THE ABA HEALTH LAW SECTION

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CMS MAKES MEDICARE PART D DATA AVAILABLE FOR THE FDA SENTINEL INITIATIVE, EXTERNAL RESEARCH, AND OTHER OUTSIDE USES

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As the Centers for Medicare and Medicaid Services ("CMS") recently noted, the Medicare program currently serves approximately 44 million beneficiaries.[1] Participation in Part D, the Medicare Prescription Drug Benefit enacted in 2003, is voluntary, but in 2008 Medicare Part D had about 25 million enrolled beneficiaries. Claims data for those 25 million Part D beneficiaries contains significant information about prescription drug use, particularly when combined with claims data available from Medicare Part A (institutional providers such as hospitals and skilled nursing facilities) and Medicare Part B (suppliers, including physician services, and items including durable medical equipment). CMS has now amended and finalized a regulation ("the CMS Final Rule"), 42 C.F.R. § 423.505, which will allow the release of Part D claims data for public health and safety research, quality initiatives, care coordination and other research and analysis, subject to protections for patient privacy and commercially sensitive information relating to health plans.[2]

Contemporaneously with the announcement of the CMS Final Rule, the Food and Drug Administration ("the FDA") released a white paper describing plans for its "Sentinel Initiative," which will include the development of a new electronic system that will enable the FDA to query a broad array of information to identify possible post-market adverse events.[3] CMS and the FDA are, of course, agencies within the same federal Department, the United States Department of Health and Human Services ("HHS"), but until recent years there was relatively little interaction between the two components.

Reasons for the CMS Final Rule

HHS Secretary Mike Leavitt described efforts underway at CMS and the FDA as "moving from reactive dependence on voluntary reporting of safety concerns – to proactive surveillance of medical products on the market."[4] The CMS Final Rule makes Medicare data on prescription drug use available to help government agencies and academic researchers improve the safety, quality and efficiency of healthcare services.[5] Using Medicare Part D claims data now available under the CMS Final Rule, linked to Medicare Parts A and B data which is already available, will allow the creation of a "highly robust HHS database as the prototype for the [FDA] Sentinel System."[6] The FDA's Commissioner, Andrew C. von Eschenbach, M.D., commented that the Sentinel System will allow the FDA to monitor a product's performance in millions of patients in real time, and provide an unprecedented ability to detect problems with products as they first begin to surface.[7] Benefits expected to result from the Sentinel Initiative include the compiling of information which will reduce beneficiaries' risks of dangerous drug reactions, lowering the cost of preventable medication errors, supporting CMS' e-prescribing and electronic health records efforts, and assisting in the development of better guidelines for medication use.

CMS Acting Administrator Kerry Weems noted that CMS' most recent survey of beneficiaries indicated that people with Medicare use more than twice as many medications in a year as compared to other Americans, with an average of 28 prescriptions in a year (up to 45 prescriptions in a year for those who consider themselves in poor health).[8] This high usage of medications, coupled with numerous chronic health conditions, puts Medicare beneficiaries at higher risk of adverse drug events than other populations, and makes Medicare beneficiaries the group most likely to benefit from the FDA's Sentinel Initiative. Creating an advanced surveillance system like the Sentinel System was one of the recommendations made by the Institute of Medicine in its 2006 report on ways to improve the safe use of drugs.[9] CMS estimates that the cost of treating preventable adverse drug events for Medicare enrollees is approximately $887 million per year, and hopes that research using the new Medicare claims database will lead to fewer adverse drug events over time.[10]

Summary of the CMS Final Rule

In the CMS Final Rule, published on May 28, 2008 and effective on June 27, 2008, CMS amended 42 C.F.R.§ 423.505 to set forth the parameters under which Medicare Part D claims data may be released for purposes of research, program monitoring, public health, care coordination, quality improvement, population of personal health records, and other purposes.[11] The CMS Final Rule largely followed the Proposed Rule, issued some 18 months previously, but significantly backed away from the Proposed Rule's broad access to all data elements to limit access to the original 37 Prescription Drug Event ("PDE") elements.[12] Addressing comments submitted in response to the Proposed Rule, the CMS Final Rule added additional protections

