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CMS Proposes to Expand Access to Part D Data for Research

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SPECIAL REPORT

On January 10, 2014, the Centers for Medicare and Medicaid Services (CMS) announced a proposed rule to alter key components of the Medicare Advantage (MA) and Part D Programs (Proposed Rule). Understandably, the Proposed Rule garnered significant attention with respect to its potential impact on MA and Part D plan sponsors and their beneficiaries. The Proposed Rule, however, also proposed notable expansions to Part D data access that, to date, have received much less attention from affected stakeholders.[1] While CMS recently announced that it will not finalize many parts of the Proposed Rule at this time as a result of strong public feedback it received regarding those proposals, the agency has indicated that it intends to proceed with the rulemaking process to finalize the proposed Part D data access provisions upon consideration of any public comments it has received.[2]

In the Proposed Rule, CMS proposed to rescind an existing rule that prohibits the agency from releasing unencrypted prescriber, pharmacy and plan identifiers contained in prescription drug event (PDE) records to certain external researchers.[3] The Proposed Rule would make this data available to such researchers, subject to certain conditions, and would greatly expand access to this rich data asset. CMS also clarified that it is permitted to release Part D "non-final action data" to entities outside of CMS, which will enable both external entities and non-CMS government agencies to distinguish original prescription data from amended or deleted versions of the Part D data.[4]

When considered in light of other proposed data initiatives by the administration, the Proposed Rule presents the possibility of a federal government increasingly open to the proposition that, alongside rigorous privacy and security controls, there may need to be a strategy for leveraging data to solve, explore, understand and ultimately address the crises of coverage, care and quality facing the U.S. health system. As CMS contemplates further expanding external researchers' access to Part D data, it will be important for stakeholders to be cognizant of how CMS will ultimately finalize these provisions in the forthcoming final rule. As proposed, the changes enumerated by CMS will have notable implications for transparency, fraud and abuse oversight, outcomes and other data-driven research projects, and data-powered public health initiatives.

Background on Medicare Part D Data Collection

Under the Medicare Part D Program, private prescription drug plan sponsors (each a Part D Sponsor) must submit to CMS a PDE record that contains comprehensive information for every prescription filled under a Part D plan. At the same time, the under-representation in prospective pharmaceutical clinical research studies of elderly patients—who comprise Medicare Part D beneficiaries—is well documented.[5] CMS recognizes, therefore, the potential value of retrospective Part D data in supplementing prospective research data on senior citizens.[6] Although the Social Security Act authorizes research on Part D claims data to improve public health as deemed appropriate by the Secretary of the U.S. Department of Health and Human Services (HHS), rulemaking was necessary to clarify and formalize the parameters within which CMS could make this data available.[7] CMS subsequently interpreted the statutory language as authority to allow external third-party researchers to receive and leverage Part D data in addition to CMS and other federal agencies.[8] In rulemaking and sub-regulatory guidance, CMS has created a process for providing data to researchers, both within government and

[1] Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program, 79 Fed. Reg. 1918 (proposed Jan. 10, 2014) (to be codified at 42 C.F.R. pt. 423).

[2] Letter from Marilyn Tavenner, Adm'r, Ctrs. for Medicare & Medicaid Servs., to Hon. Henry Waxman, Ranking Member, House Comm. on Energy & Commerce (Mar. 10, 2014), *available at* http://www.modernhealthcare.com/assets/pdf/CH93497310.PDF.

[3] 42 C.F.R. § 423.505(m)(1)(D) (2013).

[4] Contract Year 2015 Policy and Technical Changes to Medicare Prescription Drug Benefit, 79 Fed. Reg. at 1990.

[5] *See* Donna M. Zulman *et al*., *Examining the Evidence: a Systematic Review of the Inclusion and Analysis of Older Adults in Randomized Controlled Trials*, 26 J. Gen. Intern. Med. 783 (2011).

[6] Ctrs. for Medicare & Medicaid Servs., CMS-4119-F, Fact Sheet: Final Medicare Part D Data Regulation 2 (2008).

[7] *See* 42 U.S.C. 1395w-112(b)(3)(D)(i).

[8] Medicare Program; Medicare Part D Claims Data, 73 Fed. Reg. 30,664, 30,665-66 (May 28, 2008).

externally, and has set certain limitations to Part D data sharing.

