January 3, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4205-P
7500 Security Blvd
Baltimore, MD 21244

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

Re: Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications (Docket No. CMS-4205-P)

Dear Administrator Brooks-LaSure:

Premier Inc. appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) regarding the Notice of Proposed Rulemaking (NPRM) on Policy and Technical Changes to the Medicare Advantage (MA) and Medicare Prescription Drug Benefit (Part D) Programs for Contract Year (CY) 2025. The proposed rule seeks public comment on CMS' proposals to ensure timely access to care, protect beneficiaries from predatory marketing practices, strengthen quality, advance health equity, improve access to behavioral health services and improve drug affordability and access in Part D.

Premier appreciates CMS' commitment to enabling access to high-quality, equitable care, as evidenced by the proposed policies in this rule. In our detailed comments below, Premier specifically recommends the following:

- Expand network adequacy data collection and monitoring to ensure beneficiaries' access to care;
- Tighten medical loss ratio (MLR) transparency requirements to strengthen accountability around the use of Medicare premium dollars for medical benefits;
- Finalize the proposal to permit Part D sponsors to treat formulary substitutions of non-interchangeable biosimilars as "maintenance changes" that do not require approval from CMS;
- Support the wider adoption of interoperable health information technologies across the spectrum of care, particularly in long-term care and post-acute care (LTPAC) settings;
- Finalize the new National Council for Prescription Drug Programs (NCPDP) SCRIPT standard 2023011 as the Part D electronic prescribing standard by January 1, 2027 to align electronic prescribing standards with the Office of the National Coordinator for Health Information Technology (ONC) regulations;
- Set the Electronic Prescribing of Controlled Substances (EPCS) implementation date to January 1, 2027 so that it aligns with the overall electronic prescribing date;
- Finalize the adoption of the NCPDP Real-Time Prescription Benefit (RTPB) standard version 13; and
- Finalize the adoption of the NCPDP Formulary and Benefit (F&B) version 60.

I. BACKGROUND ON PREMIER INC.

Premier is a leading healthcare improvement company and national supply chain leader, uniting an alliance of 4,350 hospitals and approximately 300,000 continuum of care providers to transform healthcare. With

integrated data and analytics, collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost. Premier's sophisticated technology systems contain robust data gleaned from nearly half of U.S. hospital discharges, 812 million hospital outpatient and clinic encounters and 131 million physician office visits. Premier is a data-driven organization with a 360-degree view of the supply chain, working with more than 1,300 manufacturers to source the highest quality and most cost-effective products and services. Premier's work is closely aligned with healthcare providers, who drive the product and service contracting decisions using a data driven approach to remove biases in product sourcing and contracting and assure access to the highest quality products. In addition, Premier operates the nation's largest population health collaborative, having worked with more than 200 accountable care organizations (ACOs).

A Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with healthcare providers, manufacturers, distributors, government and other entities to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Headquartered in Charlotte, North Carolina, Premier is passionate about transforming American healthcare.

II. ENSURING NETWORK ADEQUACY IN MEDICARE ADVANTAGE

Premier strongly supports CMS' recent regulatory efforts to protect beneficiaries' access to care. In the CY 2024 MA and Part D final rule, CMS codified new requirements for health plans to prevent inappropriate use of utilization management, ensure clear and accurate marketing and communication to beneficiaries and reaffirm MA organizations' responsibilities to cover behavioral health services. In this CY 2025 MA and Part D proposed rule, CMS aims to further tighten oversight of marketing, communications and broker compensation to protect consumers from purchasing health insurance that does not actually meet their needs.

Proposals to Expand Access to Outpatient Behavioral Health

Under current regulations, there are four behavioral health specialty types that are part of CMS' network adequacy requirements for MA: 1) psychiatry; 2) clinical psychology; 3) clinical social work; and 4) inpatient psychiatric facility services. In the CY 2025 proposed rule, CMS proposes to add to this list a combined "outpatient behavioral health" services specialty type, which includes Marriage and Family Therapists (MFTs) and Mental Health Counselors (MHCs), Opioid Treatment Programs and Community Mental Health Centers, as well as physician assistants, nurse practitioners, clinical nurse specialists, addiction medicine physicians or outpatient mental health and substance use disorder treatment facilities who regularly furnish behavioral health counseling or therapy services. CMS also proposes to add corresponding time and distance standards for Outpatient Behavioral Health services. Further CMS proposes to add Outpatient Behavioral Health to the list of specialty types that will receive a 10 percentage point credit toward the percentage of beneficiaries residing within published time and distance standards if the MA plan's contracted network includes one or more telehealth providers of that specialty type.

