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Leslie V. Norwalk, Esq., Acting Administrator
Centers for Medicare & Medicaid
Services, Department of Health and
Human Services, Attention: CMS–4119–P
P.O. Box 8017
Baltimore, MD 21244–8017

**RE: Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] RIN # 0938–AO58**

Dear Administrator Norwalk:

The American Psychiatric Association (APA), the national medical specialty society representing more than 36,000 psychiatric physicians, appreciates the opportunity to submit these comments in response to the proposed rule by the Centers for Medicare & Medicaid Services (CMS), entitled "Medicare Program; Medicare Part D Data," concerning 42 C.F.R. Part 423 and published in the Federal Register on October 18, 2006.[1]

CMS intends, through this rule, to implement regulations under authority of Section 1860D–12(b)(3)(D) of the Social Security Act (the Act) that essentially broaden access to Part D prescription drug data. CMS proposes to add contract terms with Part D prescription drug plan sponsors (PDPs), under Section 1860D–12(b)(3)(D), "to allow the Secretary to collect the same claims information now collected under the authority of section 1860D–15 of the Act for research, internal analysis, oversight, and public health purposes."[2] CMS later elaborates that it does not actually intend to *collect* this data, rather just to *access* the data already collected under Section 1860D–15.[3] CMS'

[1] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)].

[2] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61446.

[3] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61447:

reasoning for why the Section 1860D–15 restriction would not apply to the data collected under Section 1860D–15 is that CMS *could have* collected it under Section 1860D–12(b)(3)(D). CMS' stated intent is to allow uses for Part D data that would have been restricted under Section 1860D–15 without those contractual terms.[4]

CMS supports its position for the proposed rule by asserting that Section 1860D–15 data-use restrictions do not apply to Part D data collected in the following situations:

> "Where information is collected under an independent authority (even if the collected information duplicates the data collected under section 1860D–15 of the Act). . .
>
> (I)f the Secretary determines it is necessary and appropriate for him to collect Part D data in order to carry out responsibilities outside section 1860D–15 of the Act, then section 1860D–15 of the Act would not serve as an impediment to such collections." [5]

CMS' rationale, above, seems contrary to its intent not to actually collect the Section 1860D–15 data in any other way. CMS does not explain convincingly how data can be "collected under an independent authority" yet not actually be collected at all, how accessing data is synonymous with collecting it or how data admittedly collected under the authority Section 1860D–15 is not subjected to Section 1860D–15 restrictions just because CMS accesses that data for another purpose.

APA strongly objects to CMS' approach in this proposed rule both on legal and public policy bases. APA does not find a supportable legal basis for CMS to create regulations under the authority of one statutory provision that are designed expressly to circumvent another statutory provision. The goal of the proposed rule is to broadly expand the access and use of Part D prescription data. If implemented, this rule would launch Part D data into spheres that have been intentionally precluded from such access and use through federal statute. This sweeping approach is contrary to sound public policy.

The negative ramifications for doing so include increased risk of patient privacy violations, use of the data to pressure physicians to alter prescribing patterns and to pressure patients to request or accept certain drugs. APA agrees that there may be a degree of public benefit in carefully chosen entities using Part D data for certain, discrete

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"We would be collecting the same claims information collected under section 1860D–15 of the Act. We note that although section 1860D–12(b)(3)(D) of the Act would permit us to independently collect claims data from Part D sponsors, in order to ensure that Part D sponsors would not have to submit the claims information twice, we propose to access the claims data submitted under section 1860D–15 of the Act. This access avoids Part D sponsors engaging in duplicative efforts."

[4] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61446.

[5] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61447.

activities. However, we do not agree with CMS' rationale for this proposed rule or that this is the most carefully tailored means by which to attain this goal.

**Part D Program Evaluation**

CMS implies that it needs to proposed rule to evaluate various aspects of the effectiveness and efficiency of Part D program, including matching individual patient-level statistics from Part D with Parts A and B data.[6] However, if CMS wishes to match Part D data with that from Parts A & B, Section 1860D–15(c)(C) already requires CMS to collect such linkable data from PDPs, data which is subject to use restrictions elsewhere in that section:

"(c) ADJUSTMENTS RELATING TO BIDS.—

> (C) DATA COLLECTION.—In order to carry out this paragraph, the Secretary shall require—
> (i) PDP sponsors to submit data regarding drug claims that can be linked at the individual level to part A and part B data and such other information as the Secretary determines necessary; and
> (ii) MA organizations that offer MA-PD plans to submit data regarding drug claims that can be linked at the individual level to other data that such organizations are required to submit to the Secretary and such other information as the Secretary determines necessary."

Contrary to CMS' implications in the proposed rule, current laws and regulations do not appear to prevent CMS from using data collected under Section 1860D–15 from evaluating the Part D program. Section 1860D–15 allows the Secretary a wide range of discretion in determining the uses to which it puts the data collected: "for the purposes of, and to the extent necessary in, carrying out this section." If CMS wishes to collect Part D-related data on a PDP's operations, i.e., utilization management,[7] that CMS is not already collecting under Section 1860D–15, CMS can require PDPs to provide the data in future contracts, under Section 1860D-12. CMS would not appear to be precluded from matching separately collected operations data with Part D data collected under Section 1860D–15 for its program evaluation purposes.

**Reporting to Congress and the Public**

APA agrees when CMS states that, "we do not believe that section 1860D–15 of the Act was intended to prohibit the Secretary from reporting to both the public and to the Congress."[8] It is illogical that Section 1860D–15 would mean to preclude CMS from compliance with Section 101(e) of the Medicare Prescription Drug, Improvement, and

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[6] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61447.

[7] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61449.

[8] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61447.

Modernization Act of 2003 (MMA) that specifically requires CMS to study the Part D program and report to Congress annually on its operation.[9] Those activities would appear to fall clearly within the Section 1860D–15 test: "for the purposes of, and to the extent necessary in, carrying out this section."

CMS essentially asserts that, if it uses Part D data to report to Congress, or if that data is otherwise not used to "carry out responsibilities outside Section 1860D–15" then Section 1860D–15 restrictions on the use of that data do not apply, even though the data was originally collected under Section 1860D–15.[10] Section 1860D–15 data-use restrictions are effective immediately to any data collected under Section 1860D–15, which specifically limits use of the data "for the purposes of, and to the extent necessary in, carrying out this section." That plainly means that use of that data for purposes outside of carrying out Section 1860D–15 responsibilities is specifically prohibited.

There is nothing in Section 1860D–15 suggesting that HHS is precluded from preparing mandated reports to Congress on Part D data collected under that section, making internal budget neutrality calculations that affect payments, or assessing appropriate use of medications to determine propriety of payments. All of these activities are permissible, as they relate to Part D PDP payments.[11] While reporting to Congress is required of CMS, reporting on Part D data directly to the public is not required; in fact, it is prohibited by Section 1860D–15, unless it is for the strict programmatic purposes of the section.

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[9] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61449, footnote 2:
"2 Section 101(e) of the MMA specifically extended the study authority in section 1875(b) to include the prescription drug program under Title XVIII. Section 1875 now states in pertinent part that the Secretary ''shall make a continuing study of the operation and administration of this title * * * and shall transmit to the Congress annually a report concerning the operation of such programs.'''

[10] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61447:
"For example, we are required to report to the Congress regarding whether mandated disease management demonstrations are budget neutral and whether beneficiaries in these demonstrations are on the appropriate medications. Part D claims data are needed for these budget neutrality calculations as well as quality measures assessing appropriate use of medications. We may also need to make reports under the Part D program, for example, the publication of statistics detailing aggregate Medicare and beneficiary spending by class of drug, average number of drugs used by beneficiaries, total Medicare program spending, and other similar statistics. In order to derive such statistics, we would need to collect Part D claims data. These examples demonstrate that in a wide variety of situations it will be ''necessary and appropriate'' for CMS to evaluate the same information collected under section 1860D–15 of the Act, even though such information would not be used to implement section 1860D–15 of the Act. In these situations, we believe the clear language of section 1860D– 12(b)(3)(D) of the Act provides the authority to collect the necessary information, and nothing about such collection will be inconsistent or in conflict with any other part of the statute."

