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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 423

[CMS-6107-IFC]

RIN 0938-AS60

Medicare Program; Changes to the Requirements for Part D Prescribers

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

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period revises requirements related to beneficiary access to covered Part D drugs. Under these revised requirements, pharmacy claims and beneficiary requests for reimbursement for Medicare Part D prescriptions, written by prescribers other than physicians and eligible professionals who are permitted by state or other applicable law to prescribe medications, will not be rejected at the point of sale or denied by the plan if all other requirements are met. In addition, a plan sponsor will not reject a claim or deny a beneficiary request for reimbursement for a drug when prescribed by a prescriber who does not meet the applicable enrollment or opt-out requirement without first providing provisional coverage of the drug and individualized written notice to the beneficiary. This interim final rule with comment period also revises certain terminology to be consistent with existing policy and to improve clarity.

DATES: Effective date: These regulations are effective on June 1, 2015.

Applicability date: The provisions at § 423.120(c)(6) are applicable January 1, 2016.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [Insert date 60 days after date of publication in the **Federal Register**].

ADDRESSES: In commenting, please refer to file code CMS-6107-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four 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-6107-IFC,
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-6107-IFC,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC--
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW.,
Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

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

FOR FURTHER INFORMATION CONTACT:

Frank Whelan, (410) 786-1302 for enrollment issues.

Lisa Thorpe, (410) 786-3048, for provisional coverage, notice, and all other issues.

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 Web site as soon as possible after they have been received: <http://regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Background

A. Purpose

Under this interim final rule with comment period (IFC), pharmacy claims and beneficiary requests for reimbursement for Medicare Part D prescriptions, written by prescribers other than physicians and eligible professionals who are permitted by state or other applicable law to prescribe medications, will not be rejected at the point of sale or denied by the plan if all other requirements are met. In addition, a plan sponsor will not reject a claim or deny a beneficiary request for reimbursement for a drug on the grounds that the prescriber has not enrolled in or opted out of Medicare without first providing provisional coverage of the drug and individualized written notice to the beneficiary. These changes are necessary to help make certain that Medicare beneficiaries continue to have access to needed Part D medications. As explained in section III. of this IFC, we believe that we have good cause to make these changes in an IFC because the ordinary notice-and-comment process would be contrary to the public interest; furthermore, we believe that notice-and-comment rulemaking for the technical changes we are making in this IFC (as described in sections II.D., II.E., and II.F. of this IFC) is unnecessary because

these changes are not substantive and do not alter current policy.

B. Legal Authority

There are four principal statutory authorities for the provisions in this IFC.

First, sections 1102 and 1871 of the Social Security Act (the Act) provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

Second, section 1866(j) of the Act provides specific authority with respect to the Medicare enrollment process for providers and suppliers.

Third, section 6405(c) of the Affordable Care Act gives the Secretary the authority to require that pharmacy claims and beneficiary reimbursement requests for covered Part D drugs prescribed by a physician (as defined in section 1861(r) of the Act) or eligible professional (as defined in section 1848(k)(3)(B) of the Act) are not payable unless the prescribing physician or eligible professional is enrolled in Medicare under section 1866(j) of the Act.

Fourth, section 1860D-12(b)(3)(D) of the Act authorizes the Secretary to include in a contract with a Part D sponsor such other terms and conditions that are not inconsistent with Part D as the Secretary may find necessary and appropriate.

C. Provider Enrollment Process

The Medicare CMS-855 enrollment application collects information from providers and suppliers to confirm that they meet all Medicare requirements. Such data includes, but are not limited to, the provider's or supplier's licensure, tax identification number, National Provider Identifier (NPI), practice locations, final adverse action

history, and owning and managing individuals and organizations. Upon receiving a CMS-855 application from a physician or eligible professional, the CMS contractor validates the information and performs various screening activities, such as reviewing the System for Award Management (SAM) to confirm that the individual is not debarred from receiving payments under any federal health program. As explained in section II. of this IFC, we have taken measures to improve the provider enrollment process to determine whether enrolling physicians and eligible professionals meet all Medicare requirements.

D. Section 6405 of the Affordable Care Act and the May 23, 2014 Final Rule

As noted previously, section 6405(c) of the Affordable Care Act gives the Secretary the authority to extend the requirements of sections 6405(a) and (b) of the Affordable Care Act to all other categories of items or services under title XVIII of the Act that are ordered, prescribed, or referred by a physician or eligible professional, including covered Part D drugs. Sections 6405(a) and (b) of the Affordable Care Act require physicians and eligible professionals who order or certify durable medical equipment, prosthetics, orthotics, supplies, or home health services to be enrolled in Medicare.

In accordance with section 6405(c) of the Affordable Care Act, we established new § 423.120(c)(6) as part of a May 23, 2014 final rule titled, "Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" (79 FR 29843). Our objective was to help confirm that Part D drugs are prescribed only by physicians and eligible

professionals who are qualified to do so under state law and under the requirements of the Medicare program. Section 423.120(c)(6) currently contains the following provisions:

- A Part D sponsor must deny, or must require its pharmaceutical benefit manager (PBM) to deny, a pharmacy claim for a Part D drug if an active and valid physician or eligible professional National Provider Identifier (NPI) is not contained on the claim.
- A Part D sponsor must deny, or must require its PBM to deny, a pharmacy claim for a Part D drug if the physician or eligible professional-- is not enrolled in the Medicare program in an approved status; and does not have a valid opt-out affidavit on file with a Part A/B Medicare Administrative Contractor (MAC).
- A Part D sponsor must deny, or must require its PBM to deny, a request for reimbursement from a Medicare beneficiary for a drug if the request is not for a Part D drug that was dispensed in accordance with a prescription written by a physician or eligible professional who is identified by his or her legal name in the request; and
 - ++ Is enrolled in Medicare in an approved status; or
 - ++ Has a valid opt-out affidavit on file with a Part A/B MAC.
- In order for a Part D sponsor to submit to CMS a prescription drug event record (PDE), the PDE must contain an active and valid individual prescriber NPI and must pertain to a claim for a Part D drug that was dispensed in accordance with a prescription written by a physician or eligible professional who-- is enrolled in Medicare in an approved status; or has a valid opt-out affidavit on file with a Part A/B MAC.

