December 18, 2020

Centers for Medicare & Medicaid Services
P.O. Box 8013
Baltimore, MD 21244-8013

RE: RIN 0938-AT91, Most Favored Nation (MFN) Model

Introduction

On behalf of National Taxpayers Union (NTU), the nation's oldest taxpayer advocacy organization, I write in regard to the Centers for Medicare and Medicaid Services' (hereafter referred to as "the Agency") interim final rule with comment period (IFC), "Most Favored Nation (MFN) Model." NTU is deeply concerned with the substance of the IFC and the process by which the Agency is implementing the IFC, and we urge the Agency to withdraw the IFC as soon as possible.

NTU's Stake in Prescription Drug Policy

Taxpayers around the nation have a significant stake in how federal and state governments approach prescription drug development, deployment, and payment. The federal government either directly purchases prescription drugs or subsidizes prescription drug coverage for tens of millions of Americans through the Medicare and Medicaid programs. Regulations on both health insurance plans and manufacturers impact when drugs are available to the majority of Americans with private coverage and how much those products will cost. In short, taxpayers have a lot to gain from prudent drug policy in Congress, at federal agencies, and in state capitals—and a lot to lose from policy proposals that interfere with the market dynamics that have provided Americans with unparalleled access to new cures.

NTU's Concerns With the MFN Model

NTU has numerous concerns with the IFC—significant enough to underscore our strong belief that the Agency should withdraw the IFC in its entirety. Our objections to the substance of the IFC include the following:

- As more than 150 economists wrote to Secretary of Health and Human Services (HHS) Alex Azar in December 2018 on the Agency's International Pricing Index (IPI) proposal, price controls in the prescription drug market "can lead to a reduction in patient access to certain drugs, less investment in the research and development of new drugs, and cost-shifting that raises the prices of other therapeutics."[1] These concerns are even more relevant to the MFN Model, which relies more heavily on price controls than the 2018 IPI proposal.

[1] National Taxpayers Union. (December 6, 2018). Economists' Letter to HHS. Retrieved from: https://www.ntu.org/library/doclib/2018/12/Economists-Letter-to-HHS-1.pdf

- Although the IFC purports to stress the need for global competition in the prescription drug market, the MFN Model would actually *reduce* competition around the world by having Medicare rely on the aggressive government price controls of foreign countries to pay for drugs in Part B. This runs contrary to the Administration's concern with drug price controls in Europe and elsewhere.
- The MFN Model adds a troubling price control not present in previous iterations of MFN or IPI: a penalty on manufacturers who raise drug prices faster than the rate of inflation. NTU has previously pointed out that such inflation caps would have the government effectively control prices, pushing manufacturers to recoup their costs elsewhere.[2]
- The Agency acknowledges that it will not review quality of care outcomes from the MFN Model until four years into the Model's seven-year existence. This is far too late into the Model's lifespan to investigate a paramount concern stakeholders have raised with the Model — that it might negatively impact patients' access to treatments.
- Indeed the Agency acknowledges that the Model may have a negative impact on patients' access to treatments, with some of the alleged savings the Model produces for taxpayers a result of seniors foregoing care. The Agency offers a proverbial shrug to this potential impact of the Model, when in reality it should be reason enough to stop implementation of the IFC.
- The Agency acknowledges that manufacturers could respond to the IFC by raising prices on its drugs not subject to the Model, or by increasing its drug prices internationally (or both). Again, the Agency offers a proverbial shrug to these potential impacts, failing to address them substantially in the IFC or to engage stakeholders on how best to mitigate these potential outcomes.
- The Agency acknowledges that its projections for the Model's financial and health care impacts are subject to considerable uncertainty, not only because the Model is unprecedented but because the COVID-19 pandemic has clouded the range of possible Model outcomes. Nevertheless, the Agency appears intent on barreling ahead with an IFC, an untenable decision given the degree of uncertainty around the Agency's own projections.