[11] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61447.

However, CMS does not cite to a statutory mandate requiring reporting of Part D data to the public, apart from through its reports to Congress, which may become publicly available records. Contrary to CMS's interpretation that Section 1860D–15 was not intended to prohibit HHS reporting to the public, Section 1860D–15 specifically prohibits such use of the data, unless it complies with this section because it is "for the purposes of, and to the extent necessary in, carrying out this section." Whether or not a given type of public reporting complies with this requirement becomes a question of legal interpretation.

**Sharing Data with External Researchers**

CMS gives examples of ways in which it could share Part D data with external entities, if the proposed rule were implemented. A number of these examples refer to current uses or those that are already enabled by existing laws and regulations. Considerable Medicare data is already accessible to other entities and researchers. CMS currently sponsors two major, publicly available data sets each year on Medicare beneficiaries, "Access to Care" and "Cost and Use," that involve various claims data and can be purchased for only $480 each from the Internet.[12, 13]

CMS states, for example, that this proposed rule would allow CMS to give Part D data to the Food and Drug Administration (FDA) "in order to oversee the safety and effectiveness of prescription drugs and conduct postmarket surveillance . . ."[14] However,

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[12] Medicare Current Beneficiary Survey (MCBS) website: ". . . MCBS, which is sponsored by the **Centers for Medicare & Medicaid Services** (CMS), is the only comprehensive source of information on the health status, health care use and expenditures, health insurance coverage, and socioeconomic and demographic characteristics of the entire spectrum of Medicare beneficiaries."
Retrieved December 11, 2006: http://www.cms.hhs.gov/apps/mcbs/default.asp

"The Access to Care PUF contains information on beneficiaries' access to health care, satisfaction with care, and usual source of care. . . To facilitate analysis, the information collected in the survey is augmented with data on the use and program cost of Medicare services from Medicare claims data under fee-for-service. . .

The MCBS cost and use files link Medicare claims to survey-reported events and provides complete expenditure and source of payment data on all health care services, including those not covered by Medicare."
Retrieved December 11, 2006: http://www.cms.hhs.gov/apps/mcbs/DFDesc.asp#ATCfd

[13] **Purchasing Information**
CMS releases MCBS data only under a data use agreement. CMS will release some billing and administrative data with the MCBS survey data, commensurate with demonstrated need. Researchers who have specific needs for more detailed geographic information or for Medicare claims data may request Limited Data Set (LDS) Files from CMS. Requests for these files must include a study protocol with specific justification for the additional data required, along with an Identifiable Data Use Agreement.
Retrieved December 11, 2006: http://www.cms.hhs.gov/apps/mcbs/FileAval.asp

[14] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61448:
"(W)e believe that when information is collected under the auspices of section 1860D–12(b)(3)(D) of the Act, the restrictions of section 1860D–15 of the Act would not apply to such collections. Thus, any information collected for Part D purposes under this proposed rule would no longer be subject to the

FDA already routinely monitors prescription drugs, biologics, and medical devices for drug safety and effectiveness from clinical trials to the post-marketing stage, under its own regulatory authority through its own data collection and usage channels. CMS does not indicate that FDA has sought out Part D claims data from CMS or that it would use it.

The 37 data elements CMS lists on 2006 Part D claims data that are collected under Section 1860D–15 (subject to its use restrictions) do not contain data on patient outcomes, complaints, clinical signs or symptoms, or even the patient's diagnosis for which a drug is prescribed. It is unclear how CMS's sharing of Part D claims data with FDA could be used to accurately monitor "unsafe or suboptimal patterns of use" by drug type, dosage or duration, or identify rare drug complications at the patient or population levels.[15, 16] There would not appear to be claims data to support a causation or correlation between a given prescription and a patient's medical status or outcome at a given point, apart from documenting receipt of a prescription. These listed elements do not show a diagnosis that prompted the prescription or that the patient took the medication even once. All these characteristics of Part D claims data limit their application for certain studies. Also, Medicare beneficiaries constitute only a specific subpopulation of patients, which is a limiting factor in the use of data on them.

It is unclear whether FDA would be willing to use Part D claims data or whether it would improve FDA's work. There are reliability problems inherent with any claims data and issues with meshing Part D data with FDA's own databases. If FDA decided it needed additional data, presumably FDA could collect it without this proposed CMS rule. In certain circumstances, CMS may have the option to collect data separately under Section 1860D–12(b)(3)(D) for FDA or other purposes without of Section 1860D--15 restrictions applying. Those are discussed in more detail, below.

Another reason CMS posits for the proposed rule is its desire to share Part D claims information with external researchers, whose studies include those related to quality and cost of care for Medicare patients. However, CMS notes that Section 723 of the MMA already mandates that HHS develop a plan to improve care quality and reduce cost. For that purpose, Congress specifically provided for Part D data collection under Section 723(b)(3).[17] Therefore, this aspect of data collection and access has already been

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section 1860D–15 of Act limitations and could be shared outside of CMS as appropriate. Thus, for example, to the extent otherwise permitted by law, we would be able to share the data we collect under section 1860D–12(b)(3)(D) of the Act with entities outside of CMS including, for example, the Food and Drug Administration (in order to oversee the safety and effectiveness of prescription drugs and conduct postmarket surveillance) . . ."

[15] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61447, where CMS lists the 37 data elements collected in 2006 for PDP payment.

[16] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61452.

[17] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61452.

provided for, obviating any need to alter any existing federal statute or regulations to accomplish this purpose. CMS can share Part D claims data freely with its contractors who are external researchers, since this is a permissible use under Section 1860D–15. As noted previously, CMS also sponsors annual data set releases to the public for research purposes, "Access to Care" and "Cost and Use,"on Medicare beneficiaries that will soon include Part D beneficiary data.

**Section 1860D–15 Restriction on Part D Data Use**

CMS notes in the proposed rule that, "(o)ne of the incorporated provisions at section 1860D–12(b)(3)(D) of the Act is section 1857(e)(1) of the Act, which provides broad authority for the Secretary to add terms to its contracts with Part D sponsors, including terms that require the sponsor to provide the Secretary 'with such information * * * as the Secretary may find necessary and appropriate.' We believe that the broad authority of section 1860D–12(b)(3)(D) of the Act authorizes us to collect much of the information CMS is already collecting in order to properly pay sponsors under the statute."[18]

Within the provision entitled, "(d) PAYMENT METHODS," Section 1860D–15(d)(2)(A) of the Act requires, that "a PDP sponsor or MA organization" give HHS "such information as may be required to carry out this section," as a requirement for payment.[19] The immediately following provision, Section 1860D–15(d)(2)(B), refers to the (d)(2)(A) information and imposes a clear restriction on its use:

> (B) RESTRICTION ON USE OF INFORMATION.—Information disclosed or obtained pursuant to subparagraph (A) may be used by officers, employees, and contractors of the Department of

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[18] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61447:
"One of the incorporated provisions at section 1860D–12(b)(3)(D) of the Act is section 1857(e)(1) of the Act, which provides broad authority for the Secretary to add terms to its contracts with Part D sponsors, including terms that require the sponsor to provide the Secretary ''with such information * * * as the Secretary may find necessary and appropriate.'' We believe that the broad authority of section 1860D–12(b)(3)(D) of the Act authorizes us to collect much of the information CMS is already collecting in order to properly pay sponsors under the statute."

