Blog Series Part 5: CMS Proposed Rule on Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Medicaid Fee-For-Service, and Medicaid Managed Care Programs for 2020 and 2021

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Part D Plan Sponsors' Access to Medicare Parts A and B Claims Data Extracts

As detailed in previous posts in this series, one major objective that the Centers for Medicare and Medicaid Services ("CMS") addressed in a <u>proposed rule</u> issued November 1, 2018 (the "Proposed Rule"), was to implement new Social Security Act provisions that Congress added in the <u>Bipartisan Budget Act of 2018</u> ("BBA"). One such provision will open fee-for-service Medicare data up to prescription drug benefit ("Part D") plans.

Section 50354 of the BBA aims to "Promote the Appropriate Use of Medications and Improve Health Outcomes" by giving Part D sponsors access to some data on their enrollees' use of Part A and Part B benefits. The statute indicates that sponsors may use the claims data obtained through this framework for: (i) optimizing therapeutic outcomes through improved medication use; (ii) improving care coordination so as to prevent adverse healthcare outcomes, such as preventable emergency department visits and hospital readmissions; and (iii) for any other purposes determined appropriate by the Secretary. Part D sponsors are prohibited from using such data for certain other purposes including coverage determinations and marketing. Implementation questions that the BBA left to CMS' discretion include whether any additional data uses should be permitted or prohibited, as well as formats and schedules for making data available. The Proposed Rule offers CMS' tentative take on implementing this new mandate. [2]

In addition to the data uses specifically permitted by the BBA, the Proposed Rule would allow Part D sponsors to use claims data for their "health care operations," for fraud and abuse detection and compliance activities, and to comply with legal obligations (all of which uses are defined in the Proposed Rule by reference to HIPAA regulations). The Proposed Rule does not introduce new specifically *prohibited* uses of Part A and B claims data, but it does lay out mechanisms by which CMS intends to enforce the statutory provisions: Part D sponsors will have to obtain commitments from contractors and subcontractors to abstain from prohibited uses, and Part D sponsors who make unauthorized uses may forfeit their access to subsequent data releases.

If the Proposed Rule is finalized, Part D sponsors will only need to opt into access once, and will then receive periodic updates on all enrollees (no subsets) until access is terminated voluntarily or for unlawful use. A significant range of data types would be available under the current proposal, including "an enrollee identifier, diagnosis and procedure codes; dates of service; place of service; provider numbers; and claim processing and linking identifiers/codes, subject to reevaluation through further rulemaking. However, CMS has opined that only data that is "as current as practicable" serves the care-coordination purpose of the new statutory mandate; for that reason, CMS is proposing to limit disclosures to requesting Part D sponsors' enrollees at the time of each data release. Data would be released on uniform quarterly dates in a uniform format across Part D sponsors, starting with a release in August 2020 of data from the first quarter of that year.

The Proposed Rule "strongly encourages" comments on CMS' proposals to implement the new claims data release provision, suggesting that CMS is open to revising the framework outlined in the Proposed Rule. The comment period closes on December 31, 2018.

[1] See 42 U.S.C. § 1395w-104(c)(6) as amended by Pub. L. 115-123 § 50354 (2018).

[2] See 83 F.R. 54982, 55015–17 (Nov. 1, 2018).

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