Previous Part D Data Final Rule (2008)

In May 2008, CMS published its first final rulemaking[9] for the release of Part D PDE data to non-HHS federal agencies, states and external researchers under the authority provided by the Social Security Act (2008 Rule). The rulemaking sought to address three concerns raised by the provision of Part D data to entities external to HHS. First, the 2008 Rule sought to prevent undue influence from commercial interests. CMS reasoned that external research funded by commercial entities using identifiable beneficiary and prescriber information could be biased, selectively published and used to market drugs to particular prescribers.[10] Second, CMS expressed a need to protect the confidentiality and privacy of beneficiaries, because it was concerned about the unnecessary and potentially inappropriate disclosure of beneficiary identifying information attached to each drug claim.[11] Finally, CMS was concerned about safeguarding commercially sensitive drug pricing data, which may compromise the ability of Part D Sponsors to negotiate for rebates and price concessions from prescription drug companies, which helps to contain drug prices and health care spending.[12]

To address these concerns, CMS instituted a number of safeguards for disclosing Part D data for research purposes. Generally, CMS set limits on PDE data disclosures based on three tiers of recipients:

- Non-CMS divisions of HHS and congressional oversight agencies
- Non-HHS federal agencies and state agencies
- External non-governmental entities (External Researchers)

While CMS may disclose PDE data to the first two tiers of recipients for non-research purposes, it is permitted to disclose PDE data to External Researchers *only* for "legitimate" research "that will result in generalizable knowledge in the public domain."[13] Moreover, while External Researchers may be funded by commercial entities, the resulting research must "contribute to general knowledge in the public domain and the researchers must be free to publish the results of the research regardless of the findings."[14]

The 2008 Rule created a framework in which External Researchers could submit requests for PDE data elements to a CMS contractor—the Research Data Assistance Center at the University of Minnesota (ResDAC)—by providing an explanation of the research activity and the justification for requesting each data element within a PDE record, and by obtaining CMS Privacy Board approval.[15] External Researchers were required to execute a data use agreement with CMS that restricts their ability to further disclose or link the data without express CMS approval.[16] To protect prescription drug pricing data, the 2008 Rule prohibits the release of highly confidential individual drug pricing information to External Researchers, non-HHS agencies and state agencies under any circumstances.[17] Only HHS entities and congressional oversight agencies are permitted to receive certain disaggregated drug cost data in

[9] CMS also released a final rule in April 2010 that amends certain provisions of the Part D data release requirements, but the amendments are not relevant to the issues addressed in this *Special Report*.

[10] Medicare Part D Claims Data, 73 Fed. Reg. at 30,674-75.

[11] *Id.* at 30,668.

[12] *Id.* at 30,668-69.

[13] *Id.* at 30,679.

[14] *Id.* at 30,674.

[15] *Id.* at 30,675. If the research is federally supported, the researcher must also obtain approval from the researcher's federal project officer and an Institutional Review Board.

[16] *Id.* This data use agreement requirement is separate and distinct from HIPAA's requirement that a covered entity enter into a data use agreement as specified under 45 C.F.R. § 164.514(e)(3) with any recipient to whom the covered entity discloses a "limited data set." CMS's data use agreement stems from the requirements under the Privacy Act of 1974 that apply when a federal agency provides access to records that are in a "system of records" as defined under such Act. The CMS Part D records at issue in the Proposed Rule fall into this category.

[17] *Id.* at 30,669.

PDE records, such as information on dispensing fees and drug ingredient costs.[18]

Notably, the 2008 Rule also requires CMS to encrypt beneficiary, provider, plan and pharmacy identifiers included in any released Part D PDE record data, subject to two key exceptions. First, CMS may disclose unencrypted identifiers to federal or state government agencies if the identifiers are necessary for the specific project.[19] Second, CMS may disclose beneficiary, prescriber and pharmacy identifiers to an External Researcher if the External Researcher requires the identifiers to enable linking of the PDE data to other data sets, provided the identifiers are re-encrypted after linking the data.[20] Plan identifiers, however, remain unavailable to External Researchers in unencrypted format, even for data-linking purposes.[21] For example, under the current framework, External Researchers can conduct retrospective studies on Part D PDE data by linking the Part D data to other CMS files on the Medicare Part a and Part B programs that contain additional information regarding beneficiary age, gender, race and geographic location, as well as diagnoses of certain chronic conditions.[22] Without information that identifies the Part D Sponsors, however, External Researchers cannot retrieve information on the relevant Part D plan formularies and drug tier structures that would enable the External Researcher to assess the influence of plan structure on treatment choices.[23] Accordingly, the 2008 Rule includes stringent protections for provider, plan and pharmacy identifiers that are normally not treated as "sensitive information" under typical research oversight perspectives, and that limit the extent to which External Researchers can leverage Part D PDE records for public health purposes.

