DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, 423, and 460

[CMS–4201–F4 and CMS–4205–F3]

RIN 0938–AV24 and 0938–AU96

Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024—Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE); Correcting Amendment

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule; correcting amendment.

SUMMARY: This document corrects technical and typographical errors in the final rule that appeared in the April 23, 2024 **Federal Register** titled ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024—Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE).'' The effective date of the final rule was June 3, 2024.

DATES: This correcting amendment is effective August 6, 2024.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. FR 2024–07105 of April 23, 2024 (89 FR 30448), the final rule titled ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024—Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE)'', there were several typographical and technical errors that are identified and corrected in this correcting amendment.

II. Summary of Errors

A. Summary of Errors in the Preamble

On page 30448, we inadvertently omitted the applicability date specific to the Programs of All-inclusive Care for the Elderly (PACE) Past Performance (§§ 460.18 and 460.19) provisions.

On page 30524, we erroneously included language regarding a proposed provision that was not being finalized.

On page 30626, in Table FC–2, we made a technical error in a value presented in Table FC–2.

On page 30712, we are correcting an inadvertent error in a reference.

On page 30766, we inadvertently omitted language regarding the changes being finalized in § 460.120(g).

On page 30797 and 30798, we made a few typographical errors in Table J9.

B. Summary of Errors in the Regulations Text

On pages 30816, 30818, 30819, 30829, 30831, and 30832, we are correcting typographical and technical errors in the amendatory instructions by setting forth amendatory instructions, regulations text or both for §§ 422.74(d)(4)(i), 422.102(f)(4), 422.116(f)(1), 422.2274(c)(13),[1] 423.44(d)(2)(iii) through (viii), and 423.100.

On page 30818, we are also correcting a typographical error in the paragraph reference in § 422.102(f)(4)(iii)(B).

On page 30828, we are correcting typographical and technical errors in the regulations text of § 422.2267(e)(34).

On pages 30837 and 30839, we are correcting typographical errors in the numbering of paragraphs in §§ 423.501 and 423.522, respectively.

On page 30841, we are correcting typographical errors in the regulations text of § 423.584.

On page 30843, we are correcting the inadvertent omission of § 460.12(b)(3) in the regulations text.

On page 30848, in the regulations text for § 460.120(h)(4), we are correcting a technical error in referencing other applicable requirements.

III. Waiver of Proposed Rulemaking and Delay in Effective Date

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of the proposed rule in the **Federal Register** before the provisions of a rule take effect. Specifically, 5 U.S.C. 553 requires the agency to publish a notice of the proposed rule in the **Federal Register** that 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. Further, 5 U.S.C. 553 requires the agency to give interested parties the opportunity to participate in the rulemaking through public comment on a proposed rule. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment for rulemaking to carry out the administration of the Medicare program under title XVIII of the Act. In addition, section 553(d) of the APA, and section 1871(e)(1)(B)(i) of the Social Security Act (the Act) mandate a 30-day delay in effective date after issuance or publication of a rule. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the notice and comment and delay in effective date APA requirements. In cases in which these exceptions apply, sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act, also provide exceptions from the notice and 60-day comment period and delay in effective date requirements of the Act. Section

[1] CMS acknowledges that certain changes to its agent-broker compensation regulations, which were finalized as part of the April 2024 final rule, are the subject of pending litigation. On July 3, 2024, the U.S. District Court for the Northern District of Texas issued nationwide preliminary injunctions in *Americans for Beneficiary Choice* v. *HHS,* No. 4:24–cv–00439, and *Council for Medicare Choice* v. *HHS,* No. 4:24–cv–00446, which enjoined the implementation of the changes to §§ 422.2274(a), (c), (d), and (e) and 423.2274(a), (c), (d), (e). For additional guidance, please see the July 18, 2024 HPMS memorandum, ''Updated: Contract Year 2025 Agent and Broker Compensation Rates, Submissions, and Training and Testing Requirements,'' available at *https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-3-july-15-19.*

553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal rulemaking requirements for good cause if the agency makes a finding that the notice and comment process are impracticable, unnecessary, or contrary to the public interest. In addition, both section 553(d)(3) of the APA and section 1871(e)(1)(B)(ii) of the Act allow the agency to avoid the 30-day delay in effective date where such delay is contrary to the public interest and an agency includes a statement of support.

