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American Action Forum
555 13th St. NW, Suite 510 West
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Re: The Medicare Modernization Act's Prohibition Against Federal Negotiation of Drug Prices

Analysts long have debated whether the government should use Medicare Part D to negotiate prescription drug prices.[1] But in that debate there has been no serious suggestion that the government *can* negotiate drug prices under the current law: rather, as the Congressional Research Service notes, federal law "*expressly forbids* the Secretary of Health and Human Services (HHS) from negotiating the price of prescription drugs on behalf of Medicare beneficiaries."[2]

Specifically, Section 1860d-11(i) of the Medicare Modernization Act of 2003—known as the "noninterference provision"— states without exception that HHS "may not interfere with the negotiations between drug manufacturers and pharmacies and [Prescription Drug Plan] sponsors."[3]

Since 2003, various Senators and Congressmen—and the President—have proposed to repeal the noninterference provision, precisely because it unambiguously bars HHS from negotiating drug prices.[4] None of their proposals has actually been enacted, however; the Act's noninterference provision remains the law of the land.

But last month, HHS attempted to unilaterally revise the statute, by breaking sharply from the long-settled understanding of the provision's categorical prohibition against HHS interfering in Part D drug price negotiations. Specifically, in a "notice of proposed rulemaking" HHS asserted that the noninterference provision does "*not* pertain to negotiations *between Part D sponsors and pharmacies*."[5]

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1 Jim Hahn, Congressional Research Service, *The Pros and Cons of Allowing the Federal Government to Negotiate Prescription Drug Prices* (Feb. 18, 2005).

2 *Id.* at 1 (emphasis added). This interpretation also was expressed by the Government Accountability Office. *See* Testimony of John E. Dicken (Director, Health Care), Gov't Accountability Office, *Prescription Drugs: An Overview of Approaches to Negotiate Drug Prices Used by Other Countries and U.S. Private Payers and Federal Programs*, at 1 (Jan. 11, 2007) ("While the Medicare Part D benefit is characterized by multiple competing prescription drug plans that are overseen by CMS, MMA prohibits the Secretary of Health and Human Services from interfering with price negotiations between Part D plan sponsors and drug manufacturers and pharmacies.") (citing 42 U.S.C. § 1395w-111(i)).

3 The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1860d-11(i), *codified at* 42 U.S.C § 1395w-111(i).

4 *See, e.g.*, S. 117, 113th Cong. § 2(a) (2013); *see also, e.g.*, Remarks by the President in an AARP Tele-Town Hall on Health Care Reform (July 28, 2009), *at* http://www.whitehouse.gov/the_press_office/Remarks-by-the-President-in-AARP-Tele-Town-Hall-on-Health-Care-Reform.

5 Dep't of Health & Human Servs., Proposed Rule, *Medicare Program; Contract Year 2015 Policy and Technical*

As a matter of policy, HHS's proposal is terribly misguided. "Medicare Part D is an undeniable success story,"[6] as a coalition of hundreds of stakeholder groups—ranging from the Association of Community Cancer Centers to the U.S. Chamber of Commerce to the AIDS Institute—explained in a letter last week:

> The Part D program has maintained stable, affordable average monthly premiums, enjoys a 90 percent approval rating among beneficiaries, and has program costs that are more than 40 percent below original Congressional Budget Office projections. The proposed rule threatens to disrupt the positive effect the program is having on beneficiaries' health and the Medicare program as a whole."[7]

Forty percent of American senior citizens receive Medicare Part D prescription drug coverage through Prescription Drug Plans ("PDPs"),[8] and the deals negotiated between PDP networks and pharmacies may be saving the nation *billions* of dollars. One recent study found that PDPs' "[p]referred pharmacy network plans are estimated to reduce federal Medicare spending by approximately $870 million in 2014," and in the next decade "preferred pharmacy network plans are estimated to reduce federal Medicare spending by $7.9 to $9.3 billion."[9]

But HHS's effort to revise the Act is not just bad policy—it is unlawful. For the reasons set forth below, HHS's novel "interpretation" of the Act's noninterference provision is unsupported by the Act's text and history.