These requirements apply as of June 1, 2015. However, on December 3, 2014,

through the Health Plan Management System (HPMS), we announced an enforcement delay until December 1, 2015. We are now in this IFC making another change to make these requirements applicable on January 1, 2016. Accordingly, and as explained in section II.C. of this IFC, we are making conforming changes to the regulation text.

II. Provisions of the Interim Final Rule with Comment Period

A. Enrollment

There are prescribers other than physicians and eligible professionals, such as pharmacists, who are legally authorized under state or other law to prescribe covered Part D drugs. For example, under a Pharmacist Collaborative Practice Agreement, pharmacists may be legally authorized to prescribe covered Part D under state or other law. However, pharmacists are not physicians under section 1861(r) of the Act or eligible professionals under section 1848(k)(3)(B) of the Act, and are therefore not eligible to enroll in or opt-out of Medicare. Under § 423.120(c)(6), as described previously in section I.D. of this IFC, beneficiaries who have been receiving necessary prescriptions from prescribers who are not Medicare-enrolled or opted-out physicians or eligible professionals will no longer be able to obtain Part D coverage for these prescriptions once the requirements of § 423.120(c)(6) are enforced. Changes to previously finalized policies regarding § 423.120(c)(6) are necessary to preserve beneficiaries' ability to obtain prescriptions for covered Part D drugs prescribed by certain practitioners ineligible to enroll in Medicare. We note that the definition of "physician" includes dentists, hence dentists are eligible to enroll in or opt-out of Medicare. Accordingly, this IFC revises § 423.120(c)(6)(ii), (iii), and (iv) such that

prescriptions provided by "other authorized prescribers" (as defined in § 423.100) may be covered under Part D. In other words, Part D sponsors will not be required to reject pharmacy claims or deny beneficiary requests for reimbursement for prescriptions written by "other authorized prescribers" on the basis that the prescriber is not enrolled in or opted-out of Medicare. Therefore, Part D sponsors will continue to be able to cover pharmacy claims at the point of sale (POS) for prescriptions written by "other authorized prescribers," provided all other existing Part D coverage requirements are met. We note, for example, that under §423.120(c)(6)(i), an "other authorized prescriber" must have an active and valid NPI which is contained in the pharmacy claim. This change will help beneficiaries to continue to receive needed prescriptions.

In § 423.100, we are defining "other authorized prescriber" as a person other than a physician (as defined in section 1861(r) of the Act) or eligible professional (as defined in section 1848(k)(3)(B) of the Act) who is authorized under state or other applicable law to write prescriptions. This definition, which applies to § 423.120(c)(6) only, will sufficiently protect the Medicare program because "other authorized prescribers" must have prescribing authority under state or other applicable law.

B. Provisional Coverage and Notice

We conclude that, in order to further minimize interruptions to Part D beneficiaries' access to needed medications, other changes are also needed to the May 23, 2014 final rule. This conclusion is based on our analysis of Medicare prescriber enrollment levels and trends since promulgation of the final rule and discussions with various stakeholders about their concerns regarding beneficiary access once the

provisions of § 423.120(c)(6) are enforced. Thus, we are modifying the provisions of § 423.120(c)(6) to prohibit sponsors from rejecting claims or denying beneficiary requests for reimbursement for a drug on the basis of the prescriber's enrollment status, unless the sponsor has first covered a 3-month provisional supply of the drug and provided individualized written notice to the beneficiary that the drug is being covered on a provisional basis. Such provisional supply and notice will allow sufficient time for an eligible prescriber to enroll in Medicare (or submit an opt-out affidavit), so that a beneficiary can continue to receive Part D coverage for the drug if prescribed by the same prescriber, or for the beneficiary to find a prescriber who meets the Medicare requirements to write Part D prescriptions. Enrolling in Medicare to prescribe or filing an opt-out affidavit is a process that can typically be completed within 3 months. In presumably rare cases when the prescriber will not enroll in Medicare or submit an opt-out affidavit, we believe the beneficiary should have sufficient time to find a prescriber whose prescriptions are coverable by the Part D program, if the beneficiary wishes to continue to receive Part D coverage for the drug. Once the Part D sponsor has provided the written notice to the beneficiary that a drug is being covered on a provisional basis because of the prescriber's current Medicare status, and the sponsor has covered the required provisional supply of the drug, the sponsor will be required to reject future claims and deny future requests for reimbursement for the beneficiary for the same drug if the prescription is from the same prescriber (unless the prescriber has enrolled or opted out in the meantime). We will issue future guidance as necessary on how sponsors and their PBMs should operationalize the term "drug" in their adjudication systems in

addition to other guidance, as needed.