We believe that this correcting amendment does not constitute a rule that would be subject to the notice and comment or delayed effective date requirements of the APA or section 1871 of the Act. This correcting amendment corrects typographical and technical errors in the preamble and regulatory text of the final rule but does not make substantive changes to the policies that were adopted in the final rule. As a result, this correcting amendment is intended to ensure that the information in the final rule accurately reflects the policies adopted in that final rule.

In addition, even if this were a rule to which the notice and comment procedures and delayed effective date requirements applied, we find that there is good cause to waive such requirements. Undertaking further notice and comment procedures to incorporate the regulatory text correction in this document into the final rule or delaying the effective date would be unnecessary, as we are not altering our policies or regulatory changes, but rather, we are simply implementing the policies and regulatory changes that we previously proposed, requested comment on, and subsequently finalized.

This final rule correcting amendment is intended solely to ensure that the final rule and the Code of Federal Regulations (CFR) accurately reflect policies and regulatory changes that have been adopted through rulemaking. Furthermore, such notice and comment procedures would be contrary to the public interest because it is in the public's interest to ensure that the final rule accurately reflects our policies and regulatory changes. Therefore, we believe we have good cause to waive the notice and comment and effective date requirements.

IV. Correction of Errors

In FR Doc. FR 2024–07105 of April 23, 2024 (89 FR 30448), make the following corrections:

A. Corrections to the Preamble

1. On page 30448, second column, first full paragraph (continuation of the Applicability Dates), last line, the paragraph is corrected by adding the following sentence:

''The PACE Past Performance provisions at §§ 460.18 and 460.19 are applicable to PACE applications submitted beginning January 1, 2025.''.

2. On page 30524, second column, first full paragraph, lines 21–25, the phrase ''electronic health record. See section III.L.5. of this final rule for a discussion of our proposals to enable more widespread access to RTBTs through the adoption of a standard.'' is corrected to read ''electronic health record.''.

3. On page 30626, lower half of the page, in the table titled ''TABLE FC–2: EXAMPLE AGENT BROKER COMPENSATION UPDATES CY 2024–2026,'' third column, last row, the figure ''$313'' is corrected to read ''$363''.

4. On page 30712, third column, first partial paragraph, line 15, the reference ''May 2020 final rule'' is corrected to read ''June 2020 final rule''.

5. On page 30766, first column, the fourth full paragraph, last line, the phrase ''without modification.'' is corrected to read ''without modification to the requirement. Additionally, we reorganized some introductory language at § 460.120(g), (g)(1), and (g)(2) to reduce repetitive language that did not affect the substance of the requirements.''.

6. On page 30797, in the table titled ''TABLE J9: SUMMARY OF ANNUAL INFORMATION COLLECTION REQUIREMENTS AND BURDEN *'', fourth column, last row, the ''-'' is corrected to read ''1,000,000 Enrollees''.

7. On page 30798, in the table titled ''TABLE J9: SUMMARY OF ANNUAL INFORMATION COLLECTION REQUIREMENTS AND BURDEN *'', fourth column, last row, the figure ''3474836'' is corrected to read ''4,474,836''.

List of Subjects

42 CFR Part 417

Administrative practice and procedure, Grant programs—health, Health care, Health Insurance, Health maintenance organizations (HMO), Loan programs—health Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Citizenship and naturalization, Civil rights, Health, Health care, Health records, Individuals with disabilities, Medicaid, Medicare, Religious discrimination, Reporting and recordkeeping requirements, Sex discrimination.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as set forth below.