[19] Social Security Act, "SEC. 1860D-15. *[42 U.S.C. 1395w-115]"*
"(d) PAYMENT METHODS.—
(1) IN GENERAL.—Payments under this section shall be based on such a method as the Secretary determines. The Secretary may establish a payment method by which interim payments of amounts under this section are made during a year based on the Secretary's best estimate of amounts that will be payable after obtaining all of the information.
(2) REQUIREMENT FOR PROVISION OF INFORMATION.—
(A) REQUIREMENT.—Payments under this section to a PDP sponsor or MA organization are conditioned upon the furnishing to the Secretary, in a form and manner specified by the Secretary, of such information as may be required to carry out this section.
(B) RESTRICTION ON USE OF INFORMATION.—Information disclosed or obtained pursuant to subparagraph (A) may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this section."

Health and Human Services *only for the purposes of, and to the extent necessary in, carrying out this section.* (*Italics* added for emphasis.) [20]

In order to further reinforce this restriction, the drafters put this exact clause into another provision within Section1860D–15(f). Moreover, the statute mandates that this data-use restriction is to be put into each Part D (and Part C) contract:

> "(f) DISCLOSURE OF INFORMATION.— (1) IN GENERAL.—Each contract under this part and under part C shall provide that . . .
>
> (2) RESTRICTION ON USE OF INFORMATION.—Information disclosed or obtained pursuant to the provisions of this section may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this section." [21]

CMS' interpretation of this data-use restriction that appears *twice* in Section 1860D–15 is that "section 1860D–15 of the Act contains provisions that *might be viewed* as limiting such collection . . ."[22] *(Italics added for emphasis.)* The statutory drafters intentionally put the restriction into both the payment requirement and disclosure of information provisions. There is nothing equivocal about the choice of the word "only" or the fact that this restriction must be in HHS Part D contracts.

CMS cannot sidestep this clear statutory requirement by using Section 1860D–12(b)(3)(D) as authority to institute contractual terms that contravene or conflict with Section 1860D–15 provisions that govern and restrict the use of Part D data. HHS and its contractors are bound by the Section 1860D–15 data-use restriction, as they are by all applicable federal and state law. A federal agency and its private or public contractors cannot summarily pre-empt or avoid compliance with federal statutory law by contractual agreement.

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[20] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61447.

[21] Social Security Act, "SEC. 1860D-15. *[42 U.S.C. 1395w-115]*"
"(f) DISCLOSURE OF INFORMATION.—

> (1) IN GENERAL.—Each contract under this part and under part C shall provide that—
> (A) the PDP sponsor offering a prescription drug plan or an MA organization offering an MA-PD plan shall provide the Secretary with such information as the Secretary determines is necessary to carry out this section; and
> (B) the Secretary shall have the right in accordance with section 1857(d)(2)(B) (as applied under section 1860D-12(b)(3)(C)) to inspect and audit any books and records of a PDP sponsor or MA organization that pertain to the information regarding costs provided to the Secretary under subparagraph (A).
> (2) RESTRICTION ON USE OF INFORMATION.—Information disclosed or obtained pursuant to the provisions of this section may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this section."

[22] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61446.

The lucid, highly restrictive language in Section 1860D–15 makes it is obvious that Congress recognized the need for strict limitations on the ways in which Part D data could be used. This statutory restriction wisely anticipated the potential for broad dissemination and misuse of Part D data. The restrictive provisions properly preclude dissemination of this information beyond the inevitable internal needs of the Part D program. Section 1860D–15 protects against exploitation of Part D data for commercial benefit and from privacy intrusions, both from the patient's and the prescriber's perspectives. This statutory provision was well-conceived and embodies sound public policy considerations that should remain intact.

CMS basically wishes to render inapplicable Section 1860D–15 data-use restrictions by using contractual terms with PDPs, through Section 1860D–12(b)(3)(D)'s authority. This is especially confounding, as it involves use of the same Part D data that CMS acknowledges was collected under Section 1860D–15 and will not be actually collected again, under Section 1860D–12(b)(3)(D). CMS specifically states in the proposed rule that, "(w)e propose to implement section 1860D–12(b)(3)(D) of the Act to allow the Secretary to collect the same claims information now collected under the authority of section 1860D–15 of the Act for research, internal analysis, oversight, and public health purposes."[23] Instead of using an outside legal authority to support this position, CMS quotes itself from the January 28, 2005 Medicare prescription drug benefit final rule:

> [W]e interpret sections 1860D–15(d) and (f) of the Act as limiting the use of information collected under the authority of that section. If information is collected under some other authority, however, we do not believe that section 1860D–15 of the Act would limit its use-because the information would not be collected "pursuant to the provisions" of section 1860D–15 of the Act. QIOs have independent authority to collect data, and to fulfill their responsibilities. To the extent QIOs need access to data from the transactions between pharmacies and Part D sponsors, these data could be extracted from the claims data submitted to us.[24]

Section 1860D-15(c)(1)(C) allows HHS to collect Part D drug claims data from PDP sponsors. Any such data is collected "pursuant to the provisions" of 1860D-15 and is subject to Section 1860D-15(d) and (f) use and disclosure restrictions that apply to HHS "officers, employees, and contractors." QIOs and other CMS contractors gain the authority they possess with regard to collecting or using Part D claims data from the authority CMS has under federal statutes. Therefore, both CMS and its contractors must be in compliance with Part D federal statutory restrictions under Section 1860D-15(d).

There are two possible scenarios under Part D data collection may fall outside Section 1860D-15 restrictions. One is where the collected data are different from the data collected under Section 1860D-15. The other is if the data are the same as or

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[23] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61446.

[24] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61447.

overlaps Section 1860D-15 data but is actually collected pursuant to legal authority other than Section 1860D-15. It is possible that a court might determine that Section 1860D-15 restrictions would not apply under these situations. However, CMS does not offer legal authority for either of these interpretations. Even if there were extraneous data that could arguably fall outside Section 1860D-15 authority, data collected under Section 1860D-15 cannot avoid the restriction simply because there exists another avenue of collection for the same information.

Section 1860D–15 already allows for Part D data collection and use for HHS/CMS' internal programmatic purposes and even restricts use of it for that purpose. So, the obvious intent of the proposed rule is to expand access to Part D data to those whom the drafters of Section 1860D–15 clearly intended to preclude from having access and use. Despite the clear restriction on use of Part D data under Section 1860D–15, CMS finds ambiguity as to the meaning of the restriction, including as it intersects with 1860D–12(b)(3)(D). CMS explains that, "we are engaging in this rulemaking in order to resolve the statutory ambiguity, as well as to explain how we plan to implement the broad authority of section 1860D–12(b)(3)(D) of the Act."[25]

**Part D Information Collection and Access**

CMS acknowledges that, under Section 1860D–12(b)(3)(D), "(w)e would be collecting the same claims information collected under Section 1860D–15 of the Act."[26, 27] Adopting a parallel or duplicative data collection/use method would seem inconsistent with CMS' stated goal of conserving Medicare program resources for beneficiaries.

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[25] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61446.

[26] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61466-7.

SEC. 1860D-12. *[42 U.S.C. 1395w-112]* REQUIREMENTS FOR AND CONTRACTS WITH PRESCRIPTION DRUG PLAN (PDP) SPONSORS:

"(b) CONTRACT REQUIREMENTS.—

> . . . (3) INCORPORATION OF CERTAIN MEDICARE ADVANTAGE CONTRACT REQUIREMENTS.—Except as otherwise provided, the following provisions of section 1857 shall apply to contracts under this section in the same manner as they apply to contracts under section 1857(a):
> . . . (D) Additional contract terms.—Section 1857(e); except that section 1857(e)(2) shall apply as specified to PDP sponsors and payments under this part to an MA-PD plan shall be treated as expenditures made under part D.

