PREMIER TRANSFORMING HEALTHCARE TOGETHER

April 17, 2020

The Honorable Alex Azar II
Secretary
U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
US Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Additional Flexibilities Needed in Response to COVID-19 Pandemic

Dear Secretary Azar and Administrator Verma:

On behalf of the Premier healthcare alliance serving approximately 4,000 leading hospitals and health systems, hundreds of thousands of clinicians and 175,000 other provider organizations, we appreciate the rapid response of the Department of Health & Human Services (HHS) to the coronavirus pandemic. The advanced and accelerated payments, waivers, areas of enforcement discretion and additional guidance have allowed our members to shift their care practices while remaining financially stable. Below we request you adjust additional policies that will enhance our members ability to respond to COVID-19 pandemic. We also request that you help ensure that the progress that has been made in transforming the healthcare delivery system does not regress toward an emphasis on fee-for-service care. Leading health systems and providers operating in value models were able to rapidly implement strategies to respond to COVID-19, coordinating with local providers, expanding telehealth and diverting care coordinators to help manage patient outcomes. Premier has previously recommended that you consider allowing APMs to opt-in for a year of no reconciliation in 2020 and extending the Next Generation model. We appreciation your consideration of our recommendations.

CARES ACT PROVIDER RELIEF FUND

Premier appreciates HHS' action to quickly distribute the $100 billion of funding in the CARES Act, with the announcement of the immediate delivery of an initial $30 billion. This provides much needed relief to providers operating in Medicare Fee-for-Service (MFS).

Clarification of Terms and Conditions. As providers review the terms and conditions and prepare to attest by April 30, there are a few areas where additional clarification is needed. There are two requirements that reference treatment of possible COVID-19 cases; the requirement that "the recipient provides or provided after January 31, 2020 diagnoses, testing, or care for individuals with possible or actual cases of COVID-19" and "for all care for a possible or actual case of COVID-19, recipient certifies that it will not seek to collect from the patient out-of-pocket expenses in an amount greater than what the patient would have otherwise been required to pay if the care had been provided by an in-network recipient. We request that CMS provide guidance on what is considered a possible COVID-19 case. We do not believe HHS should request attestation of treating possible or confirmed COVID-19 cases as its feasible that some providers did not treat possible COVID-19 cases. For example, a clinician conducting telehealth visits in a region with lower rates of COVID-19 could only see patients requiring ongoing and routine care. As Congress designated this funding for healthcare expenses or lost revenue due to COVID, we do think all providers should be eligible to receive these funds. Finally, we ask that CMS provide sample formats for meeting the quarterly reporting requirements along with what level of detail will be required.

Provider Relief Funds for Long-Term Care Providers. We understand that one priority for the remainder of funding is providers who have a lower share of Medicare FFS payments. **Accordingly, we believe that long-term care pharmacies (LTCPs) should receive funding from the next distribution.** LTCPs deliver medications and oversee medication management for beneficiaries that reside in long-term care facilities (LTCFs) and receive the vast majority of their payments from Part D prescription drug plans and Medicare Advantage drug plans (PDPs/PBMs). In response to COVID-19 LTCPs are incurring additional costs, including but not limited to, additional staff time to gain clearance to enter the LTCF, increased personal protective equipment needs, added staff and administrative time to process and deliver medications and navigate potential drug shortages/supply chain issues, hazard and overtime pay for pharmacy staff and pharmacists, and funding to adhere to increased infection prevention measures. As CMS has recognized, LTCFs "have become an accelerator for the virus because residents, who are generally vulnerable to complications from the virus, are even more so in an enclosed environment like a nursing home."[1] Beneficiaries residing in LTCFs are among the nation's oldest and frailest. Given the average resident utilizes 8–10 prescriptions concurrently, LTCPs play an important role in keeping this patient population healthy and safe.