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that in some cases will limit the data elements provided to government agencies. CMS distinguished between HHS and Congressional oversight agencies, compared to other governmental agencies, with the main distinction being that only HHS and Congressional oversight agencies would have access to disaggregated cost elements (such as ingredient costs and dispensing fees), if needed.[13] External entities will also not have access to plan identifiers under the CMS Final Rule.[14]

As CMS noted, Part D data-sharing will provide a critical new source of information about how well drugs work and how safe they are for the elderly and disabled populations, who are often excluded from clinical trials, and hopefully will lead to fewer adverse drug events over time. Moreover, as CMS noted in its Open Door Forum, the National Institutes of Health ("NIH") indicated that this data will allow it to track individuals over time and to access both short-term and long-term treatment effects that may not otherwise be captured in clinical trials because of the small number of cases or because a health event occurred beyond the period of the trial.[15]

Protection of Commercially Sensitive and Beneficiary Information

Part D is administered by private entities serving as plan sponsors, Medicare Advantage (Medicare managed care) and other types of Medicare health organizations, who then act as payers and insurers for prescription drug benefits. These private entities compete for Part D enrollees; CMS was sensitive to the commercially sensitive information which resides in its claims data bases, and to concerns that release of such information might lead to higher Part D costs for taxpayers and beneficiaries.[16] In addition, patient privacy was of utmost concern. To best protect both concerns, in the CMS Final Rule CMS determined that only the minimum data necessary for any project would be released, at maximum limited to the 37 PDE data elements rather than all available data elements as had been set forth in the Proposed Rule. As an example of the tailored and limited need for information, CMS noted that a study of drug safety issues likely would not need cost elements, and consequently that data would not be provided.[17] Further, the rule does not extend to Part D plan-specific bid data, rebates, risk-sharing, reinsurance, or payment information collected outside of a Part D claim. Under the CMS Final Rule, CMS will not release beneficiary, prescriber, or pharmacy identifiers to other government agencies or external researchers unless these are absolutely necessary for the study (*e.g.*, to link to another database). Even the FDA will not generally receive information identifying individual patients (although patient-level information may be provided in an encrypted form).[18]

Time Period for Which Data is Available

The new data-sharing provisions set forth in the Final Rule apply to Part D claims data collected on or after January 1, 2006. The first data, relating to 2006 claims, is expected to be available by December 2008. CMS cautions that because 2006 was a partial year for Part D (enrollment continued through May 2006), and because it was a start-up year, data for this initial year may include "a fair amount of unusual activity," as well as a lower total enrollment than subsequent years.[19] On an ongoing basis, PDE data will be available approximately six to eight months after the end of the calendar year to which the claims are related. CMS is not able to release the PDE data in a more timely fashion since Part D claims are paid by Part D plan sponsors, who have up to six months to submit PDEs to CMS for purposes of payment reconciliation.[20]

Parties Eligible for Release of Information

Parties to whom this data may be released include external researchers, as well as other federal government agencies, states, and beneficiaries for their own personal health records. Under the CMS Final Rule, different entities have access to different elements, but all requests are subject to the minimum level necessary for the project. CMS has provided a chart which details data element availability by type of requestor.[21]

Linking Part D Data to Part A and Part B Data

As noted above, the Part D data can be linked with claims data for Medicare Part A (hospital and institutional benefits) and Part B (physicians and other supplier benefits) for those 17 million beneficiaries who are in the "Original Medicare" program with a stand-alone Part D prescription drug plan. For those enrolled in Medicare Advantage, only Part D data is available.

The interface of Medicare data allows a link between prescription drug information and other Medicare claims information including diagnoses, medical treatments, hospitalizations, and physician services.[22] The data is expected to serve as a rich source of information about patterns of drug treatment, health outcomes, and adverse events among the elderly and disabled.[23] It should be underscored, however, that no beneficiary medical charts will be available for review; the information to be released is limited to claims data.