HHS should withdraw the proposed rule. And if HHS persists with this new policy by promulgating it as a final rule, then the federal courts should vacate it.

I. Background: The Act's "Noninterference" Statute

The Medicare Modernization Act of 2003 (Pub. L. No. 108-173) created Medicare's "Part D" program. As one court has explained, "[a]mong other things, Medicare Part D added a new prescription drug benefit to the Medicare Program. Individuals eligible for Medicare but not enrolled in a separate Medicare Advantage Plan can obtain prescription drug benefits through a Prescription Drug Plan ('PDP')."[10]

But the Act prohibits HHS from interfering in negotiations between PDP sponsors, pharmacies, and drug companies. Specifically, Section 1860d-11(i) of the Act provides:

Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 1918, 1971 (Jan. 10, 2014) (emphasis added).

6 Letter to CMS Administrator Tavenner, at 1 (Feb. 21, 2014), *available at* http://www.hlc.org/2014/02/over-200-organizations-urge-cms-to-withdraw-proposed-new-medicare-part-d-regulations.

7 *Id.* (paragraph break omitted).

8 Paul Howard & Yevgeniy Feyman, Manhattan Institute, *A Decade of Success: How Competition Drives Savings in Medicare Part D*, at 2-3 (Dec. 2013), *available at* http://www.manhattan-institute.org/pdf/mpr_16.pdf.

9 Stephen J. Kaczmarek *et al.*, *The Impact of Preferred Pharmacy Networks on Federal Medicare Part D Costs, 2014-2023*, at p. 1 (Oct. 2013) (Milliman Client Report, prepared for the Pharmaceutical Care Management Ass'n), *available at* http://www.rxobserver.com/wp-content/uploads/2013/10/The-Impact-of-Preferred-Pharmacy-Networks-on-Federal-Medicare-Part-Costs-2014-2023.pdf.

10 *Sw. Pharmacy Solutions, Inc. v. Centers for Medicare and Medicaid Servs.*, 718 F.3d 436, 439 (5th Cir. 2013).

(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.[11]

The congressional debate that gave rise to this prohibition, and the subsequent regulatory and legislative history interpreting this statute, demonstrate that this provision categorically prohibits HHS interference between any of the three parties listed in that statute—PDP sponsors, pharmacies, and drug manufacturers—and does not implicitly include an exception for HHS interference in negotiations between PDP sponsors and pharmacies, as HHS now asserts.

A. The Noninterference Provision's Pre-Enactment Legislative History

As Congress originally debated the Act in 2003, there was substantial concern that the new Medicare Part D prescription drug program, if not subjected to clear limits, would open the door to excessive government interference with the market for prescription drugs. Thus, the Act's noninterference provision was enacted to impose such limits.

Senator Grassley of Iowa, for example, explained that the "noninterference provision is at the heart of the bill's structure for delivering prescription drug coverage through market competition that gets a good deal for consumers, rather than through price fixing by the CMS bureaucracy."[12] Senator Grassley went on to quote the CMS Administrator's candid explanation of what HHS "negotiation" would actually entail: "if Medicare negotiates prices, 'I wouldn't be negotiating; I'd just be fixing the price.'"[13]

Some in Congress still disagreed with the noninterference policy, and wanted the government to "negotiate" drug prices—but even those critics agreed that this would require eliminating the nonintervention provision, because it "strictly forbids Medicare from using its bargaining power to negotiate lower drug prices for seniors."[14]

After much debate,[15] Congress and the President enacted the noninterference provision, barring HHS from using its new Part D program to intervene in the market. As the Conference Report explained:

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[11] 42 U.S.C. § 1395w-111(i).

[12] 149 Cong. Rec. S15624 (Nov. 23, 2003).

[13] *Id.*

[14] *Id. at* S15605.

