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To: House Committee on Energy and Commerce
Attention: Robert Horne

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Subject: **Proposed Interpretation of the Noninterference Provision Under Medicare Part D**

On January 10, 2014 the Department of Health and Human Services (HHS), Centers for Medicare and Medicaid Services (CMS) published a proposed rule titled "Medicare Program: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs (Proposed Rule)."[1] In this rule, CMS proposes significant changes in the way it administers several aspects of the Medicare Program's outpatient prescription drug benefit ("Part D") program. The Part D program, which provides coverage of outpatient prescription drugs to Medicare beneficiaries who choose to enroll in this optional benefit, was created pursuant to P. L. 108-173, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA).[2]

This memorandum provides a legal analysis of the Secretary of HHS' proposed interpretation of Section 1860D-11(i) of the Social Security Act, 42 U.S.C. § 1395w-111(i) which provides as follows:

> **Section 1860D-11(i) Noninterference**
>
> In order to promote competition under this part and in carrying out this part, the Secretary –
>
> (1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and
>
> (2) may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs.

[1] 79 FED. REG. 1918-2073 (proposed January 10, 2014) (to be codified at 42 C.F.R. Parts 409, 417, 422 *et al.*), available at http://www.gpo.gov/fdsys/pkg/FR-2014-01-10/pdf/2013-31497.pdf. Comments on the Proposed Rule are due to CMS by March 7, 2014.

[2] 42 U.S.C. §§ 1395w-101 *et seq*. Prescription drug coverage is provided through private prescription drug plans (PDPs), which offer only prescription drug coverage, or through Medicare Advantage prescription drug plans (MA-PDs), which offer prescription drug coverage that is integrated with the health care coverage they provide to Medicare beneficiaries under Part C. For more information on Medicare Part D and how it relates to other aspects of the Medicare program see CRS Report R40425, Medicare Primer, coordinated by Patricia A. Davis and Scott R. Talaga.

Proposed Interpretation of the Noninterference Provision

In its preamble to the proposed regulations, CMS explains that because of the "many questions that continue to arise," the agency and Part D stakeholders would benefit from a clear, formal interpretation of Section 1860D-11(i) of the Social Security Act (Act), the noninterference provision. To this end, the agency proposes to set forth the parameters of the limits of the agency's involvement in competitive market negotiations leading to the selection of drug products to be covered under Part D formularies. CMS also provides its interpretation of the noninterference provision's requirement that CMS not require "a particular formulary or institute a price structure for the reimbursement of covered Part D drugs."

With regard to negotiations between "between drug manufacturers and pharmacies and PDP sponsors," CMS proposes a specific textual construction of the noninterference provision, arguing that the statute applies to only certain types of negotiations. The agency asserts that the noninterference clause only applies to negotiations either: (1) between drug manufacturers and plan sponsors (or intermediary contracting organizations); or (2) between drug manufacturers and pharmacies. The agency bases its interpretation on "the sequential phrasing of the clause 'negotiations between (among) drug manufacturers and pharmacies and PDP sponsors.'"[3]

> Because in general these negotiations are not among all three parties at once, and because manufacturers separately contract with pharmacies for the purchase of inventory and with sponsors for formulary placement, we believe the quoted phrase can be interpreted as recognizing these distinct types of negotiations. Under such a reading, the prohibition on interference in negotiations, as described in section 1860D-11(i)(1) of the Act, would not pertain to negotiations between Part D sponsors and pharmacies.[4]

While CMS acknowledges some specific statutory limits on its ability to involve itself in Part D sponsors' arrangements with their network pharmacies,[5] the agency views Section 1860D-11(i)(1) as not generally applicable to sponsor-pharmacy negotiations.[6] As additional support for this interpretation, the agency points to congressional intent behind the noninterference clause which it believes supports the view that the provision was enacted to primarily protect manufacturer-sponsor negotiations.[7] CMS also points to the provision's statutory context: "There are numerous statutory provisions that require us to directly intervene in the contractual relationship between Part D sponsors and network pharmacies, and these provisions clearly signal that the Congress expected CMS involvement in at least some of these negotiations."[8] In addition, the agency notes that it has observed a "growth in related-party relationships

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[3] 79 FED. REG.1970.

[4] Id.

[5] As an example, the agency will not "intervene in contractual disputes between sponsors and network pharmacies except in matters implicating CMS requirements, because to do so might distort private market outcomes in unpredictable ways." 79 FED. REG.1971.