Relevant Changes in the Proposed Rule

In the Proposed Rule, CMS recognizes that the limitations established in the 2008 Rule may impede efforts by External Researchers to fully realize the value of PDE data in improving the Part D Program and promoting public health interests.[24] For example, External Researchers who are given access to plan identifiers could compare the prescribed drug's formulary and drug tier information with alternative drug therapy coverage within the same plan.[25] Likewise, providing prescriber identifiers to External Researchers would enable the researcher to link the Part D claims data with employer data to analyze care quality and cost efficiencies of prescribing patterns.[26] Prescriber identifiers would also allow researchers to identify benchmark prescribing patterns and analyze prescriber divergence from these benchmarks.[27] Accordingly, in the Proposed Rule, CMS proposes to allow the release of unencrypted physician, pharmacy and plan identifiers to all requestors, including External Researchers (*i.e.*, "legitimate" researchers working for or on behalf of a "reputable institution"). Additionally, the Proposed Rule would allow CMS to make available non-final action data (such as information for claims that are subject to further adjustment) to entities outside of the agency.[28]

The Proposed Rule would not, however, amend current data release policies relating to beneficiary identifiers and drug pricing information, such that External Researchers would continue to receive only encrypted beneficiary identifiers and aggregated drug pricing information.[29]

[18] *Id.*

[19] *Id.* at 30,675-30,676.

[20] *Id.* at 30,668.

[21] *Id.*

[22] Vicki Fung *et al.*, *Using Medicare Data for Comparative Effectiveness Research*, 17 Am J. Managed Care 488 (2011).

[23] *Id.*

[24] Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program, 79 Fed. Reg. 1918, 1989 (proposed Jan. 10, 2014) (to be codified at 42 C.F.R. pt. 423).

[25] Fung, *supra* note 22, at 494.

[26] Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program, 79 Fed. Reg. at 1989.

[27] *Id.*

[28] *Id.*

[29] *Id.* Under the Proposed Rule, External Researchers may still use beneficiary identifiers for linking purposes as long as they do not retain the unencrypted identifiers for research.

Additionally, minimum necessary requirements would continue to apply to the release of unencrypted physician, pharmacy and plan identifiers. Finally, the Proposed Rule would not amend the current limitation that only HHS and congressional oversight agencies may receive access to minimum necessary disaggregated drug cost information, including ingredient costs and dispensing fees.[30]

Implications of the Proposed Changes

In making more unencrypted Part D data available, but still restricting access by external entities to those that are "reputable institutions" conducting "legitimate research," CMS appears to be seeking equilibrium between two conflicting policy values. On one hand, CMS believes that it is transforming "from a passive payer of claims towards a value-based purchaser of health care." It argues in the Proposed Rule that "expanded access to PDE data by external entities" will help to improve Part D Program efficiency and the prescription drug therapies that Part D beneficiaries receive.[31] On the other hand, CMS maintains some of the concerns it expressed in the 2008 Rule—specifically, that expanding access may compromise the confidentiality of beneficiaries, prescribers, pharmacies and plans, and that commercial entities may seek to use Part D data to "interfere with a physician's professional judgment."[32] Ultimately, the proposal, if finalized, would underscore an increasing willingness by the agency to divulge records under federal health care programs in the interest of public health and, in particular, to better align the delivery of health care with the shift toward quality- and value-based incentives. As described below, there are signs in the Proposed Rule and in other proposed initiatives by the current administration that the equilibrium may shift again in the near future toward even more expansions in Part D data access.

CONFIDENTIALITY CONSIDERATIONS

First, CMS appears skeptical of the continuing existence of a confidentiality interest as it relates to prescribers, plan identifiers and pharmacies. CMS notes that in almost all cases, this data is already available to researchers from other databases.[33] Part D data with prescriber information is included in commercially available data sets sold by data aggregators, while aggregated data organized by Part D Sponsor is publically available on CMS's website and through public use files.[34] Additionally, CMS argues that prescribers who make appropriate prescribing decisions should have no reason to be concerned with increased transparency in their medical decision-making.[35]

While the current availability of certain Part D data sets that include prescriber, Part D Sponsor or pharmacy identifiers may suggest that such entities do not have a privacy interest commensurate with that of beneficiaries, there are nonetheless concerns that research using Part D PDE records with such identifiers could lead to the discovery of commercially sensitive information that is not currently available in other data sources. For example, during the rulemaking process for the 2008 Rule, Part D Sponsors expressed concern that researchers could use plan identifiers to uncover drug pricing and market share data for individual medications within specific benefit plans, which may interfere with negotiations between Part D Sponsors and purchasers of drugs regarding drug price discounts and rebates.[36] This will likely remain a concern for Part D Sponsors should the Proposed Rule be finalized.