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 1. The authority citation for part 422 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–21 through 1395w–28, and 1395hh.

■ 2. Section 422.74 is amended by revising paragraph (d)(4)(i) to read as follows:

§ 422.74 Disenrollment by the MA organization.

* * * * *

(d) * * *

(4) * * *

(i) *Basis for disenrollment.* Unless continuation of enrollment is elected under § 422.54, the MA organization must disenroll an individual, and must document the basis for such action, if the MA organization establishes, on the basis of a written statement from the individual or other evidence acceptable to CMS, that the individual has permanently moved—

(A) Out of the MA plan's service area or is incarcerated as specified in paragraph (d)(4)(v) of this section.

(B) From the residence in which the individual resided at the time of enrollment in the MA plan to an area outside the MA plan's service area, for those individuals who enrolled in the MA plan under the eligibility requirements at § 422.50(a)(3)(ii) or (a)(4).

* * * * *

■ 3. Section 422.102 is amended by adding paragraph (f)(4) to read as follows:

§ 422.102 Supplemental benefits.

* * * * *

(f) * * *

(4) *Plan responsibilities.* An MA plan offering SSBCI must do all of the following:

(i) Have written policies for determining enrollee eligibility and must document its determination that an enrollee is a chronically ill enrollee based on the definition in paragraph (f)(1)(i) of this section.

(ii) Make information and documentation related to determining enrollee eligibility available to CMS upon request.

(iii)(A) Have and apply written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI; and

(B) Document the written policies specified in paragraph (f)(4)(iii)(A) of this section and the objective criteria on which the written policies are based.

(iv) Document each eligibility determination for an enrollee, whether eligible or ineligible, to receive a specific SSBCI and make this information available to CMS upon request.

(v) Maintain without modification, as it relates to an SSBCI, evidentiary standards for a specific enrollee to be determined eligible for a particular SSBCI, or the specific objective criteria used by a plan as part of SSBCI eligibility determinations for the full coverage year.

* * * * *

■ 4. Section 422.116 is amended by revising paragraph (f)(1) to read as follows:

§ 422.116 Network adequacy.

* * * * *

(f) * * *

(1) An MA plan may request an exception to network adequacy criteria in paragraphs (b) through (e) of this section when either paragraph (f)(1)(i) or (ii) of this section is met:

(i)(A) Certain providers or facilities are not available for the MA plan to meet the network adequacy criteria as shown in the Provider Supply file for the year for a given county and specialty type; and

(B) The MA plan has contracted with other providers and facilities that may be located beyond the limits in the time and distance criteria, but are currently available and accessible to most enrollees, consistent with the local pattern of care.

(ii)(A) A facility-based Institutional-Special Needs Plan (I–SNP) is unable to contract with certain specialty types required under § 422.116(b) because of the way enrollees in facility-based I–SNPs receive care; or

(B) A facility-based I–SNP provides sufficient and adequate access to basic benefits through additional telehealth benefits (in compliance with § 422.135) when using telehealth providers of the specialties listed in paragraph (d)(5) of this section in place of in-person providers to fulfill network adequacy standards in paragraphs (b) through (e) of this section.

* * * * *

■ 5. Section 422.2267 is amended by revising paragraph (e)(34) to read as follows:

§ 422.2267 Required materials and content.

* * * * *

(e) * * *

(34) *SSBCI disclaimer.* This is model content and must be used by MA organizations that offer CMS-approved SSBCI as specified in § 422.102(f). In the SSBCI disclaimer, MA organizations must include the information required in paragraphs (i) through (iii) of this section. MA organizations must do all of the following:

(i) Convey the benefits mentioned are a part of special supplemental benefits.

(ii) List the chronic condition(s) the enrollee must have to be eligible for the SSBCI offered by the applicable MA plan(s), in accordance with the following requirements.

(A) The following applies when only one type of SSBCI is mentioned:

(*1*) If the number of condition(s) is five or fewer, then list all condition(s).