Research Defined

CMS expects HHS agencies, including the FDA, NIH, and the Agency for Healthcare Research and Quality ("AHRQ"), to use Part D claims data in their research studies. States

have already requested the data for their Medicare and Medicaid dual eligible beneficiaries to support care coordination and disease management.[24] External researchers at think tanks and universities are also expected to use the data in their research projects.[25]

"Research" is defined, using the definition in the HIPAA Privacy Rule, as "a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge."[26] CMS states that it will not release identifiable data to external entities when their research is not designed to develop or contribute to generalizable knowledge. In addition, CMS will not release identifiable data for commercial purposes. However, CMS currently allows data use in situations where a commercial entity funds an independent researcher at a university or non-profit entity as long as that research is conducted independently and the results are in the public domain, whether or not they are favorable to the sponsor.[27]

Information Available

The Part D claims data will be compiled from PDE summaries. The PDE is a record which every Part D drug plan (including Medicare Advantage plans) must submit every time a beneficiary fills a prescription under Medicare Part D, and consists of summary extracts using CMS-defined standard fields. PDE information is currently used to enable CMS to make payments to Part D plans and otherwise administer Part D. As indicated above, CMS will release only the minimum data necessary to complete the study; will require that the results of the research (if applicable) be in the public domain; and if the study is conducted by an external entity, will require that the researcher have the requisite experience and be working in a reputable institution. CMS has repeatedly underscored that the available data will only cover Part D; drugs paid for by other sources, such as private employers, unions, and the Veterans Administration, will not be reflected in the released information. The data will also not reflect most over-the-counter ("OTC") medications (because these are not paid for by Part D), and some classes of drugs protected by privacy laws (*i.e.*, records maintained in connection with the performance of federally assisted alcohol and drug abuse programs) will be excluded from release.[28]

As to costs associated with the release of information, CMS has estimated that based on representative samples of about 15 to 20 percent of Part D drug events, the cost should be about $20,000, which would cover CMS' costs of reviewing, processing and monitoring the data request.[29]

Public Use Files

CMS has announced its intention to develop de-identified, limited data sets which will be available to the public, including those who wish to use them for a commercial purpose.[30] Because the new regulation allows CMS to use claims data for more than payment purposes, CMS expects to be releasing public information such as the top 100 drugs taken by Medicare beneficiaries, how many beneficiaries reach the coverage gap, how many reach catastrophic coverage, and the like.[31] CMS is seeking input as to what sorts of generic research would be helpful to external researchers.[32]

User Agreements

External researchers must sign a Data Use Agreement (Form CMS-R-0235) that outlines certain restrictions placed on use of the data, including a requirement that the data must be destroyed, with no copies retained, upon completion of the project. The agreement must be executed prior to the disclosure of data. As part of the Agreement, the user agrees to grant access to the data to authorized representatives of CMS or DHHS Office of the Inspector General for the purpose of confirming compliance with the terms of the Agreement, and acknowledges potential criminal penalties for misuse of information.[33]

MIPPA Adds Additional Authorities

Subsequent to the rulemaking process which resulted in the CMS Final Rule, Congress enacted the Medicare Improvements for Patients and Providers Act of 2008 ("MIPPA").[34] MIPPA Section 181 allows the Secretary to use the Part D PDE data for improving public health through research on the utilization, safety, effectiveness, quality, and efficiency of healthcare services, and conducting Congressional oversight, monitoring, and analysis of the program. It also requires the Secretary of HHS to make this information available to Congressional support agencies in accordance with their obligations to support Congress in their authorizing statutes. As a result of MIPPA, CMS will make conforming changes to the Regulation set forth in the CMS Final Rule.[35]

ResDAC's Role

The Research Data Assistance Center ("ResDAC") will inform the research community about how to obtain Part D data, and all requests must be submitted to ResDAC first. ResDAC is a CMS contractor which provides free assistance to academic, government and non-profit researchers interested in using Medicare and/or Medicaid data for their research. It has served as a Medicare contractor for the past 11 years, and is staffed by a consortium of epidemiologists, public health specialists, health services researchers, biostatisticians, and health informatics specialists from the University of Minnesota. As set forth on its website, ResDAC can efficiently and effectively assist researchers in understanding and obtaining the Medicare and Medicaid data files, and its staff Help Desk is experienced with the following:

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- The histories of the Medicare and Medicaid systems as they relate to research.
- The creation of CMS' administrative data files and claims processing.
- The strengths, weaknesses, and applications of Medicare and Medicaid data.
- The methods of cohort identification and file specification.
- The conversion of raw data into usable datasets.
- Medicare and Medicaid program policies and coverage issues.
- The process of requesting data from CMS.
- The use of the Decision Support Access Facility ("DSAF") and the Data Extraction System ("DESY") using the CMS Data Center.