Our objections to the Agency's process with the IFC include the following:

- Given all of the substantive reasons above and more, we believe it is a grave mistake for the Agency to proceed to an IFC. This process deprives stakeholders of vital opportunities to provide the Agency with feedback *before* the Agency implements the Model. Implementation will also take place under the backdrop of a transition between the outgoing Trump Administration and the incoming Biden Administration, and we believe the Model is too significant to serve as a "midnight" regulation.
- The Agency's deployment of the Center for Medicare and Medicaid Innovation (CMMI) in service to this policymaking is another example of executive overreach with CMMI—and we believe that it exceeds the scope of the CMMI statute as well.
- Some reporting indicates there may be political motivations for the timing of the MFN Model. As we noted in a recent statement on the MFN Model, "[i]f true, then taxpayers and, indeed, all Americans will likely view it as a startling and troubling abuse of government power. Even the slightest appearance that the federal bureaucracy is being unleashed against American businesses as political punishment should be off-limits and off the table."[3]

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[2] Lautz, Andrew. "Why NTU Opposes an Inflation Cap for Medicare Part D." National Taxpayers Union, July 16, 2019. Retrieved from: https://www.ntu.org/publications/detail/why-ntu-opposes-an-inflation-cap-for-medicare-part-d

[3] National Taxpayers Union. (November 19, 2020). "NTU Statement on Possible Most Favored Nation Regulation." Retrieved from: https://www.ntu.org/publications/detail/ntu-statement-on-possible-most-favored-nation-regulation

We consider each of the above concerns in more detail below.

NTU Concerns with the MFN Model and IFC

Numerous Economists Oppose Price Controls for Prescription Drugs

In December 2018, NTU organized over 150 economists to submit a letter to Secretary Azar, expressing deep concerns with the Agency's IPI proposal. Those economists wrote, in part:

> In general, setting price controls at below-market rates leads to shortages, squeezes the cost bubble toward some other portion of the economy, and imposes a deadweight cost on society. In this case, price controls can lead to a reduction in patient access to certain drugs, less investment in the research and development of new drugs, and cost-shifting that raises the prices of other therapeutics. Ultimately, patients will suffer as cures are delayed or entirely undeveloped, while taxpayers will be denied potential savings from drugs that could obviate more expensive treatments in government healthcare programs, and the investment of capital in development of new medicines.[4]

These concerns remain today, especially with an MFN Model that relies more heavily on price controls—by often resorting to the country with the *most* aggressive price controls—than an IPI model that would have merely averaged out the government price controls of foreign countries.

The Administration's Council of Economic Advisers (CEA) has warned of the dangers associated with prescription drug price controls on numerous occasions in recent years.

Of H.R. 3, House Democrats' legislation to force manufacturers to accept a government-set price for prescription drugs by levying a 95 percent excise tax on manufacturers who refuse to comply, the CEA wrote:

> The Council of Economic Advisers (CEA) estimates that H.R. 3 could lead to as many as 100 fewer drugs entering the United States market over the next decade, or about one-third of the total number of drugs expected to enter the market during that time. CEA also estimates that by limiting access to lifesaving drugs, H.R. 3 would reduce Americans' average life expectancy by about four months—nearly one-quarter of the projected gains in life expectancy over the next decade.[5]

Though the MFN Model may not have the same scale and scope of negative impact that H.R. 3 would have if passed, it must be noted that, like H.R. 3, the MFN Model would "effectively forc[e] drug manufacturers to accept prices set by the Secretary of Health and Human Services."[6]

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[4] National Taxpayers Union. (December 6, 2018). Economists' Letter to HHS. Retrieved from: https://www.ntu.org/library/doclib/2018/12/Economists-Letter-to-HHS-1.pdf

[5] Council of Economic Advisers. (December 3, 2019). "House Drug Pricing Bill Could Keep 100 Lifesaving Drugs from American Patients." Retrieved from: https://www.whitehouse.gov/articles/house-drug-pricing-bill-keep-100-lifesaving-drugs-american-patients/ (Accessed November 24, 2020.)