[27] SEC. 1857. *[42 U.S.C. 1395w-27]* CONTRACTS WITH MEDICARE+CHOICE ORGANIZATIONS
"e) ADDITIONAL CONTRACT TERMS.—
> (1) IN GENERAL.—The contract shall contain such other terms and conditions not inconsistent with this part (including requiring the organization to provide the Secretary with such information) as the Secretary may find necessary and appropriate."

To avoid that issue, CMS proposes to *access* the claims data already submitted under Section 1860D–15 for ostensibly non-Section 1860D–15 purposes, yet concludes that Section 1860D–15 restrictions on using that data would, nonetheless, not apply. Again, no legal authority is cited for CMS' conclusions in that regard. CMS logic is that:

> We would be collecting the same claims information collected under section 1860D–15 of the Act. We note that although section 1860D–12(b)(3)(D) of the Act would permit us to independently collect claims data from Part D sponsors, in order to ensure that Part D sponsors would not have to submit the claims information twice, we propose to access the claims data submitted under section 1860D–15 of the Act.[28]

CMS cannot legally circumvent the clear provisions of a federal statute on the basis of its own unsupported conclusions that the statute does not apply because CMS does not wish for it to apply. Once data are collected under Section 1860D–15 provisions and authority, Section 1860D–15 restrictions on use of the data automatically applies to those data, regardless of whether those data are otherwise accessible or could have been collected by other means. CMS notes that "(t)he claims data for 2006 includes 37 data elements."[29] Among these are highly sensitive information about patients, including their claim number identifying the beneficiary, birth date, gender, prescriber, drug(s) and other prescription information.

**Revised Section 423.505**

APA does not agree with or support any of CMS' proposed regulatory revisions that conflict with, pre-empt or render ineffective any provision of any federal statute. This includes Section 1860D–15 and its prohibitions on impermissible uses of Part D data. In addition, APA urges CMS to redraft this regulation to avoid any implication that it could be construed to circumvent or otherwise negate the effects of Section 1860D–15. CMS should revise the language of Part 423, including § 423.505, to require that application of Part 423 be strictly limited to Part D data CMS collects or accesses that does *not* duplicate, overlap or pre-empt data collected under Section 1860D–15.

CMS proposes to revise regulation § 423.505 "Contract provisions," including adding § 423.505(f)(5), "that would specify that we could use and share the claims information we collect under § 423.505(f) with both outside entities and other government agencies, without regard to any restriction included in § 423.322(b)."[30, 31]

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[28] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61447.

[29] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61447.

[30] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61451; 61454.

[31] "Sec. 423.322 Requirement for disclosure of information.

The restriction of § 423.322(b) mirrors the language of the Section 1860D–15 data-use restriction, stating that "(o)fficers, employees and contractors of" HHS "may use the information disclosed or obtained in accordance with the provisions of this subpart only for the purposes of, and to the extent necessary in, carrying out this subpart including, but not limited to, determination of payments and payment-related oversight and program integrity activities." CMS' proposed rule not only specifically intends to circumvent Section 1860D–15 data-use restriction; it also intends to render its prior regulation embodying that concept completely ineffectual.

**Lack of Restrictions in the Proposed Rule**

The proposed rule does not provide the restrictions required to protect physicians' professional judgment, patients' privacy and to prevent commercial exploitation of the data. The following are examples of types of restrictions that should be enumerated and articulated within such a regulation, yet are absent:

1. Names or descriptive characteristics of public and private recipient entities (i.e., healthcare-related government agencies, non-profit healthcare research organizations, etc.);
2. Permissible types of uses for the data by recipient entities;
3. Prohibitions on commercial uses or commercial gain from using the data;
4. Prohibitions on use of the data to influence physicians' prescribing patterns, including on the individual patient level;
5. Prohibitions on use of the data to influence patients' choice or acceptance of generics or certain types or brands of Part D drugs, biologics, etc.;
6. Prohibitions on transmitting the data to third parties;
7. Requirements for privacy protections within systems, policies and procedures of recipient entities; and
8. Requirements for privacy protections during the use of the data, i.e., proper use of masking of identifiers

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(a) Payment conditional upon provision of information. Payments to a Part D sponsor are conditioned upon provision of information to CMS that is necessary to carry out this subpart, or as required by law.

(b) Restriction on use of information. Officers, employees and contractors of the Department of Health and Human Services may use the information disclosed or obtained in accordance with the provisions of this subpart only for the purposes of, and to the extent necessary in, carrying out this subpart including, but not limited to, determination of payments and payment-related oversight and program integrity activities. This restriction does not limit OIG's authority to fulfill the Inspector General's responsibilities in accordance with applicable Federal law."

CMS proposes in this rule to share Part D data with "outside entities," in addition to "other government agencies." Presumably, CMS' use of the term "outside entities" in Sec. 423.505 refers to non-governmental entities, both public and private. APA is greatly concerned that the proposed rule would allow blanket access and unrestricted usage of Part D data by any entity with which CMS shares the data. Recipients could also share the data with third parties of their choice. While the proposed rule at least requires CMS to use and share the data "in accordance with applicable Federal law" (notwithstanding that doing so in contravention to Section 1860D–15 data-use restrictions would not meet this test), there is no similar compliance clause pertaining to the recipients of the data.

Also, there is absolutely no language in the proposed rule that restricts which recipients CMS can choose to receive this Part D data or how they use the data. CMS notes in the text of the proposed rule that Part D data would be useful for public health agencies such as National Institutes of Health (NIH), Food and Drug Administration (FDA) and the Agency for Healthcare Research and Quality (AHRQ). CMS also believes that oversight agencies, "such as the OIG, GAO, and CBO"[32] would need access to both aggregated and non-aggregated claims data.

However, the main purpose for use of Part D data by oversight agencies would be to perform extensive data mining to detect physicians' prescribing patterns of interest. This would be likely to result in physician profiling in an attempt to proactively identify potential fraud and abuse cases or other violations. That would promote more aggressive measures by these agencies to target physicians for enforcement efforts solely on the basis of profiling, rather than concrete evidence. While APA certainly supports legitimate enforcement efforts, there is concern that this profiling could burden many innocent physicians with having to defend themselves against undue allegations of programmatic violations and investigations.

There are no prohibitions on the nature of the use or sharing of the data by recipient entities, either internally or with third-party entities of their choice. This proposed rule, on its face, would allow Part D data recipients to use the data for commercial gain, including selling or trading the data, sharing the data with the recipient's subsidiaries, business partners, etc., or transmitting it to third parties for financial or other gain. FBI, police, life insurance companies, healthcare insurers, prospective employers and all manner of entities could potentially access and use this Part D data for whatever purposes they chose, commercial or otherwise.

**Physicians' Judgment, Patients' Privacy and Commercial Exploitation**

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[32] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61452:
"We believe oversight agencies may also require access to the Part D claims data. These agencies would include the Office of the Inspector General (OIG), the Government Accountability Office (GAO), the Congressional Budget Office (CBO), and the Medicare Payment Advisory Commission (MedPAC)."

While many benign and productive uses are possible for Part D data, widespread access to such data will inevitably be prone to misuse, breaches of privacy and commercial exploitation. APA is especially concerned that pharmaceutical companies and others with a financial interest in influencing physicians' prescribing patterns will be able to do so in a more highly targeted, effective way than is now possible. This can be done through marketing efforts, incentives and other methods that direct physicians toward prescribing drugs that provide higher a financial advantage to some entity.

Targeted pressure may be directed toward brand names, generics over brands, or certain classes of drugs over others. When detailed patient-level prescribing information is accessible, it allows for pinpointed influence attempts at the micro and macro levels. Where there is political pressure on government agencies to reduce costs for drug utilization, this can translate into increased pressure on physicians participating in such programs.

Whenever physicians are highly pressured to prescribe in a given direction, it interferes with their free exercise of professional judgment in the best interests of the patient. The managed care environment in private and public sectors already encourages more of this type of activity than is optimal for physicians and their patients. This would be markedly enhanced by CMS' proposed rule, which promotes interference with, rather than protecting, the sanctity of the physician-patient relationship.