[6] Id.

[7] "We note that in The Medicare Prescription Drug, Improvement and Modernization Act of 2003 Conference Agreement, in addition to the statutory language, MMA drafters included the following sentence: 'Conferees expect PDPs to negotiate price concessions directly with manufacturers.' We believe this statement supports our understanding that the primary focus of section 1860D-11(i) of the Act is on the negotiations between plans sponsors (or their intermediary contracting organizations) and manufacturers for rebates and other price concessions that ultimately determine which multiple source products will be placed on a sponsor's formulary." 79 FED. REG. 1970.

[8] Id.

between Part D sponsors and network pharmacies, where the distinction between the sponsor and the pharmacy is increasingly unclear,"[9] and so the agency believes Congress would not have intended that the noninterference provision prohibit agency oversight of the sponsor's dealings with itself in such cases.

CMS proposes to codify its new position in a regulation to be added at 42 C.F.R. § 423.10. The new regulation, entitled "Prohibition on intervention in negotiations with manufacturers," states that CMS is prohibited from being a party to negotiations between drug manufacturers and pharmacies, or between drug manufacturers and Part D plan sponsors, and from arbitrating disputes concerning the terms and conditions of agreements between those parties.[10] Implicit in this proposed regulation is CMS's position that the noninterference statutory provision does not limit CMS's authority to promulgate rules that affect negotiations between Part D plan sponsors and pharmacies.

CMS's proposed regulation also addresses the second part of the statutory noninterference provision, section 1860D-11(i)(2), which states that CMS "may not require a particular formulary." Since there are other provisions in the Part D statute that give CMS specific authorities with regard to formularies, CMS proposes to interpret that part of the noninterference provision to mean that CMS cannot determine the specific drug products to be included on Part D sponsor formularies or any tier placement of such products. CMS proposes to codify this interpretation in 42 C.F.R. § 423.10(c). Exceptions to this policy will exist where other provisions of the statute require CMS oversight of formularies, such as requirements that particular types of drug entities be on all formularies, or on preferred tiers, in order to provide non-discriminatory access to drugs necessary to treat conditions in all Medicare beneficiaries, or to address drug classes of clinical concern.[11]

Finally, CMS's proposed regulation addresses the last part of section 1860D-11(i)(2) which states that CMS may not institute "a price structure for the reimbursement of covered Part D drugs." The agency interprets that as prohibiting it from "establishing either absolute or relative indices of prices for Part D drugs." Specifically, CMS proposes that 42 C.F.R. § 423.10(d) specify that CMS does not establish drug product pricing standards or the dollar level of price concessions at any stage in the drug distribution channel for Part D drugs.[12] CMS notes that this prohibition must be interpreted consistently with other provisions of Part D which require the agency to "regulate many aspects of how drug costs are made available and displayed to beneficiaries and treated in Part D bidding and payment processes."[13] To this end, CMS states in proposed section 423.10(d)(2) that nothing in the noninterference provision limits CMS's authority to require full disclosure or uniform treatment and reporting of drug costs and prices under its regulations.

Judicial Review of the Secretary's Interpretation of the Noninterference Provision

If the Secretary's proposed interpretation of the noninterference provision were finalized and challenged as being outside the scope of the Agency's authority under the Administrative Procedure Act,[14] a

[9] Id. at 1971.

[10] 42 C.F.R. § 423.10(b).

[11] *See* Section III.A.14 of the Proposed Rule at 79 FED. REG. 1936.

[12] 79 FED. REG. 1972.

[13] Id.

[14] The Administrative Procedure Act (APA) provides standards of judicial review that a court will use to determine whether an (continued...)

determination of whether the Agency exceeded its delegated authority in issuing the noninterference regulation under Medicare Part D may hinge on the degree of deference that a reviewing court would accord CMS's reading of the statute.[15] Courts have traditionally "recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer."[16] While it may be likely that a reviewing court would find that CMS has the authority under the Part D statute to provide "a clear, formal interpretation of [the noninterference provision's] limits" on its authority, it may be possible that the courts might not defer to CMS's specific reading of the provision's requirement that the agency not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors.