[6] *Ibid*.

CEA argued in February 2020 that "[r]educing foreign price controls [on prescription drugs] would increase profits and innovation, thereby leading to greater competition and lower prices for U.S. patients."[7] A critical point must be made here: the CEA does *not* blame high U.S. drug prices on American taxpayers, patients, or pharmaceutical companies. The Council explicitly states that foreign government price controls have led to drugs being sold for "below the value they generate" in those countries, leaving Americans to foot the bill for these innovations.

The MFN Model would lean *into* foreign price controls for prescription drugs, rather than putting pressure on foreign countries to reduce their government price controls. It is not a stretch to see this Model leading to the opposite outcomes outlined by CEA earlier this year: reduced profits, reduced innovation, reduced competition, and higher prices for U.S. patients.

The MFN Model Relies on Countries With Aggressive Government Price Controls

As mentioned above, the MFN Model effectively doubles down on the foreign government price controls that this Administration has previously opposed. Consider an analysis conducted by Democrats on the House Committee on Ways and Means, which examined prescription drug price controls in the United Kingdom, Japan, Ontario (Canada), Australia, Portugal, France, the Netherlands, Germany, Denmark, Sweden, and Switzerland.[8] Every country on this list but Portugal is included in the MFN Model.

The Committee found that every country on this list had an internal reference pricing system (where prices are set by comparing one drug's prices to another drug's prices within the same country) and/or an external reference pricing (ERP) system where a country sets drug prices based on a basket of prices in other countries (much like the MFN Model). The Committee also found that "[w]ith the exceptions of Denmark, Sweden, and the U.K., almost every European country – and most other developed nations – has established some form of an ERP."[9]

In relying on the lowest price available for a drug in a basket of countries, the MFN Model is even more aggressive with its proposed price controls than those found in many European countries, which the Committee reported typically rely on "the average of all prices in the basket as a benchmark."[10] In other words, the MFN Model contains more severe price controls than many of the countries the Administration has criticized *for* its government price controls.

Many of these countries also set the prices that manufacturers will receive from private payers. The MFN Model does not propose to do so, but this simple fact underscores that the Administration's implementation of the Model would tacitly endorse and entrench the aggressive steps foreign governments have taken to set drug prices at below cost. If the Administration is truly committed to reducing foreign price controls around the world, it should immediately withdraw the IFC.

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[7] Council of Economic Advisers. (February 2020). "Funding the Global Benefits to Biopharmaceutical Innovation." Retrieved from: https://www.whitehouse.gov/wp-content/uploads/2020/02/Funding-the-Global-Benefits-to-Biopharmaceutical-Innovation.pdf?mod=article_inline (Accessed November 24, 2020.)

[8] House Committee on Ways and Means. (September 2019). "A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices." Retrieved from: https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf (Accessed November 24, 2020.)

[9] *Ibid*.

[10] *Ibid*.

The Model Includes Additional Price Controls Like an Inflation Penalty

The Agency makes a troubling addition to its MFN Model in the IFC that was not present in prior iterations of MFN or IPI: an inflation penalty on participating manufacturers during both the MFN Price phase-in and after the phase-in.

> As discussed in section III.E.9. of this IFC, we will also accelerate the applicable phase-in formula when the applicable ASP for an MFN Model drug rises faster than both a designated inflation factor and the change in MFN Price, and lower the MFN Drug Payment Amount below the MFN Price by a certain percentage if the applicable ASP for an MFN Model drug continues to increase faster than the inflation factor and the MFN Price after the full phase-in of the MFN Price.