These changes are consistent with responses from CMS' January 2022 proposed rule Request for Information emphasizing the importance of expanding network adequacy standards to include other outpatient behavioral health physicians and health professionals that treat substance use disorders. CMS indicates that in future rulemaking, as the landscape of providers changes, CMS may propose separately assessing the provider types that it now proposes under the one facility specialty type of "Outpatient Behavioral Health." ***Premier has long championed full and equitable access to medically necessary behavioral health services, and urges CMS and the Administration to continue to play a leading role in closing significant gaps in treatment access for mental health, substance use and co-occurring disorders.***

Recommendations to Ensure Continued Access and Transparency

Premier has significant concerns about the potential impact of health plan vertical integration on patient access to care. Between 2016 and 2019 alone, the share of medical expenses sent to related businesses by large, national, vertically-integrated payers rose exponentially – increasing more than 500% for one of the largest MA plan sponsors in the country. While obtaining certain types of goods and services through related businesses could improve MA plans' efficiency and reduce overall spending, MA benchmarks and spending have continued to increase year-over-year despite accelerating vertical integration trends among payers.

Premier urges CMS to more stringently monitor and enforce network adequacy and medical loss ratio (MLR) requirements in MA. Specifically, Premier recommends that CMS collect data on payment delays and denials between MA plans and their contracted network of providers. Premier and our members have significant concerns that the increasing frequency or payment delays and denials violate CMS' expectations around network adequacy – while MA plans may claim a contracted network of providers on paper, executing on those contracts and rendering payment and coverage to ensure those contracted networks function is critical to ensuring continued beneficiary access to care. Premier recommends that CMS use the data collected to monitor whether the contracted provider networks that MA plans claim to run are in line with CMS' contractual network adequacy expectations.

Further, Premier is concerned that vertical integration may weaken regulations aimed at reducing the potential for overpayment of MA plans. One important such regulation is the rule governing MA plans' Medical Loss Ratio (MLR), the ratio of plan spending on health care claims to its premium revenues. The Affordable Care Act required MA plans to maintain an MLR of at least 85 percent to improve alignment of medical benefit costs and payments. If a plan repeatedly uses less than 85 percent of premium revenues for health expenses (as opposed to administrative costs or profits), then it could be subject to sanctions. However, plan spending directed to related businesses (such as physician groups and PBMs owned by the payer parent company) is treated as a cost and counted as claims spending when calculating the MLR, even if some of that spending represents profits for the parent company.

The current MLR rules thus give rise to two types of incentives that could cause vertical integration to raise actual or reported MA claims spending. First, payer-owned related businesses (e.g., provider groups) not subject to MLR rules may set the "transfer prices" used to value transactions with MA plans in the same parent company above market-level prices as a means of relaxing the constraint on profits posed by MLR rules. This behavior would increase reported claims spending. Additionally, parent companies may direct their MA plans to purchase goods and services from related businesses to take advantage of this opportunity to circumvent the MLR rules. Shifting spurred solely by efforts to evade MLR rules would likely reduce efficiency and thus increase plans' spending. To address these concerns, ***Premier recommends that CMS require MA plans to be more transparent with reporting the amount of medical benefits spending that is paid to payer-owned related businesses versus contract providers.***

III. FLEXIBILITY TO SUBSTITUTE LOWER COST BIOSIMILAR PRODUCTS FOR THEIR REFERENCE PRODUCTS

The proposed rule would permit Part D sponsors to treat formulary substitutions of non-interchangeable biosimilars as "maintenance changes" that do not require approval from CMS. A maintenance change permits the substitution to apply to all enrollees, including those who have already begun therapy, after a 30-day notice. CMS also proposes that the replacement product must be placed on the same or lower cost-sharing tier as the reference product that it replaces, or the replacement product will be subject to negative formulary changes.

Premier applauds CMS for proposing flexibility to Part D sponsors to treat formulary substitutions of non-interchangeable biosimilars as maintenance changes that do not require approval from CMS.