The following discussion provides the rationale for adopting a same drug/same prescriber policy. First, beneficiaries may not readily know which prescribers are enrolled in or opted-out of Medicare and which are not. Therefore, our policy means that beneficiaries will receive a provisional supply and written notice about each unenrolled prescriber they see. Second, beneficiaries may need to fill multiple prescriptions from the same unenrolled prescriber, and we are particularly concerned about instances when beneficiaries need to do so in a short time period before their prescriber has been able to enroll or they have been able to find an enrolled prescriber. Therefore, our policy allows beneficiaries to receive more than one provisional supply from the same unenrolled prescriber for a different drug.

The pertinent regulation text in this IFC states that the Part D sponsor must do the following: "provide the beneficiary with... a 3-month provisional supply (as prescribed by the prescriber...)." This means that the Part D sponsor will be required to cover a full 3-month supply, if prescribed by the unenrolled practitioner, regardless of how the supply is dispensed. For example, a beneficiary may receive a provisional supply in accordance with a prescription written for a month's supply with two subsequent refills; a prescription written for a one-time 3-month's supply; or three prescriptions written for a 1-month's supply each. Conversely, an unenrolled prescriber might not prescribe a full 3-month's supply, and in such a case, the sponsor would of course not be required to provide a 3-month's provisional supply.

In addition, certain prescriptions cannot be refilled, such as Schedule II controlled

substances, and continuing supplies of such drugs are dispensed only upon a new prescription. For this reason, the regulation text also states that the provisional supply must be "allowed by applicable law."

We believe that a sponsor tracking dispensed provisional drug supplies is easier than tracking a timeframe after a dispensing event. Otherwise, in order to ensure a beneficiary receives a provisional supply of each drug prescribed by an unenrolled prescriber, Part D sponsors would have to keep track of rolling timeframes associated with the first dispensing event of each drug.

We note that providing beneficiaries with a provisional supply of a drug is consistent with other CMS requirements and Part D policies designed to provide reasonable access to needed medications. Under the Part D transition policy, for example, sponsors are generally required to cover off-formulary drugs (including drugs that are on-formulary but require prior authorization or step therapy) when a beneficiary changes prescription drug benefit plans and in other circumstances, in order to give the beneficiary and his or her prescriber time to find a suitable on-formulary drug or pursue an exception to continue taking the same drug.

The existing Part D transition policy is an example of an instance in which a beneficiary might not receive a full 3-months' supply under the provisions of this IFC, even when prescribed the full 3 months' supply, due to other existing Part D transition requirements which take precedence. If an unenrolled physician prescribes an off-formulary drug for a beneficiary that is subject to the transition requirements set forth in § 423.120(b)(3), and thus the provisional supply and notice requirements are

simultaneously triggered, the beneficiary would not be able to receive more than a 30-day supply of the drug from a retail pharmacy, unless a formulary exception is approved, consistent with existing transition requirements. Conversely, if a formulary exception is approved, the beneficiary could receive the remaining provisional supply. We will issue guidance as to how sponsors should provide written notices to the beneficiary when the sponsor is required to issue both a transition notice under § 423.120(b)(3)(iv) and a provisional supply notice under the revised requirements of § 423.120(c)(6).

Other examples when a beneficiary might not receive a full 3-month's provisional supply, or any provisional supply at all, is when the prescriber does not have an active and valid NPI. Under §423.120(c)(6)(i), the Part D sponsor or its PBM must reject a pharmacy claim unless it contains an active and valid prescriber NPI. Thus, a sponsor or its PBM cannot cover a provisional supply when the applicable pharmacy claim does not contain an active and valid prescriber NPI. Without a prescriber NPI, the sponsor or PBM would not be able to determine whether a drug should be covered on a provisional or regular basis, because the sponsor cannot determine the prescriber's Medicare enrollment or opt out status. An additional example is when the drug prescribed is subject to approved prior authorization or step therapy requirements by the plan. Such utilization management edits will still apply to provisional supplies. For these reasons, the regulation text in this IFC states that the Part D sponsor or its PBM must provide the beneficiary with a provisional supply and written notice "subject to all other Part D rules and plan coverage requirements."

In light of our previous discussion for provisional coverage, we have made the

following changes to § 423.120(c)(6):

- Revised paragraphs (c)(6)(ii)(A) and (c)(6)(iii) to add the clause "Except as provided in paragraph (c)(6)(v) of this section." The revised paragraphs would otherwise require Part D sponsors and their PBMs to reject pharmacy claims and deny beneficiary requests for reimbursement based on the Medicare status of the prescriber.

- Added new paragraph (c)(6)(v) to require that a Part D sponsor or its PBM not reject a pharmacy claim for a Part D drug under paragraphs (c)(6)(ii) or (c)(6)(iii) of this section unless the sponsor has provided the provisional coverage of the drug and written notice to the beneficiary required by paragraph (c)(6)(v)(B)..

- Added new paragraph (c)(6)(v)(B) to require that upon receipt of a pharmacy claim or beneficiary request for reimbursement for a Part D drug that a Part D sponsor would otherwise be required to reject or deny in accordance with paragraphs (c)(6)(ii) and (iii) of this section, a Part D sponsor or its PBM must provide the beneficiary with the following two things, subject to all other Part D rules and plan coverage requirements.

- Added new paragraph (c)(6)(v)(B)(1)(i) to require a Part D sponsor to provide a 3-month provisional supply of the drug (as prescribed by the prescriber and if allowed by applicable law).

