the internal governmental procedure for handling advisory opinion requests involving conduct that is the same or similar to an ongoing investigation or proceeding. The modification likely will result in a similar outcome for most advisory opinion requests involving conduct that is the same or similar to an ongoing investigation in that those requests likely would not result in favorable advisory opinions. This rule does not modify eligibility of a party to request an advisory opinion or the process for requesting an advisory opinion.

OIG expects that this final rule will further the public's interest with minimal burden by fulfilling the statutory obligations to consult with DOJ as part of the advisory opinion process, providing greater flexibility for OIG in its procedures to be followed in responding to a request for an advisory opinion, and potentially promoting greater transparency regarding factors the Government may consider in evaluating compliance with certain Federal fraud and abuse laws and distinguishing between similar arrangements. Because this rule is procedural, notice and comment rulemaking is not required under 5 U.S.C. 553(b)(A).

B. Executive Order 12866 and Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for this rule, the provisions of the RFA do not apply. Furthermore, this document does not meet the criteria for a significant regulatory action as specified in Executive Order 12866.

[4] 42 U.S.C. 1320a–7a(b).

[5] 42 U.S.C. 1320a–7.

[6] 62 FR 7350 (Feb. 19, 1997).

[7] 63 FR 38311 (July 16, 1998).

[8] 73 FR 15937 (Mar. 26, 2008); 73 FR 40982 (July 17, 2008).

[9] OIG, OIG Modernization Initiative To Improve Its Publicly Available Resources—Request for Information, 86 FR 53072 (Sept. 24, 2021).

C. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104–4, requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any one year by State, local, or tribal governments in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation). We believe that this final rule will not impose any mandates on State, local, or tribal governments or the private sector that would result in an expenditure of $100 million or more (adjusted for inflation) in any given year, and that a full analysis under the Unfunded Mandates Reform Act is not necessary.

D. Executive Order 13132

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirements or costs on State and local governments, preempts State law, or otherwise has federalism implications. In reviewing this final rule under the threshold criteria of Executive Order 13132, Federalism, we have determined that this final rule would not significantly limit the rights, roles, and responsibilities of State or local governments. We have determined, therefore, that a full analysis under Executive Order 13132 is not necessary.

E. Executive Order 13771

Executive Order 13771 requires that the costs associated with significant new regulations ''to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This final rule imposes no more than *de minimis* costs and is neither a regulatory nor a deregulatory action under Executive Order 13771.

IV. Paperwork Reduction Act

In accordance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we are required to solicit public comments, and receive final Office of Management and Budget (OMB) approval, on any information collection requirements set forth in rulemaking. This final rule will not impose any information collection burden or affect information currently collected by OIG.

List of Subjects in 42 CFR Part 1008

Administrative practice and procedure, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set out in the preamble, 42 CFR part 1008 is amended as follows:

PART 1008—ADVISORY OPINIONS BY THE OIG

■ 1. The authority citation for part 1008 continues to read as follows:

Authority: 42 U.S.C. 1320a–7d(b).

■ 2. Section 1008.15 is amended by revising paragraph (c) to read as follows:

§ 1008.15 Facts subject to advisory opinions.

* * * * *

(c) An advisory opinion request will not be accepted, and/or an opinion will not be issued when—

(1) The request is not related to a named individual or entity; or

(2) An informed opinion cannot be made, or could be made only after extensive investigation, clinical study, testing, or collateral inquiry.

* * * * *

Dated: January 3, 2022.

Christi A. Grimm,

Principal Deputy Performing Duties of the Inspector General.

Xavier Becerra,

Secretary.

[FR Doc. 2022–00313 Filed 1–7–22; 8:45 am]

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