In order to ensure LTCPs can maintain service levels for beneficiaries residing in LTCFs, **we urge HHS to provide additional payments to cover the added cost of providing these services during the COVID-19 pandemic.** We believe CMS could use existing vehicles to make payments to LTCPs. For example, CMS could develop payments using retroactive data or could develop a payment in real time as claims are processed and paid. To utilize retroactive data, CMS could develop a formula to be paid to the pharmacy for each prescription dispensed to a beneficiary residing in an LTCF based on scripts filled the previous year. Or to utilize real-time data, CMS could use Part D prescription data, which includes a patient location field if the patient resides in a LTCF to make an additional payment to pharmacies each time a claim is processed for a patient in a LTCF.

ACCELERATED AND ADVANCED PAYMENTS

The Coronavirus Aid, Relief, and Economic Security (CARES) Act (H.R. 748) provides additional authority for the Secretary to make changes to the accelerated payment program for hospitals. We are pleased that CMS implemented advanced and accelerated payments for all providers. We request that CMS make three essential changes to the program.

Repayment timeline. As we do not know how long the current public health emergency will last or how long it will take for health systems and other providers to return to normal operations, we believe it may be difficult for providers to begin repaying in four months. CMS should **delay repayment until after the conclusion of the public health emergency and provide up to two years for repayment prior to accruing interest.** As currently structured, it is likely that when repayment begins a provider's claims payment will have to be reduced to 0 percent for the duration of the repayment period in order to fully repay the advanced/accelerated payment. This approach simply delays when health systems and other providers will face significant challenges due to decreased revenue. Extending the repayment timeline will allow providers to have a lower claims offset during the repayment period, mitigating the financial impact during repayment. Under section 553(b)(B) of the APA, the Secretary may waive the requirement to engage in notice and comment rulemaking to change a regulation when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rules issued) that notice and public procedure are impracticable, unnecessary, or contrary to the public interest. In this instance, we believe the COVID-19 public health emergency provides good cause for waiving notice and comment

[1] "Trump Administration Issues Key Recommendations to Nursing Homes, State and Local Governments." April 2, 2020. Accessed at: https://www.cms.gov/newsroom/press-releases/trump-administration-issues-key-recommendations-nursing-homes-state-and-local-governments

rulemaking when doing so will provide immediate relief to hospitals and physicians. **We request that the Secretary use this authority to delay the start of repayments and extend the repayment timeline.**

Establish an Accelerated/Advanced Payment Forgiveness Program. Additionally, we believe that many providers will not be able to fully reconcile their advanced/accelerated payments during the repayment period. We request that HHS use funds provided in the CARES Act or any future funds authorized by Congress for provider response to the coronavirus to reduce or eliminate repayment of the advanced/accelerated payment.

Reduce Interest. An interest rate of 10.25 percent at the conclusion of the repayment period presents another financial hurdle for providers that receive advance/accelerated payments. As we state above, many providers will be unable to fully repay the accelerated/advanced payment in the allowed timeline. We suggest that CMS use its enforcement discretion to waive the collection of interest or set a lower interest rate.

REDUCE PROVIDER BURDEN

Delay implementation timelines. The COVID-19 pandemic has required an unprecedented response from healthcare providers that has left them with limited time or resources to implement new policies. As a result, we request that CMS reduce burden on providers by delaying implementation of the following policies:

- Delay implementation timeline for the recently finalized Hospital Price Transparency rule, which is set to go into effect on January 1, 2021, to give providers more time to prepare for these policy changes.
- Delay implementation of policies applicable to providers in both the CMS Interoperability and Patient Access Final Rule and the ONC 21st Century Cures Act Final Rule.
- Delay implementation of the proposed Medicare survey of 340B hospitals drug acquisition costs.

Additional flexibilities around beneficiary notifications. We appreciate the additional guidance that CMS has provided on existing flexibilities that providers can utilize in meeting beneficiary notification requirements, such as the Medicare Outpatient Observation Notice (MOON). However, even with these existing flexibilities, there may be instances when a provider is unable to furnish the necessary documentation in the required timeframe even over the phone or email due to the COVID-19 pandemic. We request that CMS utilize its enforcement discretion to allow additional flexibility in instances where a provider has made a good faith effort to notify beneficiaries and their representatives but may have been unable to meet all the requirements of the notification during the public health emergency.