- Added new paragraph (c)(6)(v)(B)(1)(ii) to require a Part D sponsor to provide written notice within 3 business days after adjudication of the claim or request in a form and manner specified by CMS.

- Added new paragraph (c)(6)(v)(B)(2) to require that a Part D sponsor or its PBM must ensure that reasonable efforts are made to notify the prescriber of a

beneficiary who was sent a notice.

C. Revision to Dates in § 423.120(c)(5) and (c)(6)

The requirements of § 423.120(c)(5), which address certain NPI submission and verification activities related to pharmacy claims for Part D drugs, apply before June 1, 2015. As mentioned in section I.C. of this IFC, the requirements of § 423.120(c)(6) apply beginning June 1, 2015. On December 3, 2014, we announced an enforcement delay of § 423.120(c)(6) until December 1, 2015. We are now in this IFC making another change to make these requirements applicable on January 1, 2016. This is to help make certain that stakeholders, such as beneficiaries and plan sponsors, have sufficient time to prepare for the requirements of § 423.120(c)(6).

To prevent potential confusion over the applicability of § 423.120(c)(5) and (c)(6), we are revising the dates identified therein. The beginning of § 423.120(c)(5) will be changed from "Before June 1, 2015, the following are applicable" to "Before January 1, 2016, the following are applicable". The beginning of § 423.120(c)(6) will be changed from "Beginning June 1, 2015, the following are applicable" to "Beginning January 1, 2016, the following are applicable". We believe these revisions are necessary so that stakeholders will understand precisely when the requirements of § 423.120(c)(5) and (c)(6) apply to them.

D. Rejection of Pharmacy Claims

This IFC also makes a technical change to § 423.120(c)(6)(i) and (ii) by replacing language that requires plan sponsors to "deny" pharmacy claims that do not meet the requirements of § 423.120(c)(6) with language requiring plan sponsors to "reject" such

claims. POS claim transactions are not considered coverage determinations under Part D program rules unless the plan chooses to treat the presentation of the prescription as a request for a coverage determination. Therefore, a Part D plan sponsor is not subject to the requirements for coverage determinations in part 423, subpart M, such as the timeframe and notification rules, nor to the requirements to conduct clinical review or to provide notice of appeal rights when a prescription cannot be filled under the Part D benefit at the POS. With the requirements finalized in the May 23, 2014 final rule (79 FR 29843), we did not intend to redefine the nature of POS transactions in the Part D program specifically for claims that are not paid at the POS because the prescriber does not meet the enrollment or opt-out requirements. We believe the word "deny" in the regulation text may incorrectly be interpreted to require plans to issue a standardized denial notice with appeal rights (OMB approval 0938-0976, "Notice of Denial of Medicare Prescription Drug Coverage", CMS-10146) for rejected claims at POS, rather than follow our existing requirements at §§ 423.128(b)(7)(iii) and 423.562(a)(3). These provisions require plans to arrange with their network pharmacies to distribute a copy of the standardized pharmacy notice (OMB approval 0938-0975, "Medicare Prescription Drug Coverage and Your Rights", CMS-10147) to the enrollee. We believe that this technical change will make the requirements at § 423.120(c)(6)(i) and (ii) consistent with our other requirements for POS claim transactions and existing National Council for Prescription Drug Programs guidance. We are retaining use of the term "deny" at § 423.120(c)(6)(iii), because plan sponsors are required to treat an enrollee request for reimbursement as a coverage determination under subpart M.

E. Name on Beneficiary Reimbursement Requests

We also made a technical change at § 423.120(c)(6)(iii) by replacing "legal name" with "name" for beneficiary reimbursement requests. Requiring that beneficiary requests for coverage include the prescriber's legal name is inconsistent with the existing standard required for coverage determination requests at § 423.568(a) and related subregulatory guidance and is overly burdensome for beneficiaries. Throughout Chapter 18 of the Medicare Prescription Drug Manual (particularly section 30.3), CMS guidance to plan sponsors includes an expectation that plan sponsors will make reasonable and diligent efforts to obtain any missing information required to process beneficiary requests when the request does not include all information needed to make a decision, such as the prescriber's legal name, if necessary to determine coverage under the prescriber enrollment requirements. Additionally, Chapter 5, section 90.2.2 contains language stating that plans can require beneficiary requests for reimbursement to include prescriber name (not "legal name") and address or phone number or pharmacy name and phone number to assist the plan in locating the prescriber NPI necessary to submit the PDE to CMS. We recognize that the "legal name" standard was included in § 423.120(c)(6) because it was adopted for Part A/B ordering and referring claims at § 424.507(a)(2). However, given the regulations and manual guidance previously discussed, we do not believe this standard is appropriate for Part D beneficiary reimbursement requests.

F. Other Technical Changes

In addition to the previously described revisions, we are making the following minor technical changes to § 423.120(a)(6)(i) through (iv). (These changes will not

affect the requirements or substance of these paragraphs.)

- In paragraphs (c)(6)(i), (ii), and (iii), we replaced the word "if" with "unless," and deleted the word "not." The current versions of these paragraphs are written in the negative, which has caused confusion for some readers. We believe these changes will clarify these paragraphs.

- In paragraphs (c)(6)(i) and (iv), we replaced references to "physicians" and "eligible professionals" with the term "prescriber." The latter word is necessary to reflect that these paragraphs also apply to prescribing individuals other than physicians and eligible professionals.

