DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 422

[CMS–4185–N4]

RIN 0938–AT59

Medicare and Medicaid Programs; Risk Adjustment Data Validation

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

ACTION: Proposed rule; request for additional comment; announcement of the release of additional data.

SUMMARY: This document summarizes actions taken to date, requests public comment on additional subjects, and announces that CMS is releasing additional material, including study data, related to the Risk Adjustment Data Validation (RADV) provisions of the proposed rule titled ''Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021'' that was published in the November 1, 2018 **Federal Register**, 83 FR 55037. The comment period for the RADV provisions of this proposed rule ends on August 28, 2019.

DATES: The comment period for CMS RADV provisions (that is, section II.C.2. of the November 1, 2018 proposed rule and proposed §§ 422.300, 422.310(e) and 422.311(a) of the regulation text) closes at 5 p.m. on August 28, 2019.

ADDRESSES: In commenting, please refer to file code CMS–4185–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

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

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4185–P, 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–4185–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

FOR FURTHER INFORMATION CONTACT: Jonathan Smith (410) 786–4671 or Joanne Davis (410) 786–5127.

SUPPLEMENTARY INFORMATION:

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

I. Request for Public Comment

On November 1, 2018, we published a proposed rule containing provisions related to the Risk Adjustment Data Validation (RADV) audit program, 83 FR 55037 through 55041 and 55077, including the proposal not to apply a Fee-for-Service Adjuster (FFS Adjuster) in any RADV extrapolated audit methodology. That proposal rested on two grounds. First, we conducted a study which indicated that diagnosis error in FFS claims data does not lead to systematic payment error in the Medicare Advantage (MA) program. Second, we suggested that it would be inequitable to correct any systematic errors made in the payments to audited plans only. We continue to welcome public comment on this proposal. We are also seeking comment on whether 42 U.S.C. 1395w–23—and in particular clause (a)(1)(C), which requires risk adjustment in subclause (a)(1)(C)(i), mandates a downward adjustment of risk scores in subclause (a)(1)(C)(ii), and includes provisions about risk adjustment for special needs individuals with chronic health conditions in subclause (a)(1)(C) (iii)—mandates an FFS Adjuster, prohibits an FFS Adjuster, or should otherwise be read to inform our proposal not to apply an FFS Adjuster in any RADV extrapolated audit methodology.

II. Summary of Prior Notices

Since we published the FFS Adjuster Study on October 26, 2018,[1] we have published several related notices.

On December 27, 2018 (83 FR 66661), we announced an extension of the comment period for the RADV provisions until April 30, 2019 and a plan to release data underlying the October 26, 2018 FFS Adjuster Study.

On March 6, 2019 (84 FR 8069), we announced the release of data underlying the FFS Adjuster Study, both through the Office of Enterprise Data Analytics (OEDA) and on the Private Plans Team website. Data made available to the public through a data use agreement included all of the following:

- An input file originating from a dataset that Research Triangle Institute (RTI) supplied. It represents the calibration data that RTI used for the Centers for Medicare and Medicaid Services Hierarchical Condition Category (CMS–HCC) model version that CMS used to calculate 2009 MA payments.
- An input file containing medical record review findings from a RADV-like review that CMS undertook on a sample of calendar year 2008 medical records.
- FFS data containing 10 datasets that represent the entire 5 percent sample of all final 2004 and 2005 diagnosis codes used for MA model calibrations through 2011.
- An HCC file containing the mapping from International Classification of Disease, 9th Revision diagnosis code to Version 12 of the CMS–HCC model. Diagnosis codes have been modified to remove decimals.
- A file consolidating MA data for beneficiaries who meet eligibility criteria for Contract-Level Risk RADV audits from three sources: The adjusted Monthly Membership Report (MMR), the Model Output File (MOF), and the CMS Enrollment Database (EDB).
- A file consolidating MA data for beneficiaries who did not meet all eligibility criteria for the Contract-Level RADV audits from three sources—adjusted MMR, MOF, and CMS EDB.
- Additional documentation and data related to the RADV FFS Adjuster Study was posted on the Private Plans Team website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-*

[1] The Executive Summary and Technical Appendix of the study are both available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Resources.html.*

Adjustment-Data-Validation-Program/Resources.html. This data included a RADV Data Dictionary and Provisional Coefficients workbook.