Expedite Revisions to 42 CFR Part 2. The recent changes to Part 2 in the CARES Act will greatly help in coordinating care for patients with SUDs. Specifically, Sec. 3221 changes the requirement to a one-time written consent and aligns Part 2 with HIPAA. The CARES Act also directs the Secretary of HHS to revise any pertinent regulations. We encourage HHS to use the SAMHSA guidance suspending the prohibitions on use and disclosure of patient information under Part 2 during the public health emergency as a stepping stone when revising the Part 2 rule. We request HHS to act quickly to update the Part 2 regulations to ensure patients suffering from SUDs do not have a disruption in their care

CLARIFY TELEHEALTH BILLING

Telehealth has been an essential tool for providers in addressing the healthcare needs of Medicare beneficiaries during this public health emergency. We appreciate the broad flexibilities that CMS has

granted to allow providers to expand telehealth services. There are a couple key areas where providers need additional clarity around billing to ensure telehealth can be utilized to its fullest extent during this public health emergency.

While annual wellness visits are eligible to be furnished via telehealth, providers need additional information on how to collect necessary vital sign information, such as weight and blood pressure. For example, clarity is needed on how providers can bill for these services if the provider is unable to collect this information via telehealth or if the information is self-reported by the patient.

Additionally, for many providers, especially institutional providers, this might be the first time that they are billing for telehealth services. Additional guidance is needed on how these providers should bill for telehealth services, especially in instances where these providers may have not historically submitted professional claims. For example, guidance is needed on whether institutional providers can submit claims through a Uniform Billing (UB) form for telehealth services furnished to beneficiaries in their home.

EXPAND ACCESS TO HOME INFUSION SERVICES

CMS should ensure full coverage for infusion therapy so that beneficiaries can receive treatment in their home. The home infusion pharmacy plays a central role in an array of important services inside and outside the home that allows for the safe and effective delivery and maintenance of critical medication therapy to patients in their homes. Unfortunately, CMS adopted a narrow and inappropriate definition of "infusion drug administration calendar day" prior to the COVID-19 pandemic that provides payment only when a skilled professional is present in the patient's home and does not adequately reimburse for all the important pharmacy services that are needed to treat a beneficiary. The decision runs counter to Congressional intent and overlooks those pharmacy services that are critical each day a patient receives medication therapy. Given the COVID-19 pandemic, the need for appropriate reimbursement that builds on the current home infusion structure, which is possible to implement quickly and will improve beneficiary access, is even more pronounced. CMS can do more to ensure home infusion providers can treat vulnerable patients currently in their homes as well as patients in already-burdened institutional settings who can be transitioned home for infusion therapy. Additionally, home infusion providers are incurring new expenses and challenges due to the COVID-19 pandemic and should receive additional payment from CMS to cover these costs to ensure they can remain financially viable so they can continue to serve vulnerable beneficiaries residing in their homes. ***Specifically, we urge CMS to:***

- Allow home infusion therapy suppliers to bill for remote pharmacy services under the transitional home infusion therapy services benefit and provide reimbursement for each day an applicable drug is infused;
- Extend the Part B DME transitional home infusion therapy service codes to Part D infused drugs to pay home infusion pharmacies for each day the drug is infused to beneficiaries in their homes; and
- Provide an additional fee to cover COVOD-19 costs to home infusion pharmacies for each prescription filled for a home infusion beneficiary.

