Trinity Health

October 12, 2021

Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-5528-P; Most Favored Nation Model

Submitted electronically via http://www.regulations.gov

Dear Administrator Brooks-LaSure,

Trinity Health appreciates the opportunity to comment on the Most Favored Nation (MFN) model rescission set forth in CMS-5528-P. Our comments and recommendations to the Centers for Medicare and Medicaid Services (CMS) reflect a strong interest in public policies that support better health, better care and lower costs to ensure affordable, high quality, and people-centered care for all.

Trinity Health is one of the largest multi-institutional Catholic health care delivery systems in the nation, serving diverse communities that include more than 30 million people across 22 states. We are building a People-Centered Health System to put the people we serve at the center of every behavior, action and decision. This brings to life our commitment to be a compassionate, transforming and healing presence in our communities. Trinity Health includes 94 hospitals as well as 109 continuing care locations that include PACE, senior living facilities, and home care and hospice services. Our continuing care programs provide nearly 2.5 million visits annually. Committed to those who are poor and underserved, Trinity Health returns $1.1 billion to our communities annually in the form of charity care and other community benefit programs. We have 35 teaching hospitals with graduate medical education (GME) programs providing training for more than 2,000 residents and fellows in 184 specialty and subspecialty programs. We employ approximately 133,000 colleagues, including more than 7,800 employed physicians and clinicians, and have more than 15,000 physicians and advanced practice professionals committed to 16 Clinically Integrated Networks (CINs) that are accountable for approximately 1.5 million lives across the country through alternative payment models.

Trinity Health participates in 11 markets with Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs), which includes five markets partnering as an MSSP Track 3 ACO. We also have three markets partnering as a Next Generation ACO and 2 participating in CPC+. In addition, we have 33 hospitals participating in the Bundled Payments for Care Improvement Advanced (BPCIA) initiative, and three hospitals in the Comprehensive Care for Joint Replacement (CJR) program. Our work—and experience in value-based contracting—also extends beyond Medicare as illustrated by our participation in 123 non-CMS APM contracts.

Trinity Health supports the rescission of the MFN model, as it does nothing to address the root cause of skyrocketing drug prices and would harm patient care. **We urge the Biden Administration to work with**

Congress to pass comprehensive drug reform to hold drug companies accountable, rather than place the burden on patients and providers. Further, the MFN model lacked transparency—CMS did not provide the information needed for stakeholders to replicate the MFN drug payment amounts and validate the methodology nor did they provide the details on its data sources, how it is validating the data, if it is making adjustments to the data, and how it is controlling for different factors, such as packaging in different countries and the timing of reporting. **Any future policy on drug pricing must be transparent.**

In addition, we have the following comments on the MFN Model for CMS consideration as they develop future drug payment models.

Patient Impact

The MFN Model as designed would harm patient access to critical, lifesaving drugs and force them to accept less effective treatments or skip care all together and CMS acknowledged this in the 2020 rule. In addition, CMS estimated nearly one in five Medicare Part B enrollees may have no access to drugs within three years of implementation and that the reduction in utilization of these drugs would account for half of the rule's projected savings to Medicare.

CMS should ensure that any future drug model does not harm Medicare beneficiaries as potential policy options are evaluated.

Additional financial burden on hospitals

The MFN model would create additional financial burden for hospitals and we urge CMS to avoid these negative impacts in future rulemaking or models. In the rule, CMS admitted that some providers may suffer extreme financial hardship from the policy because they would be reimbursed significantly less than what they pay for critical medicines such as cancer drugs.

Under the MFN model as designed, CMS would no longer base its reimbursement rate on the manufacturer's ASP for certain high-cost, separately payable Medicare Part B drugs and instead peg Medicare Part B payments for those drugs to the lowest price available in one of almost two dozen other countries. In addition, instead of the 6% add-on payment under the current formula, the MFN rule calculates a flat add-on payment that is the same for every drug to which the rule applies. By CMS' own estimates, MFN prices average 65% below ASP.

The flat add on payment per dose does not vary based on number of units administered to the patient per encounter, so the financial impact could be very detrimental for larger doses of high-cost drugs. For example, our highest impact drug was Pembrolizumab HCPCS J9271, which is used for cancer treatment. Medicare reimbursement per average dose in 2019 was $9,661. **At the MFN reduced payment, our reimbursement would decrease to $6,279 plus the add-on payment of $148 to a total of $6,427. The add-on payment doesn't make up for the loss of over $3,200 per average dose.**

Overall, Trinity Health estimated a $56 million net reduction annually in Medicare reimbursement for MFN drugs using CMS' own estimate of the MFN price being 65% of Medicare rate.

In the rule, CMS stated they "welcome comments on our estimate of significantly affected providers and suppliers and the magnitude of estimated effects for this proposed rule."

Table 3 in the November 2020 interim final rule described the number of entities, as well as the types of providers and suppliers, that would be most likely impacted by the MFN Model. CMS' projection from Table 3

estimates that OPPS hospitals account for 36.77% of the total MFN drugs with average allowed charges per facility of $4.2 million in 2019, where Medicare was the primary payer. **Trinity Health average allowed charges were $5.6 million, so our financial loss would be greater than CMS' projection.**

Impact on 340B Program

Trinity Health cares for a significant number of vulnerable populations, including low-income patients and those on Medicaid or who are uninsured. The 340B Program provides essential savings critical to helping our eligible hospitals comprehensively serve the most vulnerable and improve the health of communities across the country. Further, the program enables these statutorily eligible Medicaid participating facilities to purchase certain outpatient drugs at discounted prices from manufacturers. Congress created the 340B Program to enable participating entities to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services" and we believe this intent remains relevant today.

In addition to supporting important un-reimbursed and under-reimbursed services for the community, including mental health, cancer and obstetric care, our hospitals use discounts available on certain 340B-priced drugs to provide access to medications that would otherwise be financially infeasible to provide. Any cuts to Medicare Part B payments for 340B drugs challenge our ability to continue to offer these and many other services and programs.

The MFN rule would negatively impact the 340B program. Analysis done by the American Hospital Association found that 340B hospitals would see a net reduction in payment of approximately $15.4 billion over the seven-year demonstration. As the MFN prices fall below the current 340B payment rate of ASP minus 22.5% over the course of the seven-year demonstration, 340B hospitals would be reimbursed at the MFN payment rate instead of the current policy, which will result in payment reductions. In addition to these losses, the MFN rule would likely have an impact on the Average Manufacturer Price (AMP) and “best price” provision within the Medicaid Drug Rebate Program, both of which are critical in determining the 340B ceiling price for a given drug.

Trinity Health urges CMS to ensure the 340B program is not negatively impacted by any future policy.

Conclusion

We appreciate CMS's ongoing efforts to improve payment across the delivery system. If you have any questions on our comments, please feel free to contact me at jennifer.nading@trinity-health.org or 202-909-0390.

Sincerely,

/s/

Jennifer Nading
Director, Medicare and Medicaid Policy and Regulatory Affairs
Trinity Health