- In paragraph (c)(6)(ii), the current opening paragraph is incorporated into revised paragraph (c)(6)(ii)(A). Current paragraphs (c)(6)(ii)(A) and (B) are redesignated as new paragraphs (c)(6)(ii)(A)(1) and (2). The requirements pertaining to other authorized prescribers are addressed in revised paragraph (c)(6)(ii)(B). These organizational revisions of (c)(6)(ii) are necessary in order to incorporate the substantive and technical changes discussed in this IFC.

- In the opening paragraph of (c)(6)(iii), we changed the language "for a drug if the request is not for a Part D drug that was dispensed in accordance with a prescription written by" to "unless the request pertains to a Part D drug that was prescribed by". This is to make the paragraph clearer and more readable. We also--

- ++ Changed paragraph (c)(6)(iii)(A) from "Is identified by his or her legal name in the request" to "A physician or, when permitted by applicable State law, other eligible professional (as defined in section 1848(k)(3)(B) of the Act) who is identified by name in

the request; and who".

++ Redesignated current paragraphs (c)(6)(iii)(B)(1) and (2) as new paragraphs (A)(1) and (2). The requirements pertaining to other authorized prescribers are addressed in revised paragraph (c)(6)(iii)(B).

These technical revisions to (c)(6)(iii) are needed to accommodate the substantive and technical revisions heretofore discussed in this IFC.

- In paragraph (c)(6)(iv) we are making the following changes:

++ The opening paragraph is changed from "In order for a Part D sponsor to submit to CMS a prescription drug event record (PDE), the PDE must contain an active and valid individual prescriber NPI and must pertain to a claim for a Part D drug that was dispensed in accordance with a prescription written by a physician or, when permitted by applicable State law, an eligible professional (as defined in section 1848(k)(3)(B) of the Act) who" to "A Part D plan sponsor submitting a prescription drug event (PDE) to CMS must include on the PDE the active and valid individual NPI of the prescriber of the drug, who must". We believe the new language is more concise and straightforward.

++ We have redesignated current paragraphs (c)(6)(iv)(A) and (B) as new paragraphs (c)(6)(iv)(A)(1) and (2). The requirements pertaining to other authorized prescribers are addressed in revised paragraph (c)(6)(iv)(B).

These technical revisions to paragraph (c)(6)(iv) are needed to accommodate the substantive and technical revisions discussed in this IFC.

III. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed and the terms and substance of the proposed rule or a description of the subjects and issues involved. However, this procedure can be waived if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

We believe we have good cause to make our previously discussed changes in this IFC. Concerning the substantive changes, we believe that notice-and-comment rulemaking is contrary to the public interest for the reasons that follow.

Several months after publication of the May 23, 2014 final rule that imposed the enrollment or opt-out requirement as of June 1, 2015, it was brought to our attention during implementation that there are prescribers who can and do prescribe Part D medications but who are also unable to enroll in Medicare to prescribe because they do not technically meet even the broad definition of “eligible health professional.” The May 23, 2014 final rule was not only complex and controversial, but with respect to the prescriber enrollment provisions themselves, we were focused on the fact that dentists can enroll and represent the largest group of unenrolled current Part D prescribers. Additionally, we did not receive any explicit comments on the pharmacist issue.

Once we became aware of the issue, we promptly considered alternatives to address it, such as directing pharmacists to opt-out, but concluded that this is not permissible under the applicable statutory language. Ultimately, we came to the

conclusion that the May 23, 2014 rule must be updated. The existing rule could cause an unintended disruption in beneficiaries' access to Part D drugs because under the current regulations, as of June 1, 2015, pharmacists' (and potentially certain other prescribers') prescriptions could not be filled.

Additionally, we concluded that changes to the May 23, 2014 rule needed to include a provisional supply to prevent disruptions to beneficiaries' access to Part D drugs. This is based on our monitoring of prescriber enrollment levels and trends and meetings with stakeholders during implementation. Prescriber enrollment is a voluntary act, and while we remain confident that the Part D prescribers who need to enroll or opt-out will ultimately do so in large numbers, it will take some time. The non-dentist and non-pharmacist prescribers who need to enroll are ones who did not enroll to be able to order and certify under § 424.507. In addition, dentists are a group of providers that has not yet had a robust direct relationship with Medicare due to the fact that dentists generally do not bill Medicare for their services. Since it is in the public's interest that we make certain that beneficiary access to needed drugs will not be impaired when these important program integrity protections become applicable, we have also added the provisional supply provisions in this IFC. Without such swift action, we would be forced to either enforce the rule as written, which could cause beneficiary harm by disrupting access, or further delay enforcement, which also could cause beneficiary harm by continuing to permit unqualified individuals to prescribe Part D drugs. Both outcomes are contrary to the public interest. In addition, the provisional supply provisions include a written notice to the beneficiary. We believe that the written notices will result in

beneficiaries' discussing the enrollment status issue with their prescribers, which will assist in our prescriber enrollment efforts. In addition, to resolve these problems, it is necessary to implement the provisions of this IFC prior to the Medicare Part D bid deadline for the 2016 contract year, which begins on January 1, 2016. The statutory bid deadline this year is June 1, 2015. Any changes to Part D requirements for contract year 2016 must be implemented prior to the bid deadline so that Part D sponsors may account for them in their bids; we cannot impose costly new requirements on the plans for a contract year that are not accounted for in their bids for that contract year under section 1860D-12(f)(2) of the Act. Thus, an IFC is the only means for ensuring that our requirements do not cause unintended disruption to beneficiary access to Part D drugs, while ensuring that the changes that will minimize such disruptions are incorporated into Part D sponsors' 2016 bids; the length of time involved with notice-and rulemaking would prevent us from accomplishing these objectives without further delaying enforcement of the existing regulations, which for the reasons discussed later in this section, could cause beneficiary harm. Moreover, a prompt publication is necessary to give Part D plan sponsors time to implement the operational changes needed for them to be prepared for these requirements in the 2016 contract year.

