Trinity Health

September 7, 2021

Laurie Bodenheimer
Associate Director
Healthcare and Insurance
Office of Personnel Management

Douglas W. O'Donnell
Deputy Commissioner for Services and Enforcement
Internal Revenue Service

Mark J. Mazur
Acting Assistant Secretary of the Treasury (Tax Policy)

Ali Khawar
Assistant Secretary
Employee Benefits Security Administration
Department of Labor

Xavier Becerra
Secretary
Department of Health and Human Services

Re: CMS-9909-IFC; Requirements Related to Surprise Billing

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

Dear Ms. Bodenheimer and Mr. O'Donnell, Mr. Mazur, Mr. Khawar and Mr. Becerra,

Trinity Health appreciates the opportunity to comment on surprise billing policies set forth in CMS-9909-IFC. Our comments and recommendations 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 strongly supports protecting patients from surprise medical bills that result from gaps in their insurance coverage. In our comments below, we urge the departments to modify certain provisions of the rule that would create significant financial incentives for insurers and impact access to patients without any guarantee savings are passed on to consumers. In addition, the No Surprises Act is a large piece of legislation with a number of different, independent policies. Hospitals and health systems, for example, will need substantial lead time to educate staff on the new requirements, adjust work flows to account for different patient communications, and develop processes for new information sharing with plans and issuers. We ask the Departments to ensure sufficient time for all stakeholders to implement the various components and ensure adequate and comprehensive guidance.

Post stabilization Services

Services provided to a patient post-stabilization are subject to the balance billing protections outlined in the rule until the point of discharge, transfer, or consent by the patient to be balance billed. While providers—in coordination with the patient or authorized representative—have the sole responsibility for determine whether a patient is stable, we have experience with plans creating barriers for transfers or leveraging their desire to access our electronic health records (EHRs) in order to approve transfers. Such access is a privacy and security risk for patients. In addition, plans will wait days before responding to request to transfer during which a patient's condition could deteriorate and the out-of-network hospital must resume care for the patient **Trinity Health urges the Departments to clarify in the rule that plans must engage in a timely manner and cannot delay funding, authorizing an in-network placement or put conditions on transfers. In return, providers must give plans enough information to make decisions on the transfer without needing to open the door to their EHRs.**

Notice and Consent: Process Requirements

The law permits patients to waive balance billing protections if the out-of-network (OON) provider obtains the patient's consent in two narrowly prescribed circumstances: 1) post-stabilization, and 2) certain scheduled services provided by an out-of-network provider at an in-network facility.

The statute's notice requirements include information regarding care limitations such as prior authorization. The Departments have strongly urged the inclusion of specific information regarding the patient's health plan policies on care limitations. Alternatively, the Departments allow for a general default statement that informs the patient that such limitations may apply. **Trinity Health supports the adoption of a simple default statement, as this would minimize the risk of inadvertent errors and reduce the administrative burden of attempting to collect this information.**

The regulations also require alerting the plan that the notice and consent process was used and to share the signed consent form with the plan. There is no standard electronic transaction for this exchange of information at this time. **Trinity Health recommends allowing providers to notify plans on claims to minimize burden. In addition, plans should include language on patients' explanation of benefits (EOB) that**

patients owe what they have agreed to per their consent to pay for services by the out of network provider.

For post stabilization patients at in-network facilities for which consent is being sought, the notice must include a list of in-network providers at the facility that are able to furnish the services. Providers will need to either rely on the plan's provider directory or contact the plan directly to obtain information on alternative in-network providers. This process will be significantly burdensome for providers and will not guarantee accurate information. Further, this process could result in providers giving inaccurate information related to nuances in coverage rules. For example, some insurers are currently restricting coverage for certain services at in-network facilities (e.g., surgeries at hospital outpatient departments). The facility will appear in-network in the directory, but the coverage rules deny coverage for most services at those providers. **For these reasons, Trinity Health disagrees with the onus of this requirement being placed on providers. Instead, the form should direct the patient to their health plan to identify an alternative. In addition, similar to pre-operation services, plans should be required to have a 24/7 customer service available for patients or providers. In addition, regulations should ensure plans cannot use expanded and inappropriate definitions of medical necessity to include site of care and financial considerations as a reason to deny medically necessary care in a hospital setting.**

