



July 14, 2020

By electronic submission via www.regulations.gov

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Washington, DC 20201
Attn: CMS-2842-P

Re: Notice of Proposed Rulemaking for Establishing Minimum Standards in Medicaid State Drug Utilization Review and Supporting Value-Based Purchasing for Drugs Covered in Medicaid (CMS-2842-P)

Dear Administrator Verma:

The Healthcare Leadership Council (HLC) thanks the Department of Health and Human Services (HHS) Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments in response to the June 19, 2020 Notice of Proposed Rulemaking (NPRM) regarding value-based purchasing arrangements between drug manufacturers and payers.

HLC is a coalition of chief executives from all disciplines within American healthcare and the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century system that makes affordable, high-quality care accessible to all Americans. With the move toward a healthcare system based on providing better value, HLC has convened a broad group of organizations beyond its membership that recognize the transformational effect of this shift on the existing legal framework governing U.S. healthcare. In order to better coordinate and deliver patient care, the legal framework must allow appropriate patient-serving care delivery and payment models involving broader collaboration among stakeholders in order to accelerate ongoing improvements in care quality and patient safety while reducing the rate of cost growth.

HLC is appreciative of CMS' proposed changes to encourage greater value-based purchasing arrangements. As the June 202 NPRM details, some of these purchasing arrangements are incompatible with existing manufacturer compliance with the Medicaid Drug Rebate (Medicaid best price).¹ These requirements, drafted three decades ago, do not account for payment arrangements based on outcomes.

Our healthcare payment and delivery system is currently undergoing a sweeping transformation away from the volume-based system in place at the time these regulations were drafted and toward a value-based environment that incentivizes care coordination, effective care management, patient-centered care delivery, and improved patient outcomes. As such, there is an associated need to revisit the legal framework governing healthcare payment and delivery to ensure that it appropriately reflects current and emerging healthcare delivery and reimbursement models while still “ensuring the required economies, efficiencies, and quality of care” provided under federal healthcare programs – and the Medicaid program in particular.² Aligning the legal framework with the modern healthcare system is critical to ensuring that the system functions as efficiently and effectively as possible and supports stakeholder innovation and investment in systemwide improvement. HLC appreciates CMS and HHS’ shared commitment to these goals and willingness to make modifications to the relevant regulations to better reflect the changing healthcare payment and delivery environment.

HLC supports CMS and HHS’ ongoing efforts to better align the existing legal framework governing healthcare with a value-based approach to healthcare payment and delivery. The role and importance of value-based arrangements in facilitating high-quality, efficient, and affordable care cannot be overstated. We applaud efforts to relieve the regulatory burdens in place that have otherwise hampered manufacturer and state attempts at developing innovative pricing agreements that manage the costs of therapies while promoting the best patient outcomes. We also continue to support the implementation of value-based arrangements that include an array of healthcare stakeholders to support, sponsor, and to determine the range of potential benefits to diverse health systems and beneficiaries. Traditional healthcare entities may not have the capability to directly provide necessary services and supports (e.g., services and supports to address social determinants of health such as nutrition, physical activity, social connection, or transportation).

While we do not discuss the specific changes to the regulatory structure governing price reporting in the Medicaid program, we do wish to emphasize that any changes to this structure must be clear, comprehensive, and inclusive if they are to have their desired impact of improving quality and patient outcomes while reducing costs. With respect to inclusivity, we believe that this proposed rule underscores the importance of a flexible legal framework that permits multiple stakeholders to participate in value-based arrangements. The modifications proposed in this rulemaking would permit stakeholders to tie payment to patient outcomes, incentivizing high-quality care and ensuring that all stakeholders have “skin in the game.” While these changes are welcome, we advocate for a robust legal framework that allows all types of stakeholders to participate in these types of value-based arrangements. Where healthcare providers are involved with outcome measurement and reporting, it is critical that such stakeholders are permitted to participate in the value-based arrangements that rely on such data. While not the subject of this comment letter, we note that the Physician Self-Referral (Stark) Law and Anti-Kickback Statute currently present barriers to value-based arrangements; but modernized are key vehicles through which to enable collaboration among these

diverse groups of stakeholders for a variety of value-based arrangements, which could support the specific types of arrangements discussed in this proposed rule. As further changes to the federal legal framework governing healthcare payment and delivery are considered, we offer our enthusiastic support for efforts that remove barriers to value-based care and ensure that all stakeholders and industries are able to collaborate and innovate to provide the best possible care at the greatest possible value.

Thank you in advance for your consideration of the above proposals. Please contact Tina Grande at tgrande@hlc.org or 202-449-3433 with any questions.

Sincerely,

A handwritten signature in cursive script, appearing to read "Mary R. Grealy".

Mary R. Grealy
President

¹ U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services. Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements (“NPRM”), 85 Fed. Reg. 37286, 37291 (June 19, 2020).

² NPRM at 37291 (2020).