(*2*) If the number of conditions is more than five, then list the top five conditions, as determined by the MA organization, and convey that there are other eligible conditions not listed.

(B) The following applies when multiple types of SSBCI are mentioned:

(*1*) If the number of condition(s) is five or fewer, then list all condition(s), and if relevant, state that these conditions may not apply to all types of SSBCI mentioned.

(*2*) If the number of conditions is more than five, then list the top five conditions, as determined by the MA organization, for which one or more listed SSBCI is available, and convey that there are other eligible conditions not listed.

(iii) Convey that even if the enrollee has a listed chronic condition, the enrollee will not necessarily receive the benefit because coverage of the item or service depends on the enrollee being a ''chronically ill enrollee'' as defined in § 422.102(f)(1)(i)(A) and on the applicable MA plan's coverage criteria for a specific SSBCI required by § 422.102(f)(4).

(iv) Meet the following requirements for the SSBCI disclaimer in ads:

(A) For television, online, social media, radio, or other voice-based ads, either read the disclaimer at the same pace as, or display the disclaimer in the same font size as, the advertised phone number or other contact information.

(B) For outdoor advertising (as defined in § 422.2260), display the disclaimer in the same font size as the advertised phone number or other contact information.

(v) Include the SSBCI disclaimer in all marketing and communications materials that mention SSBCI.

* * * * *

■ 6. Section 422.2274 is amended by adding paragraph (c)(13) to read as follows:

§ 422.2274 Agent, broker, and other third-party requirements.

* * * * *

(c) * * *

(13) Beginning with contract year 2025, ensure that no provision of a contract with an agent, broker, or other TPMO has a direct or indirect effect of creating an incentive that would reasonably be expected to inhibit an agent or broker's ability to objectively assess and recommend which plan best fits the health care needs of a beneficiary.

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 7. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 8. Section 423.44 is amended by revising paragraphs (d)(2)(iii) through (viii) to read as follows:

§ 423.44 Involuntary disenrollment from Part D coverage.

* * * * *

(d) * * *

(2) * * *

(iii) *Effort to resolve the problem.* The PDP sponsor must make a serious effort to resolve the problems presented by the individual, including providing reasonable accommodations, as determined by CMS, for individuals with mental or cognitive conditions, including mental illness, Alzheimer's disease, and developmental disabilities. In addition, the PDP sponsor must inform the individual of the right to use the PDP's grievance procedures, through the notices described in paragraph (d)(2)(viii) of this section. The individual has a right to submit any

information or explanation that he or she may wish to the PDP.

(iv) *Documentation.* The PDP sponsor—

(A) Must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraph (d)(2)(iii) of this section, and any extenuating circumstances;

(B) May request from CMS the ability to decline future enrollment by the individual; and

(C) Must submit the following:

(*1*) The information specified in paragraph (d)(2)(iv)(A) of this section.

(*2*) Any documentation received by the individual to CMS.

(*3*) Dated copies of the notices required in paragraph (d)(2)(viii) of this section.

(v) *CMS review of the proposed disenrollment.* CMS reviews the information submitted by the PDP sponsor and any information submitted by the individual (which the PDP sponsor has submitted to CMS) to determine if the PDP sponsor has fulfilled the requirements to request disenrollment for disruptive behavior. If the PDP sponsor has fulfilled the necessary requirements, CMS reviews the information and make a decision to approve or deny the request for disenrollment, including conditions on future enrollment, within 20 working days. During the review, CMS ensures that staff with appropriate clinical or medical expertise reviews the case before making a final decision. The PDP sponsor is required to provide a reasonable accommodation, as determined by CMS, for the individual in exceptional circumstances that CMS deems necessary. CMS notifies the PDP sponsor within 5 working days after making its decision.

(vi) *Exception for fallback prescription drug plans.* CMS reserves the right to deny a request from a fallback prescription drug plan as defined in *§ 423.855* to disenroll an individual for disruptive behavior.