On April 30, 2019 (84 FR 18215), we announced an additional extension of the comment period for the RADV provision until August 28, 2019. We also announced that we would be releasing additional data underlying the FFS Adjuster Study, including additional data containing Protected Health Information, to all parties who entered an applicable data use agreement and paid the required fee. This data has been available since June 14, 2019. The forms and instructions to request this data and previously released data remain available via the CMS website at *https://www.cms.gov/research-statistics-data-and-systems/files-for-order/limiteddatasets/.* Updates to existing documentation related to the study data, as well as additional data without Protected Health Information, were posted on the CPI Private Plans Team website on April 25, 2019.

III. Release of Additional Study Material and Further Request for Public Comment

We have now replicated the FFS Adjuster Study and published a summary of that replication as an addendum to the study at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Resources.html.* The results of the replication are broadly consistent with the initial implementation of the study. The purpose of this replication was to allow us to both test our initial results and release a more complete set of underlying data. Certain intermediate data elements not saved as part of the implementation of the initial study have been preserved and published in the addendum or at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Resources.htm.* In addition, the addendum contains further discussion of the study's assumptions and methodology. We are also releasing the programming language used to implement the replication of the study, available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Resources.html,* along with a description of the technical requirements for use of that programming language. It is our intention that the release of this programming language, together with the earlier release of the data used as inputs, will allow for robust public comment on the FFS Adjuster Study.

We welcome public comment on that subject, and all subjects raised in this notice and the notices discussed previously, until 5 p.m. on August 28, 2019.

Dated: June 21, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 207, 215, 216, and 234

[Docket DARS–2019–0026]

RIN 0750–AK38

Defense Federal Acquisition Regulation Supplement: Reliability and Maintainability in Weapon System Design (DFARS Case 2019–D003)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: DOD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2018 that requires the use of reliability and maintainability sustainment factors in weapon system design.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before August 27, 2019, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2019–D003, using any of the following methods:

○ *Federal eRulemaking Portal: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by entering ''DFARS Case 2019–D003'' under the heading ''Enter keyword or ID'' and selecting ''Search.'' Select the link ''Submit a Comment'' that corresponds with ''DFARS Case 2019–D003.'' Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''DFARS Case 2019–D003'' on your attached document.

○ *Email: osd.dfars@mail.mil.* Include DFARS Case 2019–D003 in the subject line of the message.

○ *Fax:* 571–372–6094.

○ *Mail:* Defense Acquisition Regulations System, Attn: Ms. Kimberly Bass, OUSD(A&S)DPC/DARS, Room 3B941, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Kimberly Bass, telephone 571–372–6174.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is proposing to amend the DFARS to implement section 834 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2018 (Pub. L. 115–91). Section 834 amends title 10, United States Code (U.S.C.), to add section 2443, sustainment factors in weapon system design, which requires program managers or comparable requiring activity officials exercising program management responsibilities to ensure that reliability and maintainability are included in the performance attributes of the key performance parameters on sustainment during the development of capabilities requirements for major weapon systems design and contracts for the—

- Engineering and manufacturing development of a weapon system, including embedded software; or
- Production of a weapon system, including embedded software.

As a matter of policy, the Under Secretary of Defense for Acquisition and Sustainment directed application of the requirements of 10 U.S.C. 2443 to the technical maturation and risk reduction phase.

II. Discussion and Analysis

The following changes to the DFARS are proposed to implement 10 U.S.C. 2443:

DFARS 207.106(S–70)(2)(ii)(A) implements 10 U.S.C. 2443 as an additional requirement for major systems, and provides guidance to the acquisition team during acquisition planning to ensure that reliability and maintainability are included in the performance attributes of the key performance parameters on sustainment during the development of capabilities requirements.

DFARS 207.106(S–72)(5) informs the contracting officer to ensure best