For prescribers, while data aggregators currently gather data sets containing prescriber identifiers from retail pharmacies for sale to researchers and pharmaceutical companies, there are limitations in how this data may be used to study Medicare prescribing. Most importantly, unlike PDE data, such commercial data sets are not readily

[30] *Id.* at 1990.

[31] *Id.* at 1988.

[32] *Id.* at 1989.

[33] *Id.*

[34] *Id.*

[35] *Id.*

[36] Elizabeth Hargraveand Jack Hoadley, Nat'l Op. Research Ctr. at the Univ. of Chi., Pub. No. 08-02, Facilitating Access to Medicare Part D Drug Claims Data 10 (2008).

linkable to Part a and Part B claims data.[37] The linking of Part a and Part B data with Part D PDE data, combined with the availability of identifiable prescriber information, could allow researchers to compare outcomes by prescriber and draw conclusions about a particular prescriber's quality of care and effectiveness. Prescribers have an interest in learning from outcomes data without the risk of the potential commercial and reputational harms that may result from retrospective observations about their prescribing decisions. These concerns, however, may be alleviated by safeguards that CMS already has in place. When applying for access to Part D PDE data, External Researchers will still be required to justify to CMS their need for each data element. As a gatekeeper, CMS can seek to ensure that all proposed research and subsequent publications of findings will be legitimate.

Interestingly, CMS does not discuss the *beneficiary* confidentiality interest in prescriber, plan or pharmacy data and the commensurate considerations that such beneficiary confidentiality interests raise for Institutional Review Boards and the CMS Privacy Board. Although provider, pharmacy and plan identifiers do not directly identify a beneficiary, they provide a wealth of information that can narrow down the universe of individuals to which a set of patient-level data may refer. For example, unencrypted pharmacy and prescriber identifiers may provide insight as to a beneficiary's address, as patients tend to visit doctors and pharmacies located in close proximity to their respective homes or places of work. It is important to note, however, that CMS already has a number of safeguards in place to address this issue through the application process it has established for PDE data requests, including the requirement that the CMS Privacy Board review requests for PDE data and that data recipients enter into a data use agreement with the agency. It is also likely that CMS will continue to scrutinize research requests for data that includes unencrypted identifiers, and to impose restrictions on re-identification through Privacy Board oversight or data use agreements in order to protect beneficiaries. These restrictions will not necessarily affect researchers' ability to use this newly available data, as long as the application process is not overly burdensome.

TRANSPARENCY AND FRAUD AND ABUSE CONSIDERATIONS

Second, CMS downplays concerns about the potential for expanded access to Part D data to facilitate undue commercial influence by external entities that may attempt to use the data to influence prescribing decisions. In addition to noting that prescriber data is already available to commercial entities through data aggregators, CMS asserts that there are already key policy "checks" in place to prevent inappropriate commercial influences. The agency notes, by way of example, the Anti-Kickback Law and the Physician Payments Sunshine Act (enacted as part of the Affordable Care Act), the latter of which requires, among other things, certain drug, biologic, device and medical supply manufacturers to annually report certain payments or other transfers of value made to physicians and teaching hospitals. In the event CMS finalizes its proposal, recipients of the Part D data may be even better equipped to scrutinize the financial relationships between providers and industry by having a broader array of data with which to compare financial ties and prescribing patterns. The availability of Part D PDE data with unencrypted prescriber, pharmacy and plan identifiers and the enhanced scrutiny and insights it may bring underscore the importance of ensuring that all payments and transfers covered by the Sunshine Act are properly reported.

ACCESS TO PDE DATA BY COMMERCIAL ENTITIES

Finally, it is notable that CMS is also soliciting comments in the Proposed Rule on whether to continue restricting the release of Part D data for commercial purposes.[38] While CMS disclaims that it is making any specific proposal to remove the restriction,[39] the request for comments may indicate a potential willingness on the part of CMS to further expand access to Part D data in the future. If given access to Part D PDE data, it is conceivable that commercial research entities could, with appropriate privacy protections,

[37] *Id*. at 13.