Judicial Standard for Review of Administrative Interpretations

The current standard for judicial review of an agency's statutory interpretation was originally delineated in *Chevron U.S.A. Inc. v. Natural Resources Defense Council.*[17] There, the Supreme Court established that judicial review of an agency's interpretation of a statute through a formal agency process[18] consists of two steps. First, the court must determine whether Congress has spoken directly to the precise issue at hand. If the intent of Congress is clear, the inquiry is concluded, since the unambiguously expressed intent of Congress must be respected, and the "law must be given effect." [19] However, if the court determines that the statute is silent or ambiguous with respect to the specific issue at hand, the court proceeds to the second step to determine whether the agency's interpretation is based on a permissible construction of the statute. If so, the court will generally defer to the agency's position,[20] although there have been cases in which the Court has found that the agency's interpretation was unreasonable even though Congress has left the matter for agency resolution.[21]

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agency's action is valid. 5 U.S.C. §§ 702, 704. For example, the APA provides that a reviewing court must set aside agency actions that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The APA also states that a reviewing court must "hold unlawful and set aside agency actions, findings, and conclusions found to be ... in excess of statutory jurisdiction, authority, or limitations, or short of statutory right. 5 U.S.C. § 706(2)(C).

[15] A reviewing court ultimately must determine whether the agency has stayed within the bounds of its statutory authority. City of Arlington v. FCC, 133 S. Ct. 1868 (2013).

[16] Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 844 (1984) *(Chevron)*. For more information on court treatment of agency interpretations under *Chevron*, see CRS Report R43203, *Chevron Deference: Court Treatment of Agency Interpretations of Ambiguous Statutes*, by Daniel T. Shedd and Todd Garvey.

[17] 467 U.S. 837 (1984).

[18] In *United States v. Mead Corporation*, 533 U.S. 218, 229 (2001), the Court held that an agency's implementation of statutory authority "qualifies for *Chevron* deference when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." *Mead* thus established a threshold requirement (what has been referred to as "step zero") restricting *Chevron* deference to only formal rules and other interpretations holding the "force of law" and promulgated pursuant to delegated authority. Policy statements, agency manuals, and interpretive letters, on the other hand, generally do not warrant such deference. *See also* Christensen v. Harris County, 529 U.S. 576 (2000).

[19] *Chevron*, 467 U.S. at 843. The *Chevron* test, which has been cited and followed thousands of times by federal courts since 1984, requires courts to enforce the clearly expressed intent of Congress. Stephen G. Beyer et al. ADMINISTRATIVE LAW AND REGULATORY POLICY 247 (2006).

[20] *See, e.g.*, Astrue v. Capato, 132 S. Ct. 2021 (2012) (deferring to the Social Security Administration's longstanding interpretation in regulations, finding the regulations "warrant the Court's approbation" as they were "neither arbitrary or capricious in substance, [n]or manifestly contrary to statute" (internal quotations omitted)).

[21] Whitman v. American Trucking Ass'n., Inc., 531 U.S. 457 (2001).

It is important to note that the second step does not require a court to "conclude that the agency construction was the only one it permissibly could have adopted to uphold the construction, or even the reading the court would have reached if the question initially had arisen in a judicial proceeding."[22] The practical effect of this maxim is that a reasonable agency interpretation of an ambiguous statute must be accorded deference, even if the court believes the agency is incorrect.[23] Under *Chevron* then, it is generally left to federal agencies, and not the courts, to resolve ambiguities necessary to interpret and implement authority provided to the agency by Congress.

Chevron Step One

At step one under *Chevron*, a reviewing court must determine "whether Congress has directly spoken to the precise question at issue."[24] If the court, "employing the traditional tools of statutory construction," determines that Congress has directly addressed the issue, then that is the end of the matter, because the "law must be given effect."[25] As the United States Supreme Court stated in *Connecticut National Bank v. Germain*:

> [I]n interpreting a statute a court should always turn first to one cardinal canon before all others. We have stated time and again that courts must presume that a legislature says in a statute what it means and means in a statute what it says there.... When the words of a statute are unambiguous, then, this first canon is also the last: judicial inquiry is complete.[26]

CMS, in its preamble to the new Medicare Part D regulations, asserts that the plain text of section 1860D-11(i)(1) providing that the Secretary "may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors" should be read to mean that the statute applies to only certain types of negotiations, i.e., either between drug manufacturers and plan sponsors or between drug manufacturers and pharmacies. The agency bases its interpretation on "the sequential phrasing of the clause 'negotiations between (among) drug manufacturers and pharmacies and PDP sponsors.'"[27]

It is possible that a court may not agree with CMS's textual argument that the statutory language should be read disjunctively as if the final "and" were really an "or."[28] Since the statute repeatedly uses the conjunctive "and," it may be that Congress was listing the principal players involved in the Medicare Part D market, and did not intend to exclude any combination of relationships among the three named entities to which the noninterference provision applies. In such a case, a court may find that Congress has directly spoken to the issue of the Secretary's interference with negotiations between drug manufacturers, pharmacies and PDP sponsors, and that the Secretary's reading is at variance with the plain language of

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[22] *Chevron*, 467 U.S. at 843, n. 11.

