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The Epstein Becker & Green P.C., ***Special Alert*** is published by the Health Care and Life Sciences Practice to inform health care organizations of all types of new legal developments which may affect the delivery and financing of health care services.

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CMS Proposed Rule on Medicare Part D Data: Proposed Rule Would Make Data Available for a Variety of Purposes; Comments Requested

Comments Due December 18, 2006

On October 18, 2006 the Centers for Medicare and Medicaid Services ("CMS") published a proposed rule that would make Medicare Part D claims data currently collected for payment purposes available for other purposes such as research, analysis, reporting and public health functions.[1] **CMS will accept comments on this proposed rule until 5:00 PM on December 18, 2006.**

We recommend that any health care entity interested in getting access to this Medicare Part D data should review and comment on this proposed rule. The types of health care entities who are likely to be interested in getting access to this Medicare Part D data include, but are not limited to, Part D plan sponsors, pharmacy participating providers of all types, pharmaceutical manufacturers, disease management firms and others that "touch" the Part D benefit—directly or indirectly.

Currently, Part D sponsors are required to submit data and information as a condition of payment. The proposed rule would make the Medicare Part D claims data currently collected by CMS for payment purposes available for a variety of purposes and to other government entities, researchers and beneficiaries. CMS believes authority to make claims data available exists presently but wishes to resolve any ambiguity that might be found in the relevant statutory provisions.

Threshold Issue: Legal Authority

CMS cites two sets of statutory provisions that it says could be drawn upon to support the permissible uses of Part D claims information. One set of provisions limits use of this information to purposes narrowly tailored to implementation of the Part D benefit.[2] The other set of provisions is much broader. CMS takes the position that its authority to allow these uses of the data is derived from the Social Security permitting such uses "as the Secretary may find necessary and appropriate."[3]

The precise data CMS proposes to access and use is the same in any event—namely, the claims information that Part D drug plan sponsors are already required to submit to CMS. However, by proposing to base its use of this information on the statute's "necessary

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1 Medicare Program; Medicare Part D Data, 71 Fed. Reg. 61445 (proposed October 18, 2006) (to be codified at 42 C.F.R. pt. 423).

2 *See* Social Security Act §§1860D-15(c)(1)(C); 1860D-15(d)(2)(B); 1860D-15(f)(2) (codified at 42 U.S.C. §1395w-115 (2000)).

3 Social Security Act §1857(e)(1) (codified at 42 U.S.C. 1395w-27(2000)). *See also* Social Security Act §1860D-12(b)(3)(D) (codified at 42 U.S.C. § 1395w-112 (2000)).

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and appropriate" language in the statute, CMS believes it can employ this Part D data for a much broader range of policy purposes.

What Information Would Be Accessed?

The proposed rule applies to claims data Plan D sponsors are already required to submit on 100 percent of prescription drug "claims" or events—no new information collection requirements are imposed. For each "claim" or event a set of data elements must be submitted. For the current year, this data encompasses 37 elements ranging from patient-specific information, to date and site of service, to product and prescriber information, to pricing, to payment amounts, to cost information. A complete list of the 37 data elements can be found on the CMS website at http://www.cms.hhs.gov/DrugCoverageClaimsData/.

How Would CMS Use the Information?

CMS says it needs the Part D claims data "for a wide variety of statutory and other purposes."[4] The proposed rule specifies that CMS would access the claims data already submitted to CMS for purposes the Secretary deems "necessary and appropriate." Purposes include, but are not limited to: public reporting, evaluations of Medicare, legislative proposals, and demonstration and research studies. These activities are summarized below:

Public Reporting: CMS anticipates reporting to Congress and to the public on such topics as the performance of the Part D benefit program, statistics relating to "the experience of beneficiaries as their pharmacy coverage changes from the Medicaid to the Medicare program", drug utilization of the Medicare population and that population's cost-sharing.[5]

Evaluations of Medicare: CMS anticipates using the claims data to evaluate the Part D program "including evaluations and oversight of the plans themselves."[6] Evaluations of the plans, themselves, may involve analysis of a particular plan. For example, in the context of "off-prescription" drugs, CMS wishes to "preserve the ability to monitor whether: (1) The over-the-counter drugs are in fact being accessed and (2) whether it appears the step-therapy is saving money."[7]

Evaluations also may occur at the individual beneficiary level. For example, Part D claims data may be used "to determine how access to Part D drug benefits affects beneficiary utilization of services under Parts A and B of the Medicare Program" through data linkages "at the individual beneficiary level."[8]

Legislative Proposals: CMS says claims data are needed to support legislative proposals offered to Congress regarding programs administered by CMS. The claims data could be used to help "illustrate why certain changes to the Medicare statute should be considered, or why certain research and demonstration projects should be funded."[9]

Demonstration Projects and Research Studies: CMS says Part D claims data are needed to conduct demonstration projects and to aid in recommendations for improvement of the Medicare program. Part D claims data would be used for current

cont.