[15] *See, e.g.*, Robert Pear, *Medicare Debate Turns to Pricing of Drug Benefits*, N.Y. Times, Nov. 24, 2003, at A1 ("With Congress poised for final action on a major Medicare bill this week, some of the fiercest debate is focused on a section of the bill that prohibits the government from negotiating lower drug prices for the 40 million people on Medicare.").

> In order to promote competition, *the Secretary is prohibited from interfering with the negotiations between drug manufacturers and pharmacies and PDP sponsors.* Further, the Secretary may not require a particular formulary or require a particular price structure for the reimbursement of covered drugs. Conferees expect PDPs to negotiate price concessions directly with manufacturers.[16]

Again, the noninterference provision's prohibition—against any government interference with "negotiations between drug manufacturers *and* pharmacies *and* PDP sponsors"[17]—was consistently understood as prohibiting bureaucratic involvement with drug-price negotiations generally.[18] Simply put, at no stage in the pre-enactment legislative debate did Congress evince any understanding that the noninterference clause did *not* protect negotiations between "pharmacies and PDP sponsors."[19]

B. The Noninterference Provision's Post-Enactment Regulatory and Legislative History

Less than a year after the Act was signed into law, CMS confirmed Congress's understanding that the noninterference provision prohibited all government interference with drug-price negotiations among PDPs, drug manufacturers, and pharmacies.

As CMS explained in its initial notice of proposed rulemaking for Medicare Part D, the Act "envisions that most price negotiation including discounts, rebates, or other direct or indirect subsidies or remunerations would take place *between PDP sponsors . . . and pharmacies and pharmaceutical manufacturers.*"[20] PDPs would negotiate not just with national drug manufacturers; rather, they would continue "negotiating prices of prescription drugs on a *local*, *regional*, or national basis."[21] And to that end, the noninterference provision "precludes CMS interfering with negotiations between drug manufacturers and pharmacies, or PDP sponsors[.]"[22]

HHS/CMS reiterated this all-encompassing interpretation of the noninterference provision elsewhere. For example, in 2008 comments to HHS's Inspector General, CMS explained:

> This reliance on private market forces means that there are circumstances when contracting entities must be left alone to resolve issues without government direction or interference. The [Medicare

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[16] H.R. Conf. Rep. 108-391, at 461 (2003) (emphasis added).

[17] 42 U.S.C § 1395w-111(i)(1).

[18] As noted throughout the debate, the federal government has broader authority to interfere with drug-price negotiations in other limited contexts—*e.g.*, the Veterans Administration. *See, e.g.*, Hahn, *supra* note 1, at pp. 2-3.

[19] 42 U.S.C § 1395w-111(i)(1).

[20] Dep't of Health and Human Servs., Proposed Rule, *Medicare Program; Medicare Prescription Drug Benefit*, 69 Fed. Reg. 46632, 46681 (Aug. 3, 2004) (emphasis added). That rulemaking was finalized several months later. 70 Fed. Reg. 4194 (Jan. 28, 2005).

[21] *Id.* (emphasis added).

[22] *Id.*

> Modernization Act] contemplated *market negotiations between Part D plans and a wide range of pharmacies* in order to satisfy the statue's beneficiary access standards. In order to meet these requirements, PDP sponsors must contract widely, and this would not be possible in the absence of mutually acceptable, reasonable, and relevant standard contracting terms and conditions. *We interpret section 1860D-11(i) of the statute as prohibiting government interference in precisely the sort of price negotiations suggested in many of the [Inspector General's] report's recommendations.*[23]

Moreover, the noninterference provision's critics continued to call for its repeal.[24] In those debates, as in the debates leading up to the Act's original enactment, I am aware of no evidence that Congress understood the noninterference provision as not protecting negotiations between PDP sponsors and pharmacies. Rather, the noninterference provision's critics cited the need for HHS to involve itself directly in the purchase of drugs from pharmacies,[25] while the provision's supporters defended the prohibition against HHS "doing anything that would affect the prices Medicare pays for drugs."[26]