APA has ongoing privacy concerns for patients, whose intimate medical details can be gleaned directly and indirectly from Part D claims data. The more widespread the data within computerized systems, the higher the likelihood of privacy breaches. When CMS wishes to compound this problem by widening the circle of dissemination of Part D data to any entity, regardless of its relationship to the program, the privacy concerns expand logarithmically. CMS notes that the proposed rule would not affect existing HIPAA, Privacy Act or states' privacy protections.[33] Such privacy laws cover physician-patient and other healthcare interactions but can easily be averted by commercial (or other) entities that are allowed to access and use Part D data outside the umbrellas of protection.

There are other issues. Insurance companies can access and use such data to the disadvantage of patients. For psychiatric patients, once an entity discovers merely that they are prescribed certain psychotropic drugs, it is easy to extrapolate with some degree of accuracy that the patient is experiencing psychiatric illness and what type it is. Especially considering the social stigma of psychiatric illness, having such information be widely accessible can adversely affect a person's life in a substantial way.

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[33] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61453:
"The proposed revision does not affect the applicability of HIPAA to the Department or any other appropriate parties, nor does it affect the applicability of the Privacy Act (5 U.S.C. 552a and b) or the Trade Secrets Act (18 U.S.C. 1905)."

Apart from these negative consequences of Part D data dissemination, various commercial advantages can be gained when entities access and use Part D data. Patients can be subjected to highly targeted marketing efforts to request or accept certain prescription drugs. While some may find this only a minor annoyance, marketing mailings can reflect that a person has a certain disorder or is on certain types of medication. This can prove highly intrusive and disruptive to their lives. For instance, a loved one may not be aware that a patient was prescribed a certain anti-depressant, but accidentally opens a mailing that indicates this. Such marketing can also influence a patient's willingness to accept a physician's recommendation to take a certain prescription drug that may work better for that patient.

The most CMS says in the proposed rule about patient privacy protections is that data release to external researchers would be subject to CMS' "standard data use agreement protocols" and that each research request would be evaluated to determine whether "(t)he confidentiality of beneficiary information is protected."[34] These statements are less than reassuring, especially absent any privacy protection language in the proposed regulation itself.

## CONCLUSION

APA supports CMS' goals such as addressing health disparities and improving Medicare services.[35] To the extent that publicly beneficial activities are genuinely precluded by current statutory language, a conclusion for which this proposed rule does not provide convincing support, APA would support CMS working with Congress to revise or amend the statute. However, APA does not support broadening the access or use of Part D data to any public or private entity that wishes to have it. APA is especially concerned about Part D data access by private commercial entities for financial gain, i.e., through pressuring physicians to alter prescribing patterns or for marketing drugs to current or prospective beneficiaries. As conceived, the proposed rule is far too liberal in its scope of intended access. Moreover, it lacks substantive privacy protections and other limitations to protect patients' welfare.

APA urges CMS to reconsider its approach to expanding access of Part D claims data. While APA agrees that public health and other benefits may be obtained from judicious sharing of Part D data with other governmental agencies and certain carefully chosen private entities, CMS must more thoroughly think through the appropriate legal and practical methods for reaching acceptable goals in this regard. The substantial privacy interests of patients and need to prevent undue intrusion into physicians' prescribing decisions must be carefully protected. Any further data sharing must account for and weigh these interests heavily against the likelihood of commercial exploitation

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[34] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61453.

[35] Centers for Medicare & Medicaid Services (CMS) Proposed Rule: "Medicare Program; Medicare Part D Data;" [CMS–4119–P] [RIN # 0938–AO58] [Federal Register: October 18, 2006 (Vol. 71, No. 201)], at 61448.

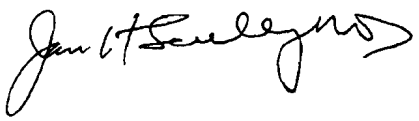
and unchecked dissemination of highly sensitive information into private and public spheres.

APA's position is that CMS's legal basis for accomplishing the goal of broader dissemination of Part D claims data is highly flawed and unsupportable. It is improper for a federal agency to deliberately design and implement a regulation specifically to avoid a federal statutory provision that protects the privacy and sanctity of Medicare beneficiaries' medical information. In addition, even if CMS' proposed method were appropriate, the language of the proposed rule is not tailored to provide any protection from patient privacy intrusions or breaches, undue influence upon prescribers, commercial exploitation, dissemination to third parties or other protections that should be required. APA believes that there is a more legally appropriate, highly tailored way to achieve most, if not all, of CMS's goals for enhancement of the Part D program by very selectively choosing certain other government agencies and researchers with which to share Part D data.

APA strongly urges CMS to weigh privacy and other interests against potential benefits, then determine with precision which government agencies and external entities truly would provide sufficient benefits to the public, if CMS were to share Part D data with them. There must be clearly delineated, specific parameters for access, use and dissemination of Part D data that comports with existing federal statutes, including Section 1860D–15 data-use restrictions, and protects patients' privacy to the utmost degree possible.

Thank you for allowing APA the opportunity to communicate its concerns.

Sincerely,



James H. Scully Jr., M.D.
Medical Director and C.E.O., American Psychiatric Association

12

December 18, 2006

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

File Code: CMS-4119-P (Medicare Program: Medicare Part D Data)

Dear Ms. Norwalk:

Thank you for the opportunity to comment on the use of Medicare Part D Data. Our comments relate to how the data would add value to existing information sources and that there is need for access to the data by a broader group of stakeholders. The Leapfrog Group believes this information is critical to analyze for a variety of stakeholders related to various healthcare policy and clinical quality issues. Individual physician prescribing information is valuable in that it allows one to examine prescribing practice patterns and provide feedback to physicians and health plans. It is also useful in identifying an episode of care, medications are often the first line of care and knowing when the treatment was initiated is vital to accurately portraying an episode of care. We support the use of the data by CMS for managing cost and clinical quality, and we also support the use of research databases from this information, as well as aggregated physician information for other uses.

The continued "protection" of individual physicians is counter to the movement of "Pay for Performance" and managing the increasing cost of care. As a representative of large employers we know that many employers are close to abandoning the traditional forms of insurance. While HSAs seem to be gaining traction there are many unintended consequences associated with these alternative forms of insurance, including not seeking care at the appropriate time. In order to make good decisions about "how much care" and "at what cost," employers need more information on physicians.

Employers need to know if dollars spent on medications in the outpatient sector can prevent hospitalizations. This Part D drug information linked to outpatient data (Part B) and hospitalization data (Part A) is invaluable, and certainly would help all of us better understand whether what appear to be excess drug costs and outpatient care, are in fact, saving dollars by avoiding inpatient care for the patient. Since only a few states have information on physicians, and then it usually does not include medications, employers and others have no options for acquiring this information. While many employers rely on their health plans for information, the health plan data may only be a small portion of a

specific physician's practice, and as a result, using the plan data is often inadequate to examine practice patterns and to establish episodes of care. Without the information that this data could provide, we are truly in the dark about the appropriateness of care.

Further, if it were possible to pool the linked data with data from private sources, we could vastly increase our ability to provide solid information to consumers caught in a vise of having to make choices for expensive healthcare with no information. It would certainly be possible to pool the data, de-identify it (except employer ID) and provide payers of the data with an opportunity to pool their information with their own. Consumers and enrollees could make better choices if there was an accurate accounting of the care quality.

We strongly urge the release of the Part D information for analytic purposes to assist CMS, and others to work on reducing the cost of care delivery and improving the quality of care; we are truly in a state of crisis and we need increasing transparency of the healthcare delivery in the outpatient sector—further protection of physicians from oversight cannot continue.