Specifically, the phase-in for any particular drug will accelerate by five percentage points if, during any quarter, an MFN Model drug's average sales price (ASP) increases faster than the "cumulative percentage increase in the Consumer Price Index for All Urban Consumers (CPI-U)." Inflation penalties after the four-year phase-in period will equal "the largest difference in the cumulative percentage increase in the applicable ASP or any of the monthly U.S. list prices for the NDCs assigned to the MFN Model drug's HCPCS code compared to the cumulative percentage increase in the CPI-U and in the MFN Price."

NTU has told policymakers before that inflation penalties or caps allow the government to effectively control the prices of a drug for both public and private payers. While some stakeholders have argued that proposals to apply inflation caps to the Medicare Part D program are *not* price controls because those proposals would only cap Medicare's 'subsidy' to manufacturers, we have countered by noting that inflation penalties in programs as large as Medicare and Medicaid *do* have the same negative impacts of government price controls.[11]

> An inflation cap, on the other hand, would effectively put the federal government in charge of drug prices, rather than a competitive free market. [President of the Foundation for Research on Equal Opportunity (FREOPP) Avik] Roy notes that "[s]ubsidies are not prices." He's correct. Subsidies, though, have a significant impact on prices, especially when the subsidy is worth 80 percent of drug costs after a certain point. Roy suggests that "Part D drugmakers can charge whatever they want" under an inflation cap. He fails to note, though, that the larger the difference between this government-imposed cap (on a program with 45 million enrollees) and the market price for a drug, the more plan sponsors and drugmakers will seek to recoup those costs elsewhere. Through the market mechanisms [NTU noted earlier in this analysis], all actors can reach an equilibrium whose long-run impacts would be less disruptive than a cap.[12]

Given inflation penalties measure how a drug's ASP is increasing relative to CPI-U, such a penalty by design looks to control prices in the free market. Even if an inflation penalty were somehow acceptable—and it is not—it would be more appropriate to measure inflation by the CPI for Medical Care rather than for the entire market of goods and services (i.e., CPI-U).

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[11] As the economists noted in the NTU-organized letter, these negative impacts include shortages and deadweight costs on society.
[12] Lautz, Andrew. "Why NTU Opposes an Inflation Cap for Medicare Part D." National Taxpayers Union, July 16, 2019. Retrieved from: https://www.ntu.org/publications/detail/why-ntu-opposes-an-inflation-cap-for-medicare-part-d

Even if the Agency is intent on maintaining this harmful Model, it could reduce the harm of the MFN Model by eliminating the inflation penalties for both the phase-in period and for the fully phased-in Model.

The Agency Will Not Review Quality of Care Outcomes Early Enough in the Model Lifespan

The Agency says it plans to "assess initial impacts of the MFN Model on quality of care, including access to drugs, prior to beginning performance year 5." This is inadvisable for a number of reasons.

The Agency's Office of the Actuary (OACT) estimates that by 2023 up to one in five non-340B Program beneficiaries who would otherwise have access to MFN Model drugs would not have access to those drugs under the Model. This lack of access is sustained through the remainder of the Model's seven-year window. As noted below, the Agency acknowledges that some of the taxpayer savings attributed to the Model are the result of "beneficiaries not accessing their drugs through the Medicare benefit, along with the associated lost utilization."

What's more, the statute governing CMMI requires that models "reduce program expenditures under the applicable subchapters *while preserving or enhancing the quality of care furnished to individuals* under such subchapters" (emphasis ours).[13] Given the significant doubts about the Model's impact on quality of care—measured through patient access to life-saving medications—it is wholly inappropriate that the Agency would pledge only to measure the Model's impacts on quality of care in the fifth year of the demonstration. If the Agency is to move ahead with the Model, it must commit to earlier reviews of the Model's impact on patient access to prescription drugs and it must consider withdrawing the Model or severely reducing its scope and scale if the Model is proven to have a negative impact on patient access to medications.

The Model May Negatively Impact Patient Access to Care

As noted above, the Agency has significant reason to believe its model may have a deleterious effect on patients' access to care. The Agency writes in the IFC: "[b]eneficiaries lacking continued availability of their drugs through their current provider or supplier are assumed to seek access outside the model, to obtain their drugs through 340B providers, or to forgo access."