II. HHS Reinterprets the Act: The January 2014 Proposed Rule

But in January 2014, HHS published a notice of proposed rulemaking that substantially re-interpreted the Act's noninterference provision, so as to allow the government to interfere with negotiations between PDPs and pharmacies.[27] Specifically, and as explained below, HHS interpreted the noninterference prohibition's scope—"negotiations between drug manufacturers and pharmacies and PDP sponsors"—as prohibiting *only* HHS interference in negotiations between drug manufacturers and pharmacies, and between drug manufacturers and PDP sponsors, but *not* prohibiting HHS interference in negotiations between pharmacies and PDP sponsors.[28]

In its new re-interpretation, HHS cites no legislative history (either pre- or post-enactment), no legal scholarship, nor any other materials indicating that HHS's new interpretation of the Act's noninterference provision was endorsed by any other commentators,

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[23] Letter from CMS Acting Administrator to Inspector General Levinson, at p. 1 (May 9, 2008) (emphasis added), *reprinted in* Dep't of Health and Human Servs., Office of the Inspector General, *Review of Medicare part D Contracting for Contract Year 2006*, Appx. M (July 2008), *at* http://oig.hhs.gov/oas/reports/region6/60700082.pdf; *see also id.* ("we believe that several of the report's other recommendations intrude into the competitive market construct established in the MMA as a fundamental feature of the Part D program").

[24] *See, e.g.*, S. 137, 110th Cong. § 2 (2007); H.R. 3200, 111th Cong. § 1186(a) (2009); S. 3415, 11th Cong. § 201(a) (2010); S. 117, 113th Cong. § 2(a) (2013); H.R. 1102, 113th Cong. § 2(a) (2013).

[25] *See, e.g.*, 153 Cong. Rec. S4649 (Apr. 18, 2007) ("If all Secretary Leavitt would do as Secretary of HHS is to buy part D prescription drugs from Main Street pharmacies, Medicare will save money. I don't understand why those who are self-labeled as conservative would not be on the side of having the Federal Government make the best deal it can to save money when it is making bulk purchases of prescription drugs.").

[26] *Id.* at S4629 ("What is the noninterference clause? The noninterference clause prohibits the Secretary of Health and Human Services from 'interfering' with the negotiations between drug manufacturers and pharmacies and drug plan sponsors. Essentially, *this provision bans the Secretary from doing anything that would affect the prices Medicare pays for drugs.*") (emphasis added).

[27] Proposed Rule, *Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs*, 79 Fed. Reg. 1918, 1969-72 (Jan. 10, 2014).

[28] *See id.*

let alone by Congress, prior to HHS's promulgation of this new proposed rule. Nor does HHS acknowledge that its new interpretation departs significantly from its previous interpretation of the Act's noninterference provision.[29]

HHS's defense of its re-interpretation of the Act begins by focusing on the noninterference provision's prefatory language, which HHS construes as indicating that Congress intended not just to prohibit HHS from intervening in the market, but also as paradoxically *requiring* HHS to actively intervene to ensure that the market is sufficiently competitive:

> In beginning with the words 'In order to promote competition under this part and in carrying out this part . . ." we believe that the Congress intended that the activities addressed in the rest of the provision should take place through private market competition. We interpret this to mean two separate but related goals. The first goal is that the Secretary through CMS should promote market competition in the selection of Part D drugs for Part D sponsor formularies. The second goal is that CMS should not create any policies that would be expected to interfere with competitive market negotiation leading to the selection of drug products to be covered under Part D formularies. Therefore, in light of these two goals *we believe there is both a duty to act*—to promote competition in the private market for Part D drugs—*and a duty to refrain from acting*—to avoid intervention in private market negotiations that take place in the context of that competitive market.[30]

In short, HHS professes to believe both that the Act's noninterference provision *forbids* regulators from intervening in the prescription drug market, *but also* that the same provision *requires* regulators to intervene in the prescription drug market.