ResDAC offers assistance at all the major health service research conferences and conducts data use workshops 4-6 times each year. Its website includes a listing of currently available CMS data and how to request that data.[36]

Data Request Process

CMS has described the process of obtaining Part D Data in its publication, *CMS Guide to Requests for Medicare Part D Prescription Drug Event (PDE) Data*, last updated on August 15, 2008.[37] In abbreviated summary, that process will include the following steps:

- Requestors will submit their data request packages to the ResDAC, the CMS contractor assisting with requests for PDE data.
- ResDAC will review the data requests for completeness and forward the completed packages to CMS. CMS will then evaluate each PDE data request package to determine if it is acceptable in accordance with its minimum data necessary policy (*see* Appendix C of the Guide).
- CMS will review each request. CMS anticipates that 2007 PDE data will be available early in 2009. Requestors should check the ResDAC website regularly for updated availability dates.
- Once the request is approved, CMS requires other government agencies and external requestors to sign a Data Use Agreement ("DUA") that outlines certain restrictions placed on the data, including a requirement that once a project is completed, the data must be destroyed. The DUA and instructions are found in the Guide, Appendix B.[38]

Conclusion

The Final Rule provides exciting opportunities to utilize Medicare Part D claims data, albeit with some significant limitations and controls due to the need for the protection of beneficiary information and commercially sensitive plan information. Use of this data, particularly when combined with information already available under Medicare Parts A and B, will provide almost real-time information to monitor drug usage, performance and adverse events for a huge end-user population whose demographics are rarely included in clinical trials.

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Endnotes

1 *HHS News Release*, May 22, 2008: *"New Efforts to Help Improve Medical Products for Patient Safety and Quality of Medical Care,"* available at http://www.hhs.gov/news/press/2008pres/05/2008/0522a.html.

2 42 C.F.R. § 423.505.

3 *HHS News Release*, May 22, 2008. *See also* U.S. Food and Drug Administration, *The Sentinel Initiative: Questions and Answers*, available at http://www.fda.gov/oc/initiatives/advance/sentinel/qanda.html. In the latter document, the FDA notes that while its current post-market surveillance programs generate very important new risk information, healthcare professionals and patients must first recognize an association between an adverse effect and a medical product, and then report it to the FDA or the manufacturer. Further, the FDA observes that most adverse events are never reported, and if they are reported, the information provided may be incomplete. With broader information available to the FDA (including that to be shared under the CMS Final Rule), it will be able to identify product problems sooner, better understand those problems, and ultimately help health professionals and patients use medical products more safely. Specific examples as identified in the *Questions and Answers* include situations where clinical trial data suggests a possible risk of cardiac effects related to a device, or post-market reports of possible adverse events that might be linked to a drug.

4 *HHS News Release* (May 22, 2008).

5 *Id.*

6 *Id.*

7 *Id.*

8 *Id.*, referencing 2004 data.

9 U.S. Food and Drug Administration, *The Sentinel Initiative: Questions and Answers*, *supra* at n. 3.

10 CMS *Fact Sheet: Final Medicare Part D Data Regulation (CMS-4119-F)*, May 22, 2008, available on the CMS website at http://www.cms.gov/PrescriptionDrugCovGenIn/Downloads/PartDClaimsDataFactSheet.pdf.

11 73 Fed. Reg. 30664 (May 28, 2008).

12 71 Fed. Reg. 61445 (Oct. 18, 2006); 73 Fed. Reg. at 30667. The PDEs include such data points as the patient date of birth and gender, the date of service, the date the claim was paid by the plan, identification of the pharmacy where the prescription was filled, identification of the prescribing healthcare professional, identification of the dispensed product using its national drug code ("NDC") number, indication of whether the drug was compounded or mixed, indication of prescriber's instruction regarding substitution of generic equivalents, etc. Two additional data elements were added in 2008 (estimated rebate amount applied to the point of sale price and the vaccine administration fee) which are not covered by the CMS Final Rule. 73 Fed. Reg. at 30667; *see also*, CMS *Questions and Answers on Obtaining Prescription Drug Event (PDE) Data*, available at http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/Downloads/PartDClaimsDataQA.pdf. Fields available to researchers are described in the data availability chart located at www.cms.hhs.gov/PrescriptionDrugCovGenIn/08_PartDData.asp.