[23] Id. at 845. *See also*, National Cable and Telecommunications Association v. Brand X Internet Services, 545 U.S. 967 (U.S. 2005) (ruling that a federal court under the "Chevron doctrine" is required to defer to an agency's interpretation of law — even if it differs from the court's own views — if the particular statute is within the agency's administrative authority, if it is ambiguous on the point in contention, and if the agency's interpretation is "reasonable").

[24] *Chevron*, 467 U.S. at 842.

[25] Id. at 843.

[26] 503 U.S. 249, 254 (1992) (citations omitted). *See also* Caminetti v. United States, 242 U.S. 470, 485 (1917) ("It is elementary that the meaning of a statute must, in the first instance, be sought in the language in which the act is framed, and if that is plain, and if the law is within the constitutional authority of the law-making body which passed it, the sole function of the courts is to enforce it according to its terms.").

[27] 79 FED. REG. 1970.

[28] *See, e.g.*, Loving v. IRS, No. 13-5061, (D.C. Cir. 2014), slip opinion at 11.

the statute. In other words, a reviewing court may find that Section 1860D-11(i)(1) cannot be read to permit CMS involvement in negotiations between pharmacies and plan sponsors, except as required under other provisions of the Part D program. In such a case, *Chevron* deference would not apply. On the other hand, if a court views the negotiation language of the noninterference provision as sufficiently non-specific to trigger deferential analysis under *Chevron*, it might then proceed to the second step of *Chevron's* two-part analysis.

A reviewing court might also note that it appears CMS is changing its prior position regarding the scope of its limitations under the noninterference provision. CMS's interpretation of the noninterference provision in its proposed new section 42 C.F.R. § 423.10, is, as CMS states, its first formal interpretation of that provision. However, CMS has informally interpreted its authority to interfere in negotiations between pharmacies and plan sponsors differently in the past. In January 2005, when CMS promulgated its initial final rule implementing the Part D program, CMS stated in response to comments in its preamble to the regulations that it interpreted the noninterference provision as extending to negotiations between any of the specified parties, including negotiations between Part D plan sponsors and pharmacies. CMS stated: "As provided in section 1860D-11(i) of the Act, we have no authority to interfere with the negotiations between Part D plans and pharmacies and therefore cannot mandate that Part D plans negotiate the same, or similar, reimbursement rates with all pharmacies."[29] Thus, the current Proposed Rule reflects a different perspective on the administration of drug benefits under the Part D program in comparison with the Agency's position nine years ago.[30] An agency clearly has the authority to change or revise a prior interpretation of a statute it administers; nevertheless a new or refined interpretation must be found to be consistent with the legislative language and Congress' intent.[31]

The Proposed Rule also defines the scope of the noninterference provision's directive that CMS may not require a particular formulary or institute a price structure for Part D covered drug reimbursements. Specifically, in proposed new 42 C.F.R. § 423.10(c) and (d), CMS states that it does not determine the specific drug products to be included on Part D sponsor formularies or any tier placement of such products, and does not establish specific drug product pricing standards or the dollar amount of price concessions at any stage in the drug distribution channel for Part D drugs. With regard to CMS's interpretation of its formulary and price structure restrictions, a court is more likely to find that Congress has provided a "delegation of authority to the agency to elucidate [the] specific provision of the statute by regulation."[32] The agency's interpretation, therefore, would likely receive judicial deference under the second part of the *Chevron* test.

Chevron Step Two

As noted above, under the second step of *Chevron*, if Congress has not directly spoken to the question at issue, the reviewing court's role is limited to determining whether the agency's interpretation was "based on a permissible construction of the statute."[33] Where Congress has not clearly expressed its intent, a

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[29] 70 FED. REG. 4194-4585 (January 28, 2005) at 4255, available at http://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/QuarterlyProviderUpdates/downloads/CMS4068F.PDF.

[30] This view includes a changed view of the relationships between Part D plan sponsors and pharmacies, preferred pharmacies, mail-order pharmacies and other aspects of Part D benefit plan administration.