And while the Agency goes on to estimate a net $85.5 billion in savings for taxpayers as a result of the Model, the Agency warns that "a portion of the savings is attributable to beneficiaries not accessing their drugs through the Medicare benefit, along with the associated lost utilization." Notably, these estimates were not conducted to estimate the effects of the COVID-19 pandemic—adding to general uncertainty around the Model's impacts.

However, we note that even a large shift in beneficiaries from non-340B providers to 340B providers would have a negative impact for taxpayers (if not patients as well). In recent comments filed with the Senate Health, Education, Labor, and Pensions (HELP) Committee and the House Energy and Commerce Committee, NTU pointed out several flaws in the 340B Drug Pricing Program that urgently require fixes from Congress, the Agency, and the Health Resources and Services Administration (HRSA).[14] Those fixes are beyond the scope of the MFN Model, but we raise them to note that it would be problematic for patients to forgo access to their

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[13] 42 U.S.C. §1315a(a)(1)

[14] Lautz, Andrew. "340B Program Must Be Reformed to Achieve Its Intended Purpose." National Taxpayers Union, October 21, 2020. Retrieved from: https://www.ntu.org/publications/detail/340b-program-must-be-reformed-to-achieve-its-intended-purpose

drugs or to shift to the 340B Program. The Agency should devote more care in addressing these concerns, and it cannot possibly do so by implementing an IFC.

Finally, we note that while the Agency projects more than $85 billion in net savings as a result of the Model, these savings for taxpayers could easily be threatened by increases in medical costs that stem from fewer life-saving treatments coming to market. Reduced access to drugs, especially blockbuster drugs, will over the long term lead beneficiaries to resort to costlier therapies like surgeries and hospital stays. The nonpartisan Congressional Budget Office has documented this phenomenon on a number of occasions.[15] The Model should include a more robust and publicly accessible consideration of these factors in developing a net figure for savings that will likely be lower or, taken over a sufficient time window, could even be negative.

Manufacturers May Raise Prices and Providers May Fail in Response to the Model

The Agency lists several possible ways that manufacturers could respond to price reductions mandated by the Model:

> Manufacturers could adopt several strategies in response to the model, such as (i) charging a lower price to providers and suppliers inside the model; (ii) refusing to adjust their price from the non-model amounts; or (iii) altering the availability and terms of their international prices.

The Agency adds that it expects manufacturers to exercise the third option, which would raise drug prices, above the other two options:

> Given that the international price data represent a challenge to their U.S. market revenues, manufacturers are expected to devote considerable resources to the third option.

Later on the Agency acknowledges that it expects international prices to begin rising as early as 2022, the first year after the Model's implementation. While it is unclear if any of these results may come to pass, the Agency's confidence that manufacturers will look to raise the international prices of their drugs at *minimum* challenges the notion that the Model will enhance global price competition for prescription drugs.

The Agency also admits that providers may go out of business as a result of the Model. In describing a hardship exemption for provider participation in the Model with a threshold of "year-over-year losses above 25 percent of total Medicare Part A and Part B payments"—a high bar for providers to meet—the Agency writes:

> We expect that few, if any, providers will have annual losses above this level, and that those who do may be insolvent and therefore unable to obtain retrospective hardship payments.

However, the Agency also acknowledges an inherent flaw in the provider hardship exemption, that a provider's accumulated losses could be severe without the provider qualifying for a hardship exemption:

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[15] See, for example, Congressional Budget Office. (November 2012). "Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services." Retrieved from: https://www.cbo.gov/sites/default/files/112th-congress-2011-2012/reports/MedicalOffsets_One-col.pdf (Accessed December 18, 2020.); Congressional Budget Office. (July 2014). "Competition and the Cost of Medicare's Prescription Drug Program." Retrieved from: https://www.cbo.gov/sites/default/files/113th-congress-2013-2014/reports/45552-PartD.pdf (Accessed December 18, 2020.)