Having constructed a "duty to act," HHS concludes that, "in light of our interpretation of the general purpose of section 1860D-11(i) of the Act, we propose a general rule at § 423.10(a) [of the proposed regulation] that CMS promotes fair private market competition in the market for Part D drugs."[31]

HHS then turns to the negotiations identified in the Act's noninterference provision: *i.e.*, "*negotiations between drug manufacturers and pharmacies and PDP sponsors.*"[32] HHS concludes that there are "distinct sets of negotiations in the private market between manufacturers and pharmacies on the one hand, and between manufacturers and plan sponsors on the other hand," and thus the Act's noninterference provision "prohibit[s] CMS involvement in negotiations

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[29] In its proposed rule, HHS asserted that "we have never formally interpreted" the Act's noninterference provision. *Id.* at 1969. But as noted above, HHS has interpreted the provision, both in a prior rulemaking and in subsequent analyses. It is unclear whether HHS meant to imply that this new interpretation is more "formal" than those previous analyses, or why it believed that its previous interpretations were insufficiently "formal."

[30] *Id.* (emphasis added; ellipsis in original).

[31] *Id.* at 1970.

[32] 42 U.S.C. § 1395w-111(i)(1).

between manufacturers and pharmacies, and between manufacturers and plan sponsors."[33]

But as to the negotiations between (in the Act's words) "PDP sponsors and pharmacies,"[34] HHS concludes that the prohibition against HHS interference does *not* apply: "we believe that a CMS role in negotiations between plan sponsors and pharmacies is not prohibited under section 1860D-11(i)(1) of the Act."[35] HHS justifies its attempt to remove the Act's protection of PDP-pharmacy negotiations by referring vaguely to other laws that give HHS influence over PDP-pharmacy negotiations:

> [W]e believe that our proposed interpretation of section 1860D-11(i)(1) of the Act as not applying to the sponsor-pharmacy negotiations is supported by the provision's 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 . . . [I]t is clear that Part D sponsors and pharmacies do not have sole discretion to interpret these specific matters . . . Therefore, it is clear that such involvement could not be what Congress intended to prohibit.[36]

HHS also suggests that its purposive analysis finds support in the Act's structure:

> Our interpretation is based on the sequential phrasing of the clause 'negotiations between drug manufacturers and pharmacies and PDP sponsors.' 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 . . . would not pertain to negotiations between Part D sponsors and pharmacies.[37]

Because HHS's new interpretation breaks so sharply from the longstanding debate over the noninterference provision's policy value, it provoked immediate reaction in Congress[38] and among analysts and stakeholders.[39]

In fact, as explained in the next section, HHS's analysis suffers from a variety of

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[33] 79 Fed. Reg. at 1970.

[34] 42 U.S.C. §1395w-111(i)(1).

[35] 79 Fed. Reg. at 1970.

[36] *Id.* at 1971.

[37] *Id.* (emphasis added).

[38] *See, e.g.*, Letter from Rep. Upton, Rep. Camp, and Sen. Hatch to HHS Sec'y Sebelius and CMS Administrator Tavenner, Feb. 19, 2014 (criticizing HHS's proposed rule as "a proposal that is inconsistent with both agency precedent and the plain letter of the law"), *available at* http://energycommerce.house.gov/letter/letter-hhs-and-cms-regarding-proposed-changes-medicare-part-d.

[39] *See, e.g.*, Letter to CMS Administrator Tavenner (Feb. 21, 2014), *supra* note 6.

fundamental flaws, and thus HHS's new interpretation should be rejected—either by HHS itself (in the eventual final rule) or by courts reviewing HHS's final rule.

III. HHS's New Interpretation Is Unfaithful to the Act's Text, Purpose, and History

Good-faith interpretation of the Act's noninterference provision must begin not with legislative history—let alone with abstract characterizations of congressional "goals"[40]—but with the text of the statute itself.[41] And in reading the statute, we are guided by the "canons of construction" developed by the Supreme Court and lower courts.