Sincerely,

Karen Linscott,
Chief Operating Office and Acting CEO
The Leapfrog Group

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
3311 Toledo Road, Room 7209
Hyattsville, Maryland 20782

December 6, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-4119-P
P.O. Box 8107
Baltimore, MD 21244-8017

Re: Sharing Data With Entities Outside of CMS

To whom it may concern:

Let me begin by stating my enthusiastic support for CMS efforts to link Medicare Part D claims data to Medicare Parts A and B and for its proposed rule to share the data with Federal agencies outside of CMS, possibly including the Centers for Disease Control and Prevention (CDC). The National Center for Health Statistics (NCHS), as part of CDC, is the Nation's principal health statistics agency. NCHS would like to link its population based surveys to the Medicare Part D data linked to Medicare Parts A and B claims data, in order to address its mission to provide accurate, relevant, and timely data resources and statistical information that guides actions and policies to improve the health of the American people.

CMS and NCHS have a long history of collaborative data sharing that has helped NCHS to fulfill its mission, beginning with linkages of NCHS survey data to Medicare Parts A and B claims data in the 1980s, and continuing till the present, most recently with the linkage of NCHS population-based surveys to Medicare enrollment and utilization data through 2000. NCHS's data linkage activities provide researchers in other federal agencies, academia, and the private sector with invaluable data sources to conduct epidemiologic, health services, and policy analyses. Linkages to date have created the data systems necessary to analyze the relationships between health risk factors and subsequent Medicare service utilization and spending.

NCHS surveys linked to claims data from the Medicare Part D linked file could be used in studies to:

- examine chronic conditions, reported or diagnosed in our surveys, and subsequent medical care and drug utilization and spending;

- analyze beneficiary characteristics, such as age, race, sex, and socio-economic information, which are more accurate from the survey data, in relation to enrollment in different types of Part D plans and use of prescription drugs; and

- investigate the incidence or prevalence of diseases, their risk factors, progression, and trends in treatment and drug use.

This type of collaboration maximizes the analytic capability of NCHS surveys and CMS administrative data, while protecting the confidentiality and privacy of NCHS survey respondents. NCHS works diligently to maintain the confidentiality of its records and, to date, there is no known instance of this confidentiality having been breached. NCHS is governed by laws and regulations under Section 308(d) of the Public Health Service Act (42 U.S.C. 242m) that provides NCHS's basic legal requirement for protecting records. In addition, NCHS requires approval from its Research Ethics Review Board for all data linkage projects. This approval process ensures that survey respondents are informed of NCHS's intention to link their data for statistical purposes and provides further protection of our survey respondent's rights to privacy and confidentiality.

NCHS's prior experience with data sharing and linkage agreements with CMS as well as its legislative requirements for data confidentiality make it well suited to conduct linkages with the Medicare Part D data, linked to data from Medicare Parts A and B. I hope this letter has provided CMS with the information needed to consider NCHS as an external Federal agency, with whom CMS will share its claims data under section 1860D-12(b)(3)(D) of the Social Security Act.

Sincerely,

Edward J. Sondik, Ph.D.
Director
National Center for Health Statistics

14.

THE UNIVERSITY
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at CHAPEL HILL

SCHOOL OF PUBLIC HEALTH

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December 1, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4119-P
P.O. Box 8017
Baltimore, MC 21244-8017

PEGGY LEATT, PhD
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To Whom It May Concern:

As faculty members in the Department of Health Policy and Administration at the University of North Carolina's School of Public Health, we read with enthusiasm the recent posting in the Federal Register (42 CFR Part 423) soliciting feedback on the proposed expansion of access to Medicare Part D claims. Access to Medicare Part D claims is critical to a fuller understanding of the treatment patterns and diagnostic history of Medicare beneficiaries.

We strongly endorse all the provisions indicated. As faculty at the University of North Carolina, we find that Section II. C. 2, page 61542 (External Researchers) is most relevant for our purposes. We fully endorse the criteria for review specified: (i) a legitimate research purpose, (ii) use of minimum data, and (iii) protection of beneficiary confidentiality. In addition to those requirements via the data request process, the University provides additional scrutiny through the Institutional Review Board process. We believe that the current regulatory limitations for external researchers provide appropriate protection against misuse.

Access to these data would enable a number of relevant research projects. Given the importance of the public provision of health insurance through programs such as Medicare and Medicaid and the large number of individuals affected by policy decisions in these programs, we believe it is critical to allow external researchers to incorporate these data in their research and evaluations. In particular, access to Part D claims would allow researchers to evaluate medication adherence by disease category, to determine the impact of Part D coverage on non-pharmaceutical treatments and services use, to examine the experience of the dually-eligible Medicaid/Medicare beneficiaries, to understand the implications of Part D on pharmaceutical markets, and to examine the effect that Medicare Part D has had on private insurers as well as the Medicaid program.

In conclusion, we appreciate the opportunity to comment on this critical provision to allow access to Medicare Part D claims data. We are strongly in support of this revision. While all faculty signing below support this comment, if you need clarification or further information, please contact Marisa Domino, Ph.D. (domino@unc.edu) at (919) 966-3891.

Respectfully submitted,

## Signatures

Sally C. Stearns, PhD
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School of Public Health

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December 15, 2006

Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services (DHHS)
Attention: CMS-4119-P Medicare Program: Medicare Part D Data
P.O. Box 8017
Baltimore, Maryland 21244-8017

Re: Comments on Centers for Medicare and Medicaid Services Proposed Rule

To Whom It May Concern:

In response to the Federal Register notice issued by the Centers for Medicare and Medicaid Services (CMS) regarding the rule on use of Medicare Part D data (42CFR Part 423), I am writing to express my support for the proposed rule and to comment on specific points in the proposed rule. The proposal by the Secretary to allow the use of Medicare Part D data for purposes beyond limited payment applications is reasonable and clearly in the public's interest. We applaud CMS for the careful work that has shaped this proposed rule.

The Secretary's proposal allows for the use of these data with appropriate review and protections. As the proposed rule notes, CMS is currently responsible for a wide range of program monitoring and evaluation tasks related to the Medicare program. Historically, these CMS functions have been critical in informing policymakers – in Congress and elsewhere – of both successes and necessary changes to Medicare. As Medicare expands to include the new Part D prescription drug program, ongoing program monitoring and evaluation will be crucial for understanding how Part D is working, and not working, for Medicare beneficiaries.

The proposed rule envisions a wide array of activities to which these data can be put: reports to Congress, legislative proposals, demonstration projects, evaluations of the Medicare program and individual demonstration projects, and generally a large number of steps to improve the Medicare program and thereby the health and wellbeing of the beneficiary population. Another explicit purpose, not called out in the current rule, envisions use of these data for detecting and analyzing the anticipated benefits and the possible risks or harms of prescription medications under actual conditions of use. We urge CMS to add this purpose unambiguously to the rule, perhaps in the section regarding "Purpose of CMS Collecting Information," to underscore CMS's goal of protecting the health of for the elderly and other Medicare populations.

The proposed rule includes provisions for other government agencies and external researchers to use these data. We note the specific language: "make available Medicare Part D claims data linked to other Medicare claims files to external researchers on the same terms as other Medicare Parts A and B data are released today, with appropriate protections for beneficiary confidentiality." We strongly support the proposition that CMS should allow these additional provisions for Part D data use. Although CMS or CMS-funded contractors conduct many Medicare-related monitoring and evaluation studies, other DHHS agencies, congressional entities, and nongovernmental researchers also carry out additional, and highly valuable, research related to the Medicare program. This work includes investigations directly about appropriate use of therapeutics, particularly pharmaceuticals. I note, as well, that this type of

research brings knowledge about issues pertinent to groups other than Medicare beneficiaries, such as populations covered by Medicaid; thus, thus this research confers benefit to the nation as a whole. In an atmosphere of budget restrictions, it is infeasible for CMS or the federal government to fund every relevant and important analysis of Medicare Part D. Therefore, the Part D data, under the proper protections, should be made available to researchers beyond CMS.