> We note in this regard that a hypothetical provider could experience revenue losses of 24.9 percent per year in each of the model's seven years, resulting in an 86.5 percent loss of revenue in Performance Year 7 compared with the pre-model base year and a 62.7 percent loss of revenue over the seven-year demonstration period, without qualifying for the hardship payments in any year.

Clearly the hardship exemption is inadequate for many providers, and it is unclear to us whether any provider could sustain even 15- or 20-percent losses for seven consecutive years without going out of business. Like many other elements of the Model, the Agency has not given sufficient thought to how manufacturers and providers may respond to this Model in ways that negatively impact patient access and, indeed, the very integrity of the Medicare program.

The Agency's Projections Are Subject to a High Degree of Uncertainty

The Agency admits throughout the IFC that both the OACT estimates and the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) estimates are subject to high degrees of uncertainty, *even without* accounting for the COVID-19 pandemic.

As the Agency puts it:

> It should be noted that this model does not have a reliable precedent in the U.S. market; consequently, there is an unusually high degree of uncertainty in these assumptions, particularly with respect to the behavioral responses.
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> ...Other estimates outside the range of the three [OACT] scenarios could be reasonable as well, due to the wide range of potential responses.

The Agency also acknowledges that the pandemic only *adds* to the level of uncertainty the Agency faces in making estimates about the impacts the Model will have on behavior:

> These values are on a pre-COVID-19 basis, and the baseline is not are [sic] adjusted for the effects of the pandemic. Similarly, the impact analysis does not include the effects of the COVID-19 pandemic. Many assumptions such as utilization, mortality, and morbidity are more uncertain than usual due to the pandemic.

This high degree of uncertainty underscores that the Agency was mistaken in advancing to an IFC (more on that below). However, we believe that the Agency should not move forward with the Model even if it were to go through a more appropriate and deliberate regulatory process, given the significant uncertainty the Agency faces implementing the Model irrespective of pandemic factors.

The IFC Process Robs Stakeholders of Valuable Opportunities for Input

While our concerns thus far have focused on the substance of the Model and the IFC, we have several concerns about the process by which the Agency is proposing to implement the Model.

The first of these concerns is that choosing to move forward with an IFC robs key stakeholders of the opportunity to weigh in and critique the Model before the Agency implements key elements of the Model.

The Agency claims that it is right to proceed to an IFC given the impact that high drug prices have on American patients and consumers:

> Already facing increased financial burden, this population is in need of urgent relief from high drug prices in order to prevent stinting on care and alleviate general financial instability worsened by the COVID-19 pandemic.

However, this claim makes little sense given the Administration has been proposing some version of the MFN Model for nearly two years now. The changes made to this iteration of the Model, compared to previous proposals, are not specifically aimed at reducing the burdens Americans face during the pandemic. Therefore, the Agency's argument that an IFC is necessary *because* of the pandemic fails to pass muster.

In issuing an IFC the Agency claims it is waiving the "notice and comment requirements under sections 553(b)(B) of the APA [Administrative Procedure Act]." That provision of statute allows for an agency to waive notice and comment requirements "when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest."[16] However, a notice and comment period is neither impractical nor unnecessary for a Model that would have significant multibillion-dollar impacts on the Medicare program and its participants.

There is also a strong argument to make that such notice and comment opportunities are *not* "contrary to the public interest"—quite the opposite. The Agency itself admits that numerous stakeholders (patients, plans, manufacturers, and taxpayers who fund the Medicare program) will be significantly impacted by the Model. Even the alleged savings to patients and taxpayers are, by the Agency's own admission, subject to a high degree of uncertainty. These admissions suggest that the Model seems to fit the very definition of being in the "public interest," and stakeholders—including those who would support this Model—should have the opportunity to provide comments *before* the Model is implemented.