In this case, the statute at issue is plainly stated and unambiguous: HHS "may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors."[42] That provision includes *no* attempt to demarcate two and only two types of negotiations among the three parties—or, as HHS put it, only negotiations "between manufacturers and pharmacies on the one hand, and between manufacturers and plan sponsors on the other hand."[43] Instead, the provision lists *all* three parties, without any commas, numbers, or other demarcations to promote or demote any of them.

Thus, the noninterference provision's applicability to "negotiations between . . . pharmacies and PDP sponsors"[44] is every bit as clear as the provision's applicability to "negotiations between drug manufacturers and pharmacies,"[45] let alone its applicability to "negotiations between drug manufacturers . . . and PDP sponsors."[46]

The federal courts recognize that grammatical distinctions chosen or eschewed by Congress can cast the statute's plain meaning in sharp relief. "In accordance with common English usage," the Second Circuit has explained, "when Congress wishes to indicate that a series of items is a set of alternatives, it consistently separates the items by commas and uses an 'or' before the last one."[47] And so if, as HHS asserts, Congress *really* intended to group the three parties into two distinct sets—"manufacturers and pharmacies" and "manufacturers and PDP sponsors"—then Congress *easily* could have drawn such distinctions, clearly and explicitly. For example: "the Secretary may not interfere with the negotiations between drug manufacturers and either pharmacies or PDP sponsors, but the Secretary may interfere with the negotiations between pharmacies and PDP sponsors." Congress did no such thing, and for good reason.

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[40] *See* HHS Proposed Rule, 79 Fed. Reg. at 1969 ("We interpret this to mean two separate but related goals").

[41] Or, as Chief Justice Roberts, Justice Felix Frankfurter, and Judge Henry Friendly have characterized the "threefold imperative" of statutory interpretation: "(1) Read the statute; (2) read the statute; (3) read the statute!" *In re England*, 375 F.3d 1169, 1181-82 (D.C. Cir. 2004) (Roberts, J.) (quoting HENRY J. FRIENDLY, BENCHMARKS 202 (1967)).

[42] 42 U.S.C. § 1395w-111(i)(1).

[43] 79 Fed. Reg. at 1970.

[44] 42 U.S.C. § 1395w-111(i)(1).

[45] *Id.*

[46] *Id.*

[47] *In re Renshaw*, 222 F.3d 82, 92 (2d Cir. 2000); *see also Ass'n of N.J. Rifle and Pistol Clubs Inc. v. Port Authority of N.Y. & N.J.*, 730 F.3d 252, 255 (3d Cir. 2013) ("Aside from its violation of the most elementary rules of grammar and punctuation, this argument posits the absurdity that Congress intended—in a single sentence, no less—to create two disjunctive categories, one cabined with all kinds of conditions and the other with none.").

Of course, one must not place so much emphasis on Congress's use of punctuation that the result frustrates Congress's plain intent: When a statute's punctuation implies one reading, but "*all* of the other evidence [of Congress's intent] points the other way," then punctuation may not be dispositive.[48] But in this case, where no such evidence rebuts the plain meaning of Congress's choice of punctuation, no "intelligent construction" of the noninterference can simply disregard Congress's precise choice of punctuation.[49]

Other considerations further undermine HHS's novel interpretation of the Act. With respect to legislative history, the Act's prohibition of HHS interference in "negotiations between . . . pharmacies and PDP sponsors"[50] is consistent with the legislators' repeated characterization of the provision in the broadest possible terms, barring HHS from interfering with drug price negotiations *generally*, not merely from specific subsets of negotiations among some of the named parties.[51] And HHS's new interpretation is further undermined by its prior interpretations, which repeatedly read the noninterference provision as applying to negotiations between PDP sponsors and pharmacies no less than to negotiations between manufacturers and either of those two groups.[52]