Additionally, the utility of these Part D data, when linked to Parts A and B claims data, extends beyond simply Part D *per se*. Rather, together they offer an unparalleled opportunity to study the quality and efficiency of episodes of care – providing a far more useful and telling account of the processes and outcomes of services made available through the Medicare program. Information from analyses that combine Parts A, B, and D will give clinicians and others numerous ways, heretofore unavailable, to improve the quality of care for these patients.

Fortunately, CMS already has well-established protocols for the review of external research proposals and protection of data privacy. These current protocols stem from traditional professional and ethical codes of conduct guiding academic research; moreover, they reflect a well-grounded peer review process; and they establish rigorous standards of research conduct that have stood the test of time. We believe that CMS can safely and efficiently extend these established protocols, terms, and procedures to cover the new Medicare Part D data, and I see little reason that CMS should have concerns about leakage or adverse consequences that exceed those for private and sensitive data already so covered and for which adequate protections exist. Similarly, use of these data will cause no additional burden on Medicare Part D providers.

As one of CMS's primary research contractors, RTI International is currently conducting a considerable amount of CMS-sponsored work related to Medicare Part D. We also do much work for other DHHS agencies, such as the Agency for Healthcare Research and Quality, that is directly related to quality of care, patient safety, elderly populations, and effectiveness and comparative effectiveness of therapeutic interventions. I can state with confidence that, without the proposed use of Medicare Part D data, these essential monitoring, evaluation, and patient-centered functions will not be possible to carry out, by us or others. In short, there are no substitutes available for the Medicare Part D prescription drug data,

Restrictions on availability and use of these data, leading to an inability to track and assess Medicare Part D effectively and to conduct broader types of studies relating to quality, efficiency, and effectiveness of care (not just for pharmaceuticals) for this critical population, cannot possibly be seen as being in the public interest. I urge CMS to adopt the proposed rule, with the amendments offered above, in the best interests of Medicare beneficiaries and the nation as a whole.

Sincerely,

Kathleen N. Lohr

Kathleen N. Lohr, Ph.D.
Distinguished Fellow

DaVita.

Rec'd 12/18/06 16
12 noon

December 18, 2006

Leslie Norwalk Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-4119 P—Medicare Part D Data

Dear Acting Administrator Norwalk:

DaVita[1] is pleased to write in support of the Centers for Medicare & Medicaid Services (CMS) proposed Part D data regulation. DaVita is a leading kidney care provider serving patients with high-quality specialized prevention and treatment services, spanning 42 states and the District of Columbia. The DaVita network includes more than 1,250 outpatient facilities and acute inpatient units in over 750 hospitals.

Medicare Part D represents a major milestone for the U.S. healthcare system. We are pleased CMS recognizes it will be crucial to provide the public with information about the cost and quality of care related to the Part D benefit. In order to facilitate transparency, and to conduct on-going program evaluation and improvement, CMS must undertake a major data collection effort. We strongly support CMS's assertions that Part D data, coupled with Part A and Part B data, offer unprecedented potential to evaluate the impact of prescription drug utilization on overall patient health and on the cost of care. As a dialysis provider serving over 100,000 patients (approximately one third of the total US End Stage Renal Disease (ESRD) population) with approximately 60% of our patients on Medicare Part D plans, DaVita is especially interested in understanding the impact the new drug benefit has on patient health.

The End Stage Renal Disease population is small but growing. The ESRD Program represents a crucial opportunity for improving health care outcomes and reducing costs. We are especially interested in partnering with CMS to determine the impact of drug adherence and utilization on patient health outcomes and quality of life. In addition, we believe the ESRD Program is noteworthy in the following ways.

- ESRD patients represent a high-risk, treatment-intensive population and ESRD beneficiaries suffer on average 2 or more (CMS recognized) co-morbid conditions and use an average of 7 to 9 prescription medications on an on-going basis[2]
    - Poor medication adherence diminishes the health benefits of pharmacotherapies.
    - Patients with ESRD frequently require treatment with multiple medications, placing them at increased risk for non-adherence. Factors for non-adherence include adverse effects, multiplicity of prescribing

[1] The DaVita patient population includes over 100,000 patients who have been diagnosed with End-Stage Renal Disease (ESRD), a group representing approximately one-quarter of all Americans with ESRD and approximately one-third of all Americans receiving dialysis services. DaVita's nationwide network is staffed by 28,000 teammates and more than 1,000 medical directors.

[2] St. Peter et al., *Evaluation of Medication Use and Costs in CKD Patients – Focus on Medicare Part D*, USRDS presentation at ASN Conference (Oct. 2005); Q3 2005 DaVita Internal Data

physicians, polypharmacy, transportation challeges in getting to a pharmacy, and frequent (more than once daily) dosing, and high costs.
    - A sustained high level of adherence identifies a pattern of healthy behaviors[3] and allows medications shown to be effective in clinical trials to improve outcomes, but this is difficult to achieve with many chronic conditions.
    - ESRD patient adherence to physician-prescribed oral medication is only 50% - 60%[4] (DaVita internal data, Pharma benchmarks). Inability to afford prescription medications contributes substantially to non-adherence.
- ESRD per-patient expenditures approximate $70,000 to $80,000 per year. (1% of the Medicare population and 7% of the program costs).
    - Of this total, 30 to 40% arises from provision of inpatient services.
    - An average of 2 inpatient stays per year for a total of about 15 inpatient days per year[5], rendering hospitalization a major component of current Program cost
    - Over 40% of the ESRD population will have Part D drug costs that exceed $4000[6]
    - Since 50-60% of ESRD beneficiaries are dual eligible, total federal health care expenditures may be still higher.

The Medicare Part D Program creates a tremendous opportunity to advance scientific and economic understanding of healthcare for seniors and all Medicare beneficiaries. Linking Medicare Parts A, B, and D data together will assist researchers in several important ways. Researchers will be able to study chronic illnesses more comprehensively, which will improve our ability to care for these populations. In addition, through demonstration projects, researchers will be able to develop recommendations for improving the financial stability, and the overall efficiency and effectiveness of the Medicare Program. With this comment, DaVita aims to reinforce the most significant issues raised in 4119P. It is critically important to understand – in a holistic sense – the impact of Medicare Part D on patient health and the total cost of care. The new prescription drug benefit extends drug coverage to millions of Americans who were previously uninsured. In addition, Part D has the potential to reduce the cost of health care for patients by improving overall quality of health and reducing the necessity of certain healthcare services. Given the substantial public investment in the Part D Program, CMS has a responsibility to evaluate and report on its impact across both quality and cost dimensions.

DaVita has unique skills and experience working with CMS. We have taken the lead on two CMS demonstration projects, and have partnered with another organization on a third demonstration including the Care Management for High Cost Beneficiaries (a demonstration similar to the Medicare Health Support Demonstration with a focus on beneficiaries who have kidney disease but not yet on dialysis) in New York. We are uniquely placed to help CMS develop a health care delivery system with improved levels of communication and outcomes for Medicare beneficiaries with both End Stage Renal Disease, chronic kidney disease, and their related co-morbid conditions.

***A. Information to Be Collected***

[3] Simpson SH, Eurich DT, Majumdar SR, et al. A meta-analysis of the association between adherence to drug therapy and mortality. *BMJ*. doi:10.1136/bmj.38875.675486. 2006;333:15.
[4] DaVita internal data, Pharma benchmarks
[5] USRDS 2005 ADR.
[6] St. Peter et al., *Evaluation of Medication Use and Costs in CKD Patients – Focus on Medicare Part D*, USRDS presentation at ASN Conference (Oct. 2005); Q3 2005 DaVita Internal Data; pag. 80.