If Part D sponsors were unable to account for these new requirements in their 2016 bids, we would have to delay the applicability date of the enrollment/opt-out requirements to no sooner than January 1, 2017. We believe that such an outcome similarly is contrary to the public interest because it would unduly delay the extremely important program integrity and basic quality assurance protection for Medicare

beneficiaries that we implemented in our May 23, 2014 final rule, and beneficiaries could be harmed as a result. As we explained in the May 23, 2014 final rule, we have been concerned about instances where unqualified individuals are prescribing Part D drugs. In fact, in a June 2013 report the OIG found that the Part D program inappropriately paid for drugs ordered by individuals who did not appear to have the authority to prescribe. (See "Medicare Inappropriately Paid for Drugs Ordered by Individuals Without Prescribing Authority" (OEI-02-09-00608).) There have also been reports that the prescriptions of physicians with suspended licenses have been covered by the Part D program.

The Centers for Disease Control and Prevention (CDC) has characterized prescription drug abuse as an epidemic, and found that an increase in painkiller prescribing is the key driver of the increase in prescription overdoses.¹ The CDC reports that the drug overdose death rate has more than doubled from 1999 through 2013, and more than half of those deaths were related to pharmaceuticals.² The Department of Health and Human Services has several initiatives to address prescription drug abuse; for instance, the National Institute on Drug Abuse, the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration are working with public and private stakeholders to reduce opioid overdoses. CMS has also adopted an approach to reduce opioid overutilization in Medicare Part D.

The new enrollment requirements addressed in the May 23, 2014 final rule represent an important component of this effort and are a crucial program integrity and basic quality assurance protection for Medicare beneficiaries, for the requirements help

¹ <http://www.cdc.gov/vitalsigns/pdf/2014-07-vitalsigns.pdf>

² <http://www.cdc.gov/homeandrecreationalafety/overdose/facts.html>

us to confirm that prescribers are qualified to prescribe Part D drugs. It is important that these protections are in place as soon as possible. We have identified 68,000 prescribers that have been removed from Medicare for reasons such as licensure issues, operational status, or exclusion by the OIG, and we have a responsibility to enforce these protections to beneficiaries as soon as possible without compromising continuity of care or beneficiary access to needed medications. The CDC has recommended swift regulatory action against health care providers acting outside the limits of accepted medical practice to decrease provider behaviors that contribute to prescription painkiller abuse, diversion, and overdose.³

Thus, for all of these reasons, we find good cause to waive prior notice and comment with respect to the substantive changes being made in this IFC.

With respect to the technical changes being made in this IFC, we believe notice-and-comment rulemaking is unnecessary because these changes are not substantive and do not alter current policy.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

³ <http://www.cdc.gov/drugoverdose/pdf/policyimpact-prescriptionpainkillerod-a.pdf>

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.

- The accuracy of our estimate of the information collection burden.

- The quality, utility, and clarity of the information to be collected.

- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on the following section of this document that contains information collection requirements (ICRs).

We believe the principal information collection requirement associated with this IFC is that some Part D sponsors and PBMs will need to collect information about which NPIs are for "other authorized prescribers" in order to properly adjudicate pharmacy claims containing such prescriber NPIs in light of the revised provisions of §423.120(c)(6) in this IFC. However, we estimate that half of the 30 Part D sponsors and PBMs with Part D adjudications systems already collect information about the prescriptive authority of prescriber NPIs in order to mitigate current potential audit risks associated with submitting PDEs to CMS for Part D drugs that were not dispensed upon a valid prescription.

In a CMS analysis of PDE data, there were just over 1.3 million prescribers writing Part D prescriptions in 2013. Approximately 17,000 of these prescribers have NPIs a taxonomy in the National Provider & Plan Enumeration System (NPPES) that would fall under the definition of "other authorized prescribers" (largely pharmacist taxonomies).

NPIs and the addresses and taxonomy codes that pertain to them are publicly available information through the CMS website for NPPES. We estimated that collecting information about which NPIs are for "other authorized prescribers" would take an average of 30 minutes (0.5 hours) per NPI associated with a pharmacist or 8,500 hours, and the estimated total burden for 15 sponsors/PBMs to be 17,500 hours for 2016. The estimated total annual cost for this burden is \$3,343,050. This is based upon the national median hourly rate of \$26.22 for insurance claim and policy processing clerk multiplied by the number of burden hours in 2016. We did not estimate any burden in 2017 and 2018 for the collection of information about "other authorized prescriber" NPIs, as the number of new pharmacist NPIs and existing pharmacist NPIs becoming inactive will be negligible in light of the fact that there are only approximately 17,000 total "other authorized prescribers" writing Part D prescriptions in 2013.

We note that since NPPES is not a provider credentialing system, but rather an enumeration system that contains self-reported credentials, Part D sponsors might not rely upon a taxonomy in NPPES as documentation that an NPI in fact belongs to a pharmacist with an active license who is permitted to prescribe. We have used data from NPPES to provide an estimate as to how many "other authorized prescribers" NPIs about which Part D sponsors and PBMs will need to collect information.