Finally, HHS's attempt to justify interference in PDP-pharmacy negotiations by pointing to *other* statutes allowing limited HHS influence over such negotiations contradicts another important canon of construction: "Where Congress explicitly enumerates certain exceptions to a general prohibition, additional exceptions are not to be implied, in the absence of evidence of a contrary legislative intent."[53] In this case, therefore, any statutory powers invoked by HHS must be read as no more than strictly limited exceptions to the noninterference provision's generally applicability to PDP-pharmacy negotiations, and not as a wholesale nullification of the Act's protection of PDP-pharmacy negotiations.[54]

In sum, HHS's novel interpretation of the Act's noninterference provision strains the statutory text beyond reasonable limits, and it contradicts Congress's undisputed understanding of the provision (as well as HHS's own longstanding interpretation of the Act).

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[48] ANTONIN SCALIA & BRYAN A. GARNER, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 165 (2012) (quoting *U.S. Nat'l Bank of Or. v. Indep. Ins. Agents of Am.*, 508 U.S. 439, 454-55 (1993)) (emphasis added).

[49] SCALIA & GARNER, *supra* note 46, at 161.

[50] 42 U.S.C. § 1395w-111(1)(i).

[51] *See supra* Part I.A.

[52] *See supra* Part I.B.

[53] *TRW, Inc. v. Andrews*, 534 U.S. 19, 28 (2001). This longstanding canon is often known by the Latin phrase, "*expressio unius est exclusio alterius*."

[54] For present purposes, it is not necessary to consider the *opposite* relationship between the 2003 Act and other previous statutes: namely, whether the 2003 Act's categorical prohibition against HHS interference in drug price negotiations should be construed as implicitly limiting those other statutes. "The 'classic judicial task of reconciling many laws enacted over time, and getting them to 'make sense' in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute.'" *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 143 (2000). But "repeals by implication are not favored and will not be presumed unless the intention of the legislature to repeal is clear and manifest," *Hui v. Castaneda*, 559 U.S. 799, 810 (2010). Good-faith statutory interpretation requires that *both* statutes be given their fullest possible meaning. *Morton v. Mancini*, 417 U.S. 535, 551 (1974) ("When there are two acts upon the same subject, the rule is to give effect to both if possible").

IV. HHS's Unlawful Interpretation Cannot Be Saved By Judicial "Deference"

Some may suggest that HHS's unsupported interpretation of the noninterference provision can yet be saved in judicial review by general rules of judicial "deference" to administrative agencies' statutory interpretations (known as "*Chevron* deference"[55]). But judicial deference cannot save this particular HHS action, for the following reasons:

First, courts do not give *Chevron* deference to an agency's statutory interpretation when the statute's meaning is unambiguous. For statutes such as the Act's noninterference provision, when the "traditional tools of statutory construction" indicate that "Congress had an intention on the precise question at issue, that intention is the law and must be given effect."[56] Because the Act's noninterference provision is unambiguous in protecting PDP-pharmacy negotiations, the agency's interpretation to the contrary should receive no deference.

Second, an agency's statutory interpretation receives *Chevron* deference only if Congress delegated to that agency the authority to make such interpretations with the binding force of law.[57] Such delegations often can be inferred from Congress's grant of broad rulemaking power to the agency.[58] But such an inference is *not* appropriate when Congress gave the agency targeted rulemaking authority over *some* of the Act's provisions yet *not* over the precise provision at issue.[59] That is the case here: while many parts of Section 1860d-11 delegate to HHS the power (or discretion) to promulgate regulations enforcing the provisions' terms,[60] the Act does *not* include such a grant of rulemaking power for the noninterference provision.[61] This specific statutory silence indicates that Congress did *not* delegate interpretive authority over the noninterference provision to HHS.

Congress's refusal to give HHS binding interpretive power over the Act's noninterference provision is a matter of common sense: the provision was enacted specifically to *constrain* HHS, not to expand HHS's power. As the D.C. Circuit and the Second Circuit stress, "it seems highly unlikely that a responsible Congress would implicitly delegate to an agency the power to define the scope of its own power."[62] Thus, when Congress's emphatic concern was to *limit* HHS's discretion to interfere in the prescription drug market, it strains credulity to presume that Congress nevertheless gave HHS the very authority to define its own limits. Rather, as the D.C. Circuit reiterated just weeks ago (quoting the Supreme Court's own

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[55] *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984).