Lastly, we note that this IFC comes during one of the most important transitions between Administrations in recent history. The outgoing Administration and the incoming Administration are tackling what is a once-in-a-lifetime pandemic. The new Administration needs to be able to hit the ground running on pandemic management, COVID-19 therapeutic development, COVID-19 vaccine distribution, and more. NTU has always believed that Administrations should exercise great caution in issuing what have been popularly termed "midnight" regulations during a transition period.[17] Our concerns extend to this unique transition period and to the scale and scope of the MFN Model.

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[16] 5 U.S.C. §553(b)(B)

[17] Swift, Nan. "'YES' on H.R. 4078, the Red Tape Reduction and Small Business Job Creation Act." National Taxpayers Union, July 26, 2012. Retrieved from: https://www.ntu.org/publications/detail/yes-on-hr-4078-the-red-tape-reduction-and-small-business-job-creation-act; Swift, Nan. "Financial Services Funding Bill Would Reduce IRS Overreach." National Taxpayers Union, June 22, 2016. Retrieved from: https://www.ntu.org/publications/detail/financial-services-funding-bill-would-reduce-irs-overreach

The Model Is Too Large and Broad to Serve as a CMMI Model

NTU has warned both Republican and Democratic Administrations that some of the proposed demonstration projects under the Center for Medicare and Medicaid Innovation (CMMI) represent prime examples of executive branch overreach.[18]

Congress has taken a bipartisan interest of late in clarifying the legislature's intent for CMMI projects. In March, a group of lawmakers introduced the "Strengthening Innovation in Medicare and Medicaid Act" (H.R. 5741), which would put new guardrails and restrictions on CMMI demonstration projects.[19] The legislation has 17 cosponsors—nine Democrats and eight Republicans—which shows broad and bipartisan support for reining in CMMI. The MFN Model would instead create the largest and most unwieldy CMMI project to date—mandatory, nationwide, affecting all Medicare Part B providers, lasting seven years, and having an impact in the tens of billions of dollars.

We also believe that the MFN Model may specifically violate two requirements in the CMMI statute. The first possible violation strikes at the very purpose of CMMI—to facilitate models that "reduce program expenditures under the applicable subchapters *while preserving or enhancing the quality of care furnished to individuals*" (emphasis ours).[20] The Agency itself admits that it does not know how the Model will impact quality of care outcomes, and specifically patient access to medications. Instead, the Agency effectively guesses that overall quality of care will improve and promises to inspect quality of care issues four years into the seven-year demonstration.

The second possible violation concerns the nationwide scope of the MFN Model. The statute says that (emphasis ours):

> *Taking into account the evaluation* under subsection (b)(4), the Secretary may, *through rulemaking*, *expand* (*including implementation on a nationwide basis*) the duration and the scope of a model that is being tested under subsection (b) or a demonstration project under section 1395cc–3 of this title, to the extent determined appropriate by the Secretary...[21]

Under the MFN Model, the Agency is resorting to a mandatory nationwide model, without having evaluated the Model on a smaller scale first. Though the statute includes no explicit prohibition on a nationwide CMMI model, we believe the statutory language makes clear that Congress never intended for the first iteration of a model to be nationwide.

Reports About Political Motivations for the Model Are Deeply Troubling

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[18] National Taxpayers Union. (November 16, 2016). "Congress Must Repeal or Restrain Obamacare's CMMI." Retrieved from: https://www.ntu.org/publications/detail/congress-must-repeal-or-restrain-obamacares-cmmi

[19] "H.R.5741 - Strengthening Innovation in Medicare and Medicaid Act." Congress.gov. Introduced February 3, 2020. Retrieved from: https://www.congress.gov/bill/116th-congress/house-bill/5741/text (Accessed November 25, 2020.)