In the alternative, we understand that Part D sponsors/PBMs may purchase prescriber ID validation services from a private company that can provide them with a list of "other authorized providers." However, we do not provide a collection estimate for all options that sponsors/PBMs may have in implementing the provisions of this IFC.

We also revised the provisions of § 423.120(c)(6) to require Part D sponsors to cover a provisional supply of a drug before they reject a claim based on a prescriber's Medicare status. These modifications will also require Part D sponsors to provide written notice to the beneficiary and take reasonable efforts to provide written notice to the prescriber. The burden associated with these modifications is the time and effort necessary for Part D adjudications systems to be programmed, model notices to be created, and such notices to be generated and disseminated to perform these tasks. We estimated that this will take 30 sponsors and PBMs with Part D adjudications systems 156,000 hours for software developers and programmers to program their systems in 2016 to comply with the modifications to § 423.120(c)(6) in this IFC. In 2017 and 2018, we estimated the total burden to be 83,000 hours for each year.

We estimated the total hours by estimating a 6-month preparation and testing period. Six months includes approximately 1,040 full-time working hours. We estimated 5 full time staff (or 10 staff working half their hours on this project). Five staff x 1,040 hours x 30 sponsors/PBMs = 156,000 total hours. We estimated an hourly rate of \$64.32 for such developers and programmers, which is \$10,033,920 in total burden cost.

We also estimated 212 parent organizations will create two template notices to notify beneficiaries and prescribers under the modifications of § 423.120(c)(6). We estimated this will take 3 hours per entity for a total of 636 hours. We estimated an hourly rate of \$45.54 for a business operation specialist to create such notices. Thus, the total estimated burden cost for parent organizations to create two model notices is \$28,963.44.

Once the templates have been developed, we estimated that these notices would take an average of 5 minutes (0.083 hours) to prepare. Thus, we estimated the annual burden hours for 2016 to be 1,743,000 hours. This is based upon the national median hourly rate of \$26.22 for an insurance claim and policy processing clerk multiplied by the number of burden hours. The estimated annual burden cost for 2016 is \$45,701,460.

Therefore, we estimated the total regulatory impact for these provisions in 2016 to be \$55,764,343.44 (\$10,033,920 + \$28,963.44 + \$45,701,460).

Approximately 2 million beneficiaries enter the Part D program every year. If we assume that 25 percent of these new beneficiaries will see 1 prescriber who is not enrolled or opted out, and that prescriber prescribes 2 drugs, we anticipate that parent organizations will have to send 1 million notices in 2017 and 2018 each (250,000 beneficiaries x 2 prescriptions x 2 notices each = 1,000,000). We estimate these notices would take an average of 5 minutes (0.083 hours) to prepare. Thus, we estimate the total burden to be 83,000 hours for each year, and the annual cost to be \$2,176,260. This is based upon the national median hourly rate of \$26.22 for insurance claim and policy processing clerk multiplied by the number of burden hours.

Table 1 outlines the projected costs of this IFC commencing 2016 through 2018:

TABLE 1: PROJECTED BURDEN COSTS

	Programming	Create Notices	Send Notices	Annual Impact
2016	\$10,033,920	\$28,963.44	\$45,701,460	\$55,764,343.44
2017	N/A	N/A	\$2,176,260	\$2,176,260
2018	N/A	N/A	\$2,176,260	\$2,176,260

If you comment on these information collection and recordkeeping requirements,

please do either of the following:

1. Submit your comments electronically as specified in the ADDRESSES section of this interim final rule with comment period; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, [CMS-6107-IFC]

Fax: (202) 395-6974; or

Email: OIRA_submission@omb.eop.gov

V. 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, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Statement

We have examined the impacts of this rule 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) and Executive Order 13132 on Federalism (August 4, 1999).

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 rules with economically significant effects (\$100 million or more in any 1 year). The impact of this IFC is directly associated with the information collection requirements discussed in section IV. of this IFC and will not exceed \$100 million in any one year. Therefore, this IFC is not a major rule.

The average Part D beneficiary takes 9 drugs prescribed by three prescribers annually. Based on 2013 PDE data, approximately 380,000 (28 percent) Part D prescribers were not found in the Provider Enrollment, Chain, and Ownership System (PECOS) and are associated with just under 8,000,000 unique beneficiaries. Generally, PECOS is the CMS record database of all physicians and eligible professionals who are or were enrolled in or opted out of Medicare. Thus, these prescribers write prescriptions on average for 21 beneficiaries ($8,000,000/380,000 = 21$). For purposes of this analysis, we assumed that on January 1, 2016, 250,000 prescribers will still need to enroll in or opt-out of Medicare to prescribe coverable Part D drugs. We also assume that these 250,000 prescribers will write prescriptions for 5.25 million beneficiaries ($250,000 \times 21$). We further assume that no beneficiaries will switch prescribers until they receive a notice that a drug is being covered on a provisional basis. Additionally, we assumed that these prescribers will write on average two prescriptions for each of these beneficiaries. We assumed that Part D parent organizations will be able to send each prescriber a notice.

Finally, we did not offset our estimation in light of our expectation that, in some cases, transition and provisional supply notices will be combined into one notice. We estimated that parent organizations will send 21 million beneficiary and prescriber notices in accordance with the modifications to § 423.120(c)(6) in 2016 (5,250,000 beneficiaries x 2 prescriptions x 2 notices each = 21,000,000), which we expect to occur as a downward trend that we do not reflect in this analysis.