It has been known for years that biosimilars can improve patient access to medications while saving the US healthcare system billions of dollars, yet anticompetitive practices by vertically-integrated payers have put their own profits ahead of lowering drug costs for patients by favoring the reference biologic and lucrative rebates. Premier has long advocated for CMS to elevate policy proposals to further encourage the adoption of biosimilars, ensure payment policies are fair and unbiased, and put the patient first. Premier agrees with CMS that this policy change would enable Medicare enrollees more timely access to less expensive therapeutically equivalent drugs and support competition in the prescription drug marketplace. Further, the proposal would better align Medicare requirements with state pharmacy practices. For these reasons, ***Premier urges CMS to finalize the policy changes as proposed.***

IV. INVESTMENT NEEDED FOR INTEROPERABLE TECHNOLOGY IN LTPAC SETTINGS

As an overarching theme, which is critical to support CMS' goals of interoperability and the standards being proposed in Medicare Part D, ***Premier urges CMS to support wider adoption of interoperable health information technologies across the healthcare spectrum and particularly in LTPAC settings of care.*** Inequitable access to and use of interoperable health IT persists across the LTPAC continuum. As a result, it is more difficult to broaden data exchange between stakeholders, especially during instances of shared care and transitions of care between hospitals and the LTPAC sector. Unfortunately, the rate of adoption and use of interoperable health IT among LTPAC providers lags far behind acute and ambulatory care providers as programs authorized and funded under the Health Information Technology for Economic Clinical Health (HITECH) Act excluded LTPAC providers. The time is ripe to address technology challenges faced by these sectors so that we can move towards comprehensive bidirectional data exchange, improved patient outcomes, streamlined data collection and reporting, and so much more.

V. STANDARDS FOR ELECTRONIC PRESCRIBING

CMS proposes the adoption of the new National Council for Prescription Drug Programs (NCPDP) SCRIPT standard 2023011 as the Part D electronic prescribing standard on or before January 1, 2027. CMS also proposes to align electronic prescribing standards with the Office of the National Coordinator for Health Information Technology (ONC) regulations to avoid duplication and conflict between CMS and ONC regulations. ***Premier supports the adoption of the new standard to provide effective and efficient communication between pharmacies, payors and patients. Premier also supports the alignment of Part D with the ONC regulations which would enable updates to the standard for both programs at the same time, ensure consistency, and promote alignment for providers, payers, and health IT developers using the same prescription transactions.***

VI. ELECTRONIC PRESCRIBING OF CONTROLLED SUBSTANCES

CMS is proposing technical changes to the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) Act Drug Management programs, including the Electronic Prescribing of Controlled Substances (EPCS) NCPDP Module implementation by January 1, 2025. While the new standard includes functionality that supports a 3-way transaction among prescriber, facility, and pharmacy, which will enable electronic prescribing of controlled substances in long-term care (LTC) settings, Premier is concerned that the implementation timeline of January 1, 2025 does not allow sufficient time for LTC pharmacies to adopt the standard. ***Premier urges CMS to set the EPCS implementation date to January 1, 2027 so that it aligns with the overall electronic prescribing date described above.***

VII. NCPDP REAL-TIME PRESCRIPTION BENEFIT (RTPB) STANDARD VERSION 13

CMS previously required, as of January 1, 2021, Part D sponsors to implement one or more electronic Real-Time Prescription Benefit (RTPB) tools that are capable of integrating with at least one prescriber's electronic prescribing system or electronic health record. At the time of implementation, no single industry RTPB standard was available. With the advent of the NCPDP RTPB standard version 13, CMS proposes to require adoption by January 1, 2027. ***Premier supports the adoption of the NCPDP RTPB standard version 13 to enable patients to access coverage status, coverage restrictions and estimated patient financial responsibility, and information on alternative pharmacies and products.***

VIII. NCPDP FORMULARY AND BENEFIT STANDARD VERSION 60

CMS is proposing to require the use of NCPDP Formulary and Benefit (F&B) standard version 60 and to retire use of NCPDP F&B version 3.0 for transmitting formulary and benefit information between prescribers and Part D sponsors. The proposed deadline for implementation would be January 1, 2027. ***Premier supports the adoption of the NCPDP F&B version 60 which would provide an updated, uniform means for PDP sponsors to communicate plan-level formulary and benefit information to prescribers through electronic prescribing/EHR systems.***

IX. CONCLUSION

In closing, Premier appreciates the opportunity to submit comments on the Notice of Proposed Rulemaking on Policy and Technical Changes to the MA and Part D Programs for CY 2025. Premier looks forward to working with CMS and other stakeholders to develop reforms that meet the agency's goals and are appropriate for beneficiaries and providers. If you have any questions regarding our comments, or if Premier can serve as a resource on these issues to the agency in its policy development, please contact Mason Ingram, Director of Payer Policy, at Mason_Ingram@premierinc.com and Shara Siegel, Senior Director of Government Affairs, at shara_siegel@premierinc.com.

Sincerely,

Soumi Saha, PharmD, JD
Senior Vice President of Government Affairs
Premier Inc.