4 71 Fed. Reg. at 61448.
5 71 Fed. Reg. at 61449.
6 *Id.*
7 *Id.*
8 71 Fed. Reg. at 61448.
9 71 Fed. Reg. at 61450.

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and future projects and studies. Future activities include carrying out a new study that "would further examine the relationship between Part B and Part D drug coverage," implementing a new "data warehouse" on chronic illnesses within the Medicare population, and supporting Medicare value-based purchasing initiatives.[10]

CMS notes that the proposed rule would "permit retrospective studies of the administrative records (prescription drug event data) of Part D services for analysis after the services have already been provided."[11]

Who Besides CMS Would Have Access to the Information?

CMS says that "it is in the interest of public health" to make some of the Part D claims data available to other government entities, to researchers, and to beneficiaries.[12] CMS says that release of Part D data would be subject to current requirements of HIPAA, the Privacy Act, and the Trade Secrets Act. The categories of people and entities that CMS proposes to have access to Part D claims data are summarized below:

Government Entities: The proposed rule would allow the sharing of Part D claims data with entities outside of CMS. In particular, the proposed rule mentions public health agencies such as the National Institutes of Health ("NIH"), the Food and Drug Administration ("FDA") and the Agency for Healthcare Research and Quality ("AHRQ"), and oversight agencies such as the Office of Inspector General ("OIG"), the Government Accountability Office ("GAO"), the Congressional Budget Office ("CBO") and the Medicare Payment Advisory Commission ("MedPAC"). These agencies would use Part D claims data to "improve public health consistent with the missions" of the agencies and "to conduct evaluations of the Part D program."[13] For example, the FDA could use claims data to examine "the nature and magnitude of risk conferred by particular medications."[14] AHRQ could use claims data to facilitate comparative effectiveness evaluations that span Medicare Parts A, B, C, and D.

CMS proposes allowing "broad access" for other agencies, including those mentioned above, to Part D claims data linked with CMS's other claims data files. Agencies would enter into a data use agreement "to protect the confidentiality of beneficiary information and ensure that the use of Part D claims data serves a legitimate research purpose."[15]

CMS specifically requests comments which provide guidance on how to serve agency data needs while safeguarding against "the potential misuse of data in ways that would undermine protections put in place to ensure confidentiality of beneficiary information, and the nondisclosure of proprietary data submitted by Part D plans."[16]

Researchers: In order to support the work of external researchers, "such as those based in universities," the proposed rule would make available the chronic care condition data warehouse specified in the Medicare Modernization Act. The proposed rule also would "make available Medicare Part D claims data linked to other Medicare claims files to external researchers on the same terms as other

cont.

[10] 71 Fed. Reg. at 61450, Appendix A.
[11] *Id.*
[12] 71 Fed. Reg. at 61451.
[13] *Id.*
[14] 71 Fed. Reg. at 61452.
[15] *Id.*
[16] *Id.*

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Medicare Parts A and B data are released today, with appropriate protections for beneficiary confidentiality."[17] The proposed rule does not otherwise define the types of "external researchers" qualified to access Part D data. Indeed, CMS specifically asked for comments as follows:

> "We request comments on the proposed use of the data for research purposes that would help CMS in its efforts to improve knowledge relevant to public health. We also ask for comments on whether we should consider additional regulatory limitations for external researchers beyond our existing data use agreement protocols in order to further guard against the potential misuse of data for non-research purposes, commercial purposes, or to ensure that proprietary plan data or confidential beneficiary data is not released."

Beneficiaries: CMS is considering use of Part D claims data to construct a "personalized medication history record" that a beneficiary could access. CMS specifically requests comments on this proposed use of claims data.[18]

* * *

A wide variety of health care entities should review this proposed rule to determine what impact it may have in the context of their operations. This is especially true for those health care entities that may want access to this Medicare Part D data. **Once again, comments on this proposed rule are due before 5:00 p.m. on December 18, 2006.**

If you would like additional information regarding this topic, please contact Ted Mannen at 202/861-1380 or email tmannen@ebglaw.com or Rachael Shenkman at 202/861-5339 or email rshenkman@ebglaw.com, in the firm's Washington, DC office or the Epstein Becker & Green attorney who regularly handles your legal matters. For further information about Epstein Becker & Green's Health Care & Life Sciences Practice, or to see back issues of Special Alerts, please visit our website at www.ebglaw.com.

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[17] *Id.*
[18] 71 Fed. Reg. at 61453.

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