Prescribers are expected to enroll on a steady basis throughout 2016 as a result of the prescriber enrollment requirements. By 2017, we expect that the majority of Part D prescribers will have enrolled in or opted out of Medicare in order for their prescriptions to be coverable by the Part D program. When a prescriber does not enroll or opt out, the beneficiary will either change to a prescriber who is enrolled or opted out, or the beneficiary will pay out of pocket for the prescriptions written by that prescriber. Nevertheless, parent organizations will have to send notices on an ongoing basis to beneficiaries who are new to the Part D program and receive a prescription from a prescriber who is not enrolled in or opted out of Medicare.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most entities and most other providers and suppliers are small entities, either by nonprofit status or by having revenues between \$7.5 million and \$38.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We do not believe that this IFC would have a significant economic impact on a substantial number of small businesses, as Part D

sponsors and parent organizations do not generally meet the definition of a small business.

Section 1102(b) of the 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 that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined and the Secretary certified that this IFC would 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 (UMRA) 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 2015, this is approximately \$144 million. We believe that this IFC will have no consequential effect 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 requirements or costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable. In accordance with the provisions of Executive Order 12866, this IFC was

reviewed by the Office of Management and Budget.

List of Subjects in 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.

For the reasons stated in the preamble of this interim final rule with comment period, the Centers for Medicare & Medicaid Services amends 42 CFR part 423 as follows:

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG PROGRAM

- 1. The authority citation for part 423 continues to read as follows:

Authority: Secs. 1102, 1106, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh).

- 2. Amend § 423.100 by adding a definition of "Other authorized prescriber" in alphabetical order to read as follows:

§ 423.100 Definitions.

* * * * *

Other authorized prescriber means, for purposes of § 423.120(c)(6) only, an individual other than a physician (as defined in section 1861(r) of the Act) or eligible professional (as defined in section 1848(k)(3)(B) of the Act) who is authorized under State or other applicable law to write prescriptions.

* * * * *

- 3. Amend § 423.120 by revising paragraphs (c)(5) introductory text and (c)(6) to read as follows:

§ 423.120 Access to covered Part D drugs.

* * * * *

(c) * * *

* * * * *

(5) Before January 1, 2016, the following are applicable:

* * * * *

(6) Beginning January 1, 2016, the following are applicable:

(i) A Part D plan sponsor must reject, or must require its pharmaceutical benefit manager (PBM) to reject, a pharmacy claim for a Part D drug unless the claim contains the active and valid National Provider Identifier (NPI) of the prescriber who prescribed the drug.

(ii)(A) Except as provided in paragraph (c)(6)(v) of this section, a Part D plan sponsor must reject, or must require its PBM to reject, a pharmacy claim for a Part D drug unless the physician or, when permitted by applicable State law, the eligible professional (as defined in section 1848(k)(3)(B) of the Act) who prescribed the drug ---

(1) Is enrolled in the Medicare program in an approved status; or

(2) Has a valid opt-out affidavit on file with a Part A/B Medicare Administrative Contractor (MAC).

(B) Pharmacy claims for Part D drugs prescribed by an other authorized prescriber (as defined in § 423.100) are not subject to the requirements specified in paragraph (c)(6)(ii)(A) of this section.

(iii) Except as provided in paragraph (c)(6)(v) of this section, a Part D plan sponsor must deny, or must require its PBM to deny, a request for reimbursement from a Medicare beneficiary unless the request pertains to a Part D drug that was prescribed by--

(A) A physician or, when permitted by applicable State law, other eligible professional (as defined in section 1848(k)(3)(B) of the Act) who is identified by name in the request and who--

(1) Is enrolled in Medicare in an approved status; or

(2) Has a valid opt-out affidavit on file with a Part A/B MAC; or

(B) An other authorized prescriber (as defined in § 423.100) who is identified by name in the request.

(iv) A Part D plan sponsor submitting a prescription drug event (PDE) to CMS must include on the PDE the active and valid individual NPI of the prescriber of the drug, who must--

(A)(1) Be enrolled in Medicare in an approved status, or

(2) Have a valid opt out affidavit on file with a Part A/B MAC; or

(B) Be an other authorized prescriber (as defined in § 423.100).

(v)(A) A Part D sponsor or its PBM must not reject a pharmacy claim for a Part D drug under paragraph (c)(6)(ii) of the section or deny a request for reimbursement under paragraph (c)(6)(iii) of this section unless the sponsor has provided the provisional coverage of the drug and written notice to the beneficiary required by paragraph (c)(6)(v)(B) of this section.

(B) Upon receipt of a pharmacy claim or beneficiary request for reimbursement for a Part D drug that a Part D sponsor would otherwise be required to reject or deny in accordance with paragraphs (c)(6)(ii) or (iii) of this section, a Part D sponsor or its PBM must do the following:

(1) Provide the beneficiary with the following, subject to all other Part D rules and plan coverage requirements:

(i) A 3-month provisional supply of the drug (as prescribed by the prescriber and if allowed by applicable law).

(ii) Written notice within 3 business days after adjudication of the claim or request in a form and manner specified by CMS.

(2) Ensure that reasonable efforts are made to notify the prescriber of a beneficiary who was sent a notice under paragraph (c)(6)(v)(B)(1)(ii) of this section.

* * * * *

CMS-6107-IFC

Dated: April 17, 2015.

Andrew M. Slavitt,
Acting Administrator,
Centers for Medicare & Medicaid Services.

Dated: April 29, 2015.

Sylvia M. Burwell,
Secretary,
Department of Health and Human Services.

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