[56] *See id.* at 843 n.9.

[57] *See, e.g., U.S. v. Mead Corp.*, 533 U.S. 218, 226-27 (2001); *City of Arlington, Tex. v. FCC*, 133 S. Ct. 1863, 1874 (2013); *see also Mayo Found. for Med. Educ. & Research v. U.S.*, 131 S. Ct. 704, 714 (2011) ("the ultimate question is whether Congress would have intended, and expected, courts to treat the regulation as within, or outside, its delegation to the agency of 'gap-filling' authority" (alterations omitted)).

[58] *City of Arlington*, 133 S. Ct. at 1874.

[59] *Gonzales v. Oregon*, 546 U.S. 243, 258-59 (2006).

[60] *See, e.g.*, 42 U.S.C. § 1395w-111(c)(1) ("the Secretary shall establish processes and methods for determining the actuarial valuation of prescription drug coverage"); *id.* § 1395w-111(b)(3) ("The Secretary shall establish requirements for information submission").

[61] *Id.* § 1395w-111(i).

[62] *Natural Res. Def. Council v. Abraham*, 355 F.3d 179, 199 (2d Cir. 2004) (quoting *Am. Civil Liberties Union v. FCC*, 823 F.2d 1554, 1567 n. 32 (D.C. Cir. 1987)) (quotation marks omitted, emphasis added).

warning), "*the fox-in-the-henhouse syndrome is to be avoided by taking seriously, and applying rigorously, in all cases, statutory limits on agencies' authority.*"[63]

Finally, while the Supreme Court recognizes that an agency can often abandon its prior interpretation of an ambiguous statute and embrace another reasonable interpretation, the agency must at the very least *acknowledge* that it is changing positions and offer an adequate explanation for the change.[64] Even setting aside the fact that the Act's noninterference provision is *not* ambiguous, the fact remains that HHS does not acknowledge its change in position—indeed, the agency asserts that it has "never formally interpreted" the noninterference provision before,[65] even though the agency *repeatedly* interpreted the provision, beginning with HHS's first Part D rulemaking.[66] If HHS's final rule continues to refuse to acknowledge and sufficiently explain its sudden about-face, then that is grounds for vacating HHS's final rule as "arbitrary and capricious."[67]

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In sum Congress and the courts should heed the Second Circuit's warning:

> Though the classification of congressional intent as clear or ambiguous will sometimes be in the eye of the beholder, *courts construing statutes enacted specifically to prohibit agency action ought to be especially careful not to allow dubious arguments advanced by the agency in behalf of its proffered construction to thwart congressional intent expressed with reasonable clarity*, under the guise of deferring to agency expertise on matters of minimal ambiguity.[68]

Or, as the Fifth Circuit succinctly put it, "agencies cannot manufacture statutory ambiguity with semantics to enlarge their congressionally mandated border."[69] HHS's attempt to do so here is unlawful and unsustainable.

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[63] *Loving v. IRS*, --- F.3d ---, 2014 WL 519224 at *9 (D.C. Cir. Feb. 11, 2014) (quoting *City of Arlington*, 133 S. Ct. at 1874) (quotations and alterations omitted).

[64] *Nat'l Cable & Telecomm. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005).

[65] 79 Fed. Reg. at 1969.

[66] *See supra* Part I.B.

[67] *Brand X*, 545 U.S. at 981.

[68] *Indep. Ins. Agents of Am., Inc. v. Bd. of Governors of the Fed. Reserve Sys.*, 838 F.2d 627, 632 (2d Cir. 1988) (emphasis added).

[69] *Tex. Pipeline Ass'n v. FERC*, 661 F.3d 258, 264 (5th Cir. 2011).