(vii) *Effective date of disenrollment.* If CMS permits a PDP to disenroll an individual for disruptive behavior, the termination is effective the first day of the calendar month after the month in which the PDP gives the individual written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(viii) *Required notices.* The PDP sponsor must provide the individual two notices prior to submitting the request for disenrollment to CMS.

(A) The first notice, the advance notice, informs the member that continued disruptive behavior could lead to involuntary disenrollment and provides the individual an opportunity to cease the behavior in order to avoid the disenrollment action.

(*1*) If the disruptive behavior ceases after the member receives the advance notice and then later resumes, the sponsor must begin the process again.

(*2*) The sponsor must wait at least 30 days after sending the advance notice before sending the second notice, during which 30-day period the individual has the opportunity to cease their behavior.

(B) The second notice, the notice of intent to request CMS permission to disenroll the member, notifies the member that the PDP sponsor requests CMS permission to involuntarily disenroll the member.

(*1*) This notice must be provided prior to submission of the request to CMS.

(*2*) These notices are in addition to the disenrollment submission notice required under § 423.44(c).

* * * * *

■ 9. Section 423.100 is amended by revising the definition of ''Affected enrollee'' to read as follows:

§ 423.100 Definitions.

* * * * *

Affected enrollee, as used in this subpart, means a Part D enrollee who is currently taking a covered Part D drug that is subject to a negative formulary change that affects the Part D enrollee's access to the drug during the current plan year.

* * * * *

§ 423.501 [Amended]

■ 10. Section 423.501 is amended in the definition of ''Final settlement process'' by—

■ a. Removing paragraph (4);

■ b. Redesignating paragraph (5) as (paragraph (4);

■ c. In newly redesignated paragraph (4), removing the phrase ''Takes final actions'' and adding in its place the phrase ''Takes action''.

§ 423.522 [Amended]

■ 11. Section 423.522 is amended by—

■ a. Removing paragraphs (c) and (d); and

■ b. Redesignating paragraphs (e) and (f) as paragraphs (c) and (d).

§ 423.584 [Amended]

■ 12. Section 423.584 is amended by—

■ a. In paragraph (b) introductory text, removing the phrase ''request for redetermination'' and adding in its place the phrase ''request for a redetermination''.

■ b. In paragraph (b)(4), removing the phrase ''specified the Part D'' and adding in its place the phrase ''specified in the Part D''.

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 13. The authority citation for part 460 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f).

■ 14. Section 460.12 is amended by adding paragraph (b)(3) to read as follows:

§ 460.12 Application requirements.

* * * * *

(b) * * *

(3) Any PACE application that does not include a signed and dated State assurances document that includes accurate service area information and the physical address of the PACE center, as applicable, is considered incomplete and invalid and will not be evaluated by CMS.

* * * * *

§ 460.120 [Amended]

■ 15. Section 460.120 is amended in paragraph (h)(4) by removing the phrase ''for paragraphs (h)(1) through (3) of this section.'' and adding in its place the phrase ''for complying with all other requirements of this section.''

Elizabeth J. Gramling,

Executive Secretary to the Department, Department of Health and Human Services.

[FR Doc. 2024–17024 Filed 8–5–24; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of the Secretary

43 CFR Part 2

[DOI–2023–0027;DS65100000 DWSN00000.000000 24XD4523WS DP.65102]

RIN 1090–AB28

Privacy Act Regulations; Exemption for the Law Enforcement Records Management System

AGENCY: Office of the Secretary, Interior.

ACTION: Final rule.

SUMMARY: The Department of the Interior (DOI) is issuing a final rule to amend its regulations to exempt certain records in the INTERIOR/DOI–10, DOI Law Enforcement Records Management System (LE RMS), system of records from one or more provisions of the Privacy Act of 1974 because of criminal, civil, and administrative law enforcement requirements.

DATES: The final rule is effective August 6, 2024.