[20] 42 U.S.C. §1315a(a)(1)

[21] 42 U.S.C. §1315a(c)

We were troubled when several media outlets reported that the MFN Model was rushed out the door "amid [President] Trump's frustration with pharmaceutical companies that he believes slow-walked positive coronavirus vaccine news,"[22] or in an effort to "get back at the pharmaceutical industry."[23]

These media reports led us to issue the following statement on the MFN Model:

> Lastly, several media reports have suggested that this proposal may be a way of exacting payback against certain pharmaceutical manufacturers for the timing of their recent COVID-19 vaccine trial announcements. We would certainly hope this is not the case. If true, then taxpayers and, indeed, all Americans will likely view it as a startling and troubling abuse of government power. Even the slightest appearance that the federal bureaucracy is being unleashed against American businesses as political punishment should be off-limits and off the table.[24]

Those concerns remain, and were underscored when the President hinted at his anger with manufacturers on a COVID-19 vaccine at a press event announcing the MFN Model:

> And Pfizer and others even decided to not assess the results of their vaccine; in other words, not come out with a vaccine until just after the election. That's because of what I did with favored nations and these other elements, instead of their original plan to assess the data in October. So they were going to come out in October, but they decided to delay it because of what I'm doing, which is fine with me, because frankly, this is just a very big thing. A very big thing. What I'm doing here — I don't know if anybody is going to appreciate it. These people can't even believe it.
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> ...These corrupt games will not deter us from doing what is right for the American people. And I will always put American patients first, and I think it could never be shown better than what I'm doing today.[25]

When NTU was founded in 1969, several of our earliest leaders had first-hand experience that the powers of the executive branch and the federal agencies under the President's purview are expansive, and must be wielded with great care. To create even the appearance that those powers might be employed punitively against private businesses severely risks undermining the credibility of whatever policy goal underlies them.

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[22] See, for example, Owermohle, Sarah. "Trump unveils plan linking drug payments to cheaper overseas prices." *Politico*, November 20, 2020. Retrieved from: https://www.politico.com/news/2020/11/20/trump-drug-prices-overseas-438819 (Accessed November 25, 2020.)

[23] See, for example, Cunningham, Paige Winfield. "The Health 202: Trump is angry at vaccine makers, so he's pushing a last-minute plan to lower drug prices." *The Washington Post*, November 17, 2020. Retrieved from: https://www.washingtonpost.com/politics/2020/11/17/health-202-trump-is-angry-vaccine-makers-so-he-pushing-last-minute-plan-lower-drug-prices/ (Accessed November 25, 2020.)

[24] National Taxpayers Union. (November 19, 2020). "NTU Statement on Possible Most Favored Nation Regulation." Retrieved from: https://www.ntu.org/publications/detail/ntu-statement-on-possible-most-favored-nation-regulation (Accessed November 25, 2020.)

[25] The White House. (November 20, 2020). "Remarks by President Trump on Delivering Lower Prescription Drug Prices for All Americans." Retrieved from: https://www.whitehouse.gov/briefings-statements/remarks-president-trump-delivering-lower-prescription-drug-prices-americans/ (Accessed November 25, 2020.)

Conclusion

Given all of NTU's above concerns with the substance of the MFN Model and the process by which the Agency plans to implement the Model, we are urging the Agency to immediately withdraw the IFC. We believe that any iteration of MFN or IPI would be harmful to American patients, taxpayers, and businesses, but that this particular version of the proposal is both more expansive and more inappropriately rushed than IPI.

This Administration has noted on many occasions that government price controls do not work in any context, and would lead to specific negative impacts in the prescription drug market. NTU agrees with these assessments. This is why we are puzzled and troubled that the Agency seeks to implement a proposal, in the Administration's waning months and during a pandemic, that would double down on the drug price controls set by foreign governments. The Administration has warned on many occasions that these price controls harm American patients and taxpayers. The Agency should heed the Administration's warnings and stop this IFC.

Sincerely,

Andrew Lautz
Policy and Government Affairs Manager