DaVita

DaVita supports the approach this regulation takes regarding data collection. By requesting access to claims data currently provided by Part D plans, CMS can avoid burdening its partners with an additional data collection requirement. Further, the granularity of claims data will enable CMS to investigate issues outlined in the regulation such as the role of supplemental benefits in alleviating patient burden, and the impact the catastrophic coverage threshold is having on patients. CMS should consider this provision with full consideration of HIPPA privacy laws and regulations to protect patients' confidentiality.

***B. Purposes of CMS Collecting Information***

***1. Public Reporting***

Given the significant public investment in the Part D benefit program, it is critical that CMS make data regarding the overall impact and performance of the program publicly available. In addition to generalized data, DaVita believes data related to specialized populations, such as the dual eligibles and those with chronic conditions, should be collected and shared with the public. As a care provider for over 40,000 chronic care dual eligibles, we have anecdotal evidence of the impact Part D benefit has had on patient health and healthcare costs. However, we urge CMS to utilize the Medicare Part A, B, and D data to quantitatively investigate both the economic impact Part D has on the Medicare and Medicaid population and the impact on dual eligible treatment regime adherence and quality outcomes.

***2. Evaluations of the Medicare Program***

In this section of the regulation, CMS poses what DaVita believes to be a critical question for research and evaluation: how does the Part D benefit interact with Medicare Parts A, B, C, and Medicaid? While there is considerable interest amongst healthcare researchers, very few researchers or institutions are equipped to undertake an investigation of this magnitude. In a recent study, Sokol et. al investigated the impact of drug utilization on the total cost of care for patients with chronic conditions. That study concluded that every dollar spent increasing prescription drug utilization generated between $4 and $7 dollars of savings for other healthcare expenditures for patients with hypertension, hypercholesterolemia, and diabetes[7]. Studies like this are encouraging, but rely on a limited quantity and quality of source data. Understanding the impact oral medication utilization has on the total cost of patient care is of paramount importance to CMS as it seeks to continually refine and improve the efficacy of the Medicare program. In addition, this research could also aid CMS in conducting prescription drug plan (PDP) plan oversight. CMS could better understand, for example, which utilization management techniques correlate with reduced total cost of care.

***3. Legislative Proposals***

The collection of data is essential needed to support congressional legislative proposals. Data provides initial guidance to congressional committee staff on these provisions are sought in a draft bill. As discussed in the proposed rule, data may be used to derive statistics and illustrate why certain changes to the Medicare statute should be considered or why alternative policy scenarios, research and new programs should be considered and funded.

***4. Demonstration Projects and Research Studies***

We believe demonstration projects and research studies are the key to extracting the full value from Medicare Part D data. This regulation outlines several issues for investigation, including:

- The impact of Part D on beneficiary cost sharing and utilization;
- Methods for improving CMS's ability to identify patients with chronic conditions;

[7] Sokol, M., et. al. "Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost" *Medical Care* June 2005

DaVita.

- Medication therapy management programs impact on patient compliance and adherence; and
- The relationship between prescription drug utilization and the use of other healthcare services.

Studying utilization data will help answer these and other important questions about the impact of the Part D program. In addition to utilization analysis, we believe that adherence research is paramount to understanding the link between prescription drug consumption patterns, patient health and the total cost of care.

As a dialysis provider, DaVita has a unique opportunity to partner with CMS in this type of research. We serve a specialized patient population and have extensive clinical lab data on our patients. In addition, we are well-positioned to understand patient adherence and utilization of prescription medicine. There is strong evidence that patient adherence to medications that their doctors prescribe will help keep patients healthy and will reduce their need for healthcare services. Recently, the Journal of the American Medical Association cited adherence as a significant barrier to improved patient care. This study found that Pharmacy Care Programs can significantly improve patient adherence and, in correlation, result in superior clinical outcomes.[8] The Medicare Part D benefit creates a unique opportunity for researchers to test this hypothesis with rigorous data analysis and quantify the impact utilization and adherence has on health and healthcare costs.

End Stage Renal Disease (ESRD) is unique in that the effective care of ESRD patients requires meticulous coordination of dialysis treatment and drug therapy with frequent and specialized laboratory testing. Dialysis providers have addressed the unique health care needs of ESRD patients by developing integrated health care systems that provide for dialysis treatment, medication administration and dialysis laboratory testing services for ESRD patients. These integrated health care systems also provide clinical computer systems that interface dialysis treatment, medication and other clinical data with dialysis laboratory data. This data coordination enhances the quality of care to ESRD patients, as it enables the health care provider to better evaluate the ESRD patient's response to complex therapeutic interventions. Appropriate clinical care and coordination directly impacts healthcare outcomes, costs and mortality.

Unlike other medical subspecialties, ESRD prescriptions and lab results have a direct effect on dialysis complicated pharmaceutical management and control of a myriad of co-morbidities. For example, appropriate dosing of intravenous vitamin D and oral phosphate binders unified with appropriate trending of PTH results all need to occur simultaneously in the ESRD patient to achieve the best outcomes. Compliance with oral phosphate binders is of concern, as patients are required to take a high-volume of medication (average 8 to 12 pills per day). Failure to properly evaluate and manage bone disease will cause ESRD patients to have bones that are depleted of calcium, brittle, and likely to fracture. This measure necessarily needs to be considered in conjunction with the other measures of bone and mineral metabolism, such as calcium, phosphorus, and calcium phosphorus product. Abnormalities of calcium and phosphorus metabolism have been demonstrated to show a close association with cardiovascular disease. Although causality can not be demonstrated by such studies, the association remains strong.

With access to Part D data, DaVita is uniquely positioned to assess patient and evaluate the effect of prescription drug coverage on health outcomes. Most patients with kidney failure typically receive hemodialysis to replace the blood cleaning functions of their diseased kidneys three-to-four times each week. Each dialysis session lasts for three-to-four hours, depending upon each patient's needs. Because of the repeated touches, DaVita has the ability to provide repeat counseling through multiple encounters, routine clinical assessment, education and reinforcement. In addition,

[8] Lee et. al "Effect of a Pharmacy Care Program on Medication Adherence and Persistence, Blood Pressure, and Low-Density Lipoprotein Cholesterol" *JAMA* November 2006

DaVita.

we may be able to examine medication adherence and persistence patterns, which in turn can be used to research or examine Part D effectiveness.

***C. Sharing data with entities outside of CMS-***

The ESRD program is a Medicare Part B entitlement. The economic benefits of dialysis related activities are realized in reduced Part A and appropriate Part D such as hospitalizations, medication regimens and care of multiple co-morbid conditions. Analysis of Part D and Part A data may further validate the efficacy of outpatient quality improvement initiatives. At the present time, dialysis providers have limited access to CMS data. Informing clinical practice is fundamental to improving care and making healthcare delivery more efficient. The current interest in and proliferation of pay-for-performance reimbursement initiatives makes it even more important for researchers and providers to have timely access to the data that will drive federal policy and decision-making. For DaVita, having access to such data will enable us to improve the quality of dialysis treatment and potentially reduce costs to the Medicare program.

***D. Beneficiary access to Part D data***

Allowing public access to data would support a patient-centered approach to health care, by empowering patients to take ownership of their care. If allowed, this policy should be complimented with education on patient privacy protections such a provision would not only personalize health care, but interconnect patients with their health care delivery team.

DaVita appreciates the opportunity to comment on these important policy proposals. We sincerely hope that CMS will consider our comments and incorporate our suggestions into the Final Rule. Please feel free to contact Stephanie Dyson at (202) 457- 0417 if you have any questions regarding these comments. We look forward to continuing to work with CMS to ensure that Medicare beneficiaries have access to treatment in the appropriate sites of service.

Sincerely,

Charles J. McAllister, M.D., FACP
Chief Medical Officer
DaVita

cc: Kent Thiry, Mayor and CEO, DaVita
Eric Berger, Senior Vice President, DaVita
Stephanie Dyson, Director Public Policy, DaVita
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