13 CMS *Part D Data Regulation: Side-by-Side Comparison of the Proposed and Final Rule*, available on the CMS website at http://www.cms.gov/PrescriptionDrugCovGenIn/Downloads/PartDDataRegSidebySide.pdf.

14 *Id.* The limitation on the use of plan identifiers (which indicates the organization which is paying for the drug) is designed to protect competitively sensitive financial data such as rebates, discounts, negotiated price concessions, and the like.

As CMS explains,

> We share the commenters' concerns about the need to protect the sensitive data under the Part D program. Because the Medicare drug benefit is based on a competitive business model, to release commercially or financially sensitive data to the public could negatively impact Part D sponsors' ability to negotiate for better prices, and ultimately affect the ability of sponsors to hold down prices for beneficiaries and taxpayers.

73 Fed. Reg. at 30668.

15 CMS *Special Open Door Forum on Medicare Part D Claims Regulations* (June 11, 2008 Transcript).

16 CMS *Fact Sheet* (May 22, 2008).

17 CMS *Open Door Forum* at 6.

18 Appendix D to 42 C.F.R. Part 423, 73 Fed. Reg. at 30684. As CMS explains, "[e]ncryption permits analysis on a beneficiary, plan, prescriber, or pharmacy level without disclosure of the actual identifying information." *Id.* Federal government executive branch agencies seeking access to Part D data will be required to enter into a data sharing agreement.

See also, U.S. Food and Drug Administration, "*The Sentinel Initiative: Questions and Answers*," *supra* at n. 3.

> Question 8: Will FDA use the Sentinel System to look into my medical records? Answer: No. The system will analyze large sets of data; it won't access individual medical records. In the case of Medicare data, only de-identified data will be accessed, meaning that only information without patients' names and other identifying information will be accessed. . . .

19 CMS *Open Door Forum* at 9.

20 CMS *Guide to Requests for Medicare Part D Prescription Drug Event (PDE) Data* at 15 (August 15, 2008), *supra* at n. 12.

21 73 Fed. Reg. at 30684.

22 *HHS News Release* (May 22, 2008).

23 CMS *Fact Sheet* (May 22, 2008).

24 CMS *Open Door Forum* at 7.

25 CMS *Fact Sheet* (May 22, 2008).

26 73 Fed. Reg. at 30674, citing 45 C.F.R. § 164.501. The *Standards for Privacy of Individually Identifiable Health Information* ("Privacy Rule") is a set of national standards for the protection of certain health information which were issued by HHS to implement the requirement of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), P.L. 104-191. "The Privacy Rule standards address the use and disclosure of individuals' health information – called "protected health information" by organizations subject to the Privacy Rule – called covered entities…." "Summary of the HIPAA Privacy Rule," available at http://www.hhs.gov/ocr/privacysummary.pdf.

27 CMS *Open Door Forum* at 8.

28 *Id.* at 33.

29 *Id.* at 24.

30 CMS *Fact Sheet* (May 22, 2008).

31 CMS *Open Door Forum* at 9.

32 More information about submitting comments can be found at http://www.resdac.umn.edu.

33 The regulation itself provides that CMS may release the minimum data necessary for a given purpose in accordance with CMS data sharing procedures. 42 C.F.R. § 423.505(m)(1)(ii), 73 Fed. Reg. at 30683.

34 Medicare Improvements for Patients and Providers Act of 2008, Pub. L. 110-275, 122 Stat. 2494, Section 181, amending Section 1860D-12(b)(3)(D) of the Social Security Act (42 U.S. § 1395w-112(b)(3)(D)).

35 CMS *Guide to Requests for Medicare Part D Prescription Drug Event (PDE) Data* (August 15, 2008), *supra* at n. 12.

36 ResDAC's website can be found at http://www.resdac.umn.edu.

37 This document is available on the CMS' website, *supra* at n. 12.

38 *Id.*, Appendix B, "Data Use Agreement."

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