The regulations require that facilities and providers alert the patient's health plan or issuer when the notice and consent process has been used, as well as share the signed consent form so the health plan or issuer can accurately calculate the patient's cost-sharing. However, neither the regulations nor the separately issued standard form provide any guidance on how the signed notice nor consent documents should be transmitted to the plan. **Because there is currently no standard electronic transaction for this exchange of information, Trinity Health recommends CMS adopt a standard process to ensure consistency and minimize the burden of alternate forms of transmission, such as faxing paper copies or use of health plans' and issuers' unique, proprietary portals prior to implementation. In addition, CMS should expedite the adoption of standard electronic transactions for the exchange of this information between the provider, facility and plan, and that the agency modify the standard form to reflect these transaction standards.**

The Department of Health and Human Services has developed a standard notice and consent form which requires good faith estimates of OON costs and information if the patient faces care limitations such as prior authorization. The notice and consent must be provided separately from other documents and staff must be present or available to answer questions. In addition, providers and facilities must notify health plans when balance billing protections have been waived**. These new responsibilities will require significant changes in information systems, patient processes, staffing and provider management–all of which introduce significant administrative burden. Trinity Health supports the Department's announcement through the FAQs released August 20 delaying enforcement of good faith estimates for insured patients until after future rulemaking. Trinity Health recommends the Departments delay implementation of these tasks to January 2023.**

In addition, CMS should convene a provider advisory group to better understand the operational challenges to the notice and consent process and public disclosure requirements. As outlined above, the notice and consent process will require changes to information systems, management processes, and provider relations. Such an advisory group should examine the ongoing operational challenges, as well as

explore how the notice and consent information could be shared with patients and transmitted to payers in the least burdensome way.

Initial Provider Payment

The regulations establish requirements regarding health plans' initial payment (or notice of denial) to providers. Health plans have 30 calendar days to make an initial payment or issue a notice of denial. The 30-day window begins when the health plan determines it has received a "clean claim."

Plans already abuse "clean claim" requirements to delay payments to providers—the retroactive review and denial of payment for ED visits that the proposed rule rebukes and indicates is inconsistent with regulation is just one example. Denials of claims is prevalent across all payers and has been increasing over time. These denied claims result in delayed payment, unnecessary patient debt, increased administrative burden and added waste to the nation's health care system. Administrative burden associated with denials increases cost for Trinity Health by $15 million each month. From our data:

- 8-10% of total hospital encounters incur a payer denial on first submission.
- Denials for subsequent claim submissions and secondary payor submissions consistently range 12-15% for all encounters.
- 80-95% of denied claims are undertaken with a corrective action to respond and resolve, including re-submission, correction, or appeal efforts—highlighting concerns that patients and providers were initially denied services and payments that should have been provided.
- Attempting to overturn clinical denials through the arduous appeal process is successful 55-65% of the time yet creates increased burden that often includes engaging physician involvement for peer-to-peer reviews.

While we encounter these issues with both commercial and Medicare Advantage (MA) payers, the 2018 study[1] by the Government Accountability Office (GAO) flagged widespread and consistent problems related to denials of care and payment in MA and recommended that CMS take a number of steps to stop the inappropriate denials. **We urge the Departments to implement GAO recommendations and do a similar study for commercial plans.**

Examples of plan abuse to reduce or delay payment to providers include:

- Adopting the Sepsis 3 criteria to recode DRG classifications and reducing reimbursement to providers which is inconsistent with the CMS quality measure and denies reimbursement for services provided to treat early stage sepsis treatment.
- Extending the definition of medical necessity to include location or place of service and financial considerations with the argument that services did not need to be performed in certain types of facilities—thus interfering with the ability of providers who are actually providing direct care to the patient to determine what is appropriate treatment and care.
- Implementing policies contrary to EMTALA by denying payment when patient presents to ED for certain conditions.

Trinity Health urges oversight of timeframes from initial claim submission to final payment, which should include investigations of plans with patterns of long delays. In addition, the Departments ask whether they should establish a minimum payment amount. **We urge the Departments to not set a