[31] *See* FCC v. Fox Television Stations, Inc., 556 U.S. 502, 515 (2009). When an agency changes its position on a matter within its authority to implement a statute, the courts generally require that the agency "display awareness that it is changing its position" and show that "there are good reasons for the new policy."

[32] *Chevron*, 467 U.S. at 843-44.

[33] Id. at 842-43. *See* Thomas J. Miles and Cass R Sunstein, *Do Judges Make Regulatory Policy? An Empirical Investigation of* (continued...)

court "may not substitute its own construction of a statutory provision for a reasonable interpretation" of the agency.[34] The Supreme Court has indicated that deference to an agency's interpretation under step two is appropriate "whether or not it is the only possible interpretation or even one a court might think best."[35] Thus, if a reviewing court determines that there is ambiguity as to whether the noninterference provision applies to negotiations between pharmacies and plan sponsors, and so reaches step two of the *Chevron* analysis with respect to the agency's interpretation, the court may, depending upon the record presented, consider the agency's interpretation to be a permissible construction of the statutory text, and, as such, to be accorded deference by the court.

Conclusion

In January 2014, CMS proposed significant changes in the way it administers several aspects of the Medicare Part D program. The proposed rule includes the agency's formal interpretation of Section 1860D-11(i) of the Social Security Act, the noninterference provision. This provision generally prohibits the Secretary from interfering with negotiations between drug manufacturers and pharmacies and PDP sponsors, and prevents CMS from requiring that plans have a particular formulary or instituting a price structure for the reimbursement of Part D covered drugs. The purpose of this provision is "to promote competition under [Part D]."[36]

CMS proposes to change its position regarding the scope of negotiation limitations of the noninterference provision, and to codify its interpretation of that provision in a new regulation at 42 C.F.R. § 423.10. CMS, in its preamble to the new Medicare Part D regulations, asserts that the plain text of section 1860D-11(i)(1), which provides that the Secretary "may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors," should be read to mean that the statute applies to only certain types of negotiations, i.e., either between drug manufacturers and plan sponsors or between drug manufacturers and pharmacies, but not negotiations between PDP sponsors and pharmacies. The agency bases its interpretation on "the sequential phrasing of the clause 'negotiations between (among) drug manufacturers and pharmacies and PDP sponsors,'"[37] as well as on congressional intent and the context of the noninterference provision within the Part D statute. The new regulation would also define the scope of the noninterference provision's prohibition against requiring a formulary or instituting price structures for covered Part D drugs.

Under the Supreme Court's landmark and oft-cited decision in *Chevron U.S.A. Inc. v. Natural Resources Defense Council*,[38] judicial review of an agency's interpretation of a statute through a formal rulemaking process consists of two steps. First, the court must determine whether Congress has spoken directly to the precise issue at hand. If the intent of Congress is clear, the inquiry is concluded, since the unambiguously expressed intent of Congress must be respected, and the "law must be given effect."[39] However, if the court determines that the statute is silent or ambiguous with respect to the specific issue at hand, the court

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Chevron, 73 U. Chi. L. Rev. 823 (2006) (finding that more than 90 percent of invalidations under Chevron occurred at Step One).

[34] Id. at 844.

[35] *See, e.g.*, Holder v. Gutierrez, 132 S. Ct. 2011 (2012), *citing Chevron*, 467 U.S. at 843-44.

[36] Section 1860D-11(i).

[37] 79 FED. REG. 1970.

[38] 467 U.S. 837 (1984).

[39] Id. at 843.

proceeds to the second step to determine whether the agency's interpretation is based on a permissible construction of the statute.

If the Secretary's proposed interpretation of the noninterference provision were finalized and challenged as being outside the scope of the Agency's authority under the Administrative Procedure Act, it is possible that a reviewing court might not be persuaded by the Secretary's textual argument that the noninterference provision does not clearly apply to negotiations between PDP plan sponsors and pharmacies. A court might conclude that Congress has directly spoken to the issue of the Secretary's interference with negotiations between drug manufacturers, pharmacies and PDP sponsors, and that the Secretary's reading is at variance with the plain language of the statute. In such a case, *Chevron* deference would not apply. On the other hand, if a court views the negotiation language of the noninterference provision as sufficiently non-specific to trigger deferential analysis under *Chevron*, it might then proceed to the second step of *Chevron's* two-part analysis, and possibly consider the agency's interpretation to be a permissible construction of the statutory text, and, as such, to be accorded deference by the court.