EASE PDP REQUIREMENTS FOR LTCPs

We appreciate that CMS released guidance[2] that prescription drug plans (PDPs) can waive certain requirements; however, this has result in an inconsistent response among PDPs/PBMs. LTCPs still need CMS to insist on a consistent, uniform approach by PDPs/PBMs to address administrative burdens that hinder pharmacies' ability to focus on the patient***. Premier requests that CMS provide additional guidance to PDPs/PBMs to temporarily waive or override point-of-sale edits, specifically including but not limited to prior authorization and formulary interchange edits, for the duration of the COVID-19 crisis.*** CMS implemented override codes during previous natural disasters demonstrating that CMS could act quickly and similarly in this new time of crisis.

- **Prior Authorization.** ***CMS should direct Part D plans (PDPs) to override prior authorization (PA) requirements they place on the prescriber and pharmacy before they will approve payment.*** Temporarily overriding PA requirements will alleviate the strain on prescribers and allow pharmacies to consolidate delivery of prescriptions to nursing homes.
- **Formulary Interchange.** ***CMS should direct PDPs to override formulary interchange policies that require documented justification when a prescriber issues a prescription for a plan's non-preferred drug.*** Formulary interchange requirements are a frequent occurrence for LTCF beneficiaries and lead to the LTCP obtaining a form from the prescriber justifying the use of the non-preferred/non-covered drug before the patient can gain access to their medication.

Finally, ***Premier requests that CMS temporarily waive the short-cycle dispensing Part D requirements that brand name, solid oral drugs be dispensed in increments of no more than 14-day supplies and provide guidance to plans directing them to suspend any policies, practices or procedures that deny coverage based on short-cycle dispensing requirements***. CMS should enact this policy so that less frequent deliveries are made to LTCFs, which appropriately aligns with CMS policies to minimize face-to-face contact during the COVID-19 pandemic.

ADDITIONAL POLICIES

Swing beds. Many hospitals are facing a shortage of available post-acute care facilities, such as skilled nursing facilities, for patients who have tested positive for COVID-19 but no longer require inpatient-level of care. Additionally, some post-acute care providers will not accept patients until they are tested for COVID-19 and receive a negative result, which may take several days. This has left hospitals with few options for discharging patients to other facilities. As a result, additional guidance is needed on how hospitals can utilize and expand swing bed capacity to meet this increased demand.

Lab expansions. Under its Hospitals Without Walls policy, CMS has provided broad flexibilities to allow hospitals to expand their surge capacity, including establishing alternative sites off campus. CMS has provided some guidance on how hospitals can expand laboratory services on the same hospital campus. However, without additional guidance or flexibilities, hospitals must go through the process of obtaining a new Clinical Laboratory Improvement Amendment (CLIA) license to open laboratories at alternative sites, which can cause delays in care delivery. CMS should expand its existing guidance to allow hospitals to expand their existing licensed laboratory operations to alternative sites off-campus.

Graduate Medical Education. CMS has granted several important flexibilities to help hospitals address staffing shortages and increase surge capacity. However, without additional guidance from CMS, these flexibilities could negatively affect a hospital's future graduate medical education (GME) funding. We encourage CMS to hold hospitals harmless for decreases in GME payments that are caused by changes in bed counts or staffing during the public health emergency. For example, when calculating the resident-

[2] https://www.cms.gov/files/document/hpms-memo-covid-information-plans.pdf

to-bed ratio for indirect medical education (IME) payments, CMS should not include beds that were added to increase capacity.

Additionally, CMS should not count residents that are deployed to hospitals as part of the public health emergency towards the establishment of Per-Resident Amount (PRA) cap. Without further clarification or guidance from CMS, a hospital may inadvertently trigger its PRA cap if it were to accept residents to assist with staffing shortages during the pandemic, which may negatively affect the hospitals ability to establish a residency program in the future. CMS should release guidance clarifying that the PRA caps will not be triggered in these instances.

CONCLUSION

In closing, the Premier healthcare alliance appreciates your consideration of our recommendations to enhance providers response to COVID-10. If you have any questions regarding our comments or need more information, please contact Aisha Pittman, Vice President, Policy, at aisha_pittman@premierinc.com or 202.879.8013.

Sincerely,

Blair Childs
Senior Vice President, Public Affairs
Premier healthcare alliance