[38] *Id.*

[39] *Id.*

link the information with their existing data stores and conduct useful retrospective meta-analyses of prescription drug prescribing and outcomes. Like research by academics and non-profit entities, these studies may be conducted with the intent of improving care quality and efficiency. Thus, the proliferation of Part D data, coupled with more sophisticated data linking opportunities with which to analyze such data, may enable academic researchers as well as commercial pharmaceutical, device and biotechnology companies to more easily assess product effectiveness and safety within the elderly population and to uncover other findings that may benefit and improve public health.

Of note, a bipartisan and bicameral group of lawmakers has already proposed to make Medicare claims data available to commercial entities for quality improvement activities. Within the recently released bipartisan bill to permanently repeal the Sustainable Growth Rate (SGR) formula is a proposal to expand access to Medicare claims data.[40] The proposal would allow "qualified entities," defined as groups certified by Medicare to conduct performance measurement with Medicare claims data and other data sources, to sell their data analyses to providers, suppliers, commercial insurers and employers for quality improvement activities and the development of alternative payment models.[41] These data analyses would include identifiable patient information only if the data recipient provides care or services to the patients included in the data sets.[42] Identifiable information on providers and medical suppliers, however, may be included in the data analyses so long as the providers and medical suppliers have an opportunity to review the analyses before they are sold.[43] If this measure passes into law as part of the SGR repeal, it may further influence CMS to make Part D data available to commercial entities for research purposes.

OTHER FEDERAL DATA INITIATIVES

It may be useful to consider the Proposed Rule in light of other data initiatives being considered or undertaken by the administration. First, CMS recently announced that it will, on a "case-by-case" basis, consider releasing information in response to Freedom of Information Act (FOIA) requests that seek data on Medicare reimbursement payments to physicians. The agency's change in policy—effective March 18, 2014—comes after a district court lifted a decades-old injunction that, citing the primacy of physician privacy interests over interests in public transparency, prohibited HHS from releasing Medicare reimbursement payment information that identifies individual physicians.[44] Under its new policy, CMS will evaluate each FOIA request for individual physician Medicare reimbursement information by balancing "the privacy interest of individual physicians and the public interest in the disclosure of information."[45] How the agency will perform this calculus remains to be seen, but this is another avenue through which CMS may increase the availability of Medicare program data in an effort to improve program efficiency and target fraud and abuse.

CMS's attempt to find equilibrium between privacy and the benefits of "big data" is also indicative of a larger discussion occurring within the highest levels of the federal government. In late January 2014, John Podesta, one of the top advisors to former President Clinton and now an advisor to President Obama, announced in a blog post that the president had tasked him with analyzing the government and private sector uses of large data sets and the privacy considerations surrounding these uses.[46] an intergovernmental team led by Podesta, informed by a study from the President's Council of Advisors on Science and Technology, will submit a plan of action to the president

[40] SGR Repeal and Medicare Provider Payment Modernization Act of 2014, H.R. 4015, 113th Cong. § 8 (2014).

[41] *Id.* at § 8(a)(1)(A).

[42] *Id.* at § 8(a)(3)(B).

[43] *Id.* at § 8(a)(6).

[44] Modified Policy on Freedom of Information Act Disclosure of Amounts Paid to Individual Physicians Under the Medicare Program, 79 Fed. Reg. 3205 (Jan. 17, 2014).

[45] *Id.* at 3206.

[46] John Podesta, *Big Data and the Future of Privacy*, The White House Blog (Jan. 23, 2014, 3:30 pm), http://www.whitehouse.gov/blog/2014/01/23/big-data-and-future-privacy.

within 90 days on the collection, availability and use of data in public and private data stores.[47]

Conclusion

CMS's proposed Part D rule, when viewed in combination with these initiatives to expand external access to government data, suggests that CMS is revisiting how to best protect the privacy and security of beneficiary, provider and plan data while simultaneously harnessing the power of such data to improve the government's delivery and purchase of health care. While HHS agencies such as the U.S. Food and Drug Administration, National Institutes of Health, and Agency for Healthcare Research and Quality currently conduct studies using PDE data with unencrypted identifiers,[48] CMS reiterated in the Proposed Rule the importance of external public health research in improving efficiency and clinical outcomes in the Part D program.[49] The potential expansion of access to unencrypted PDE data by External Researchers is therefore of great interest to diverse stakeholders—some of which are lobbying for greater data access, while others are concerned about privacy and proprietary considerations. Further rulemaking will likely be instructive as to how the agency believe such sometimes-competing interests should be balanced.

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[47] *Id.*

[48] Ctrs. for Medicare & Medicaid Servs., CMS-4119-F, Fact Sheet: Final Medicare Part D Data Regulation 2 (2008).

[49] Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program, 79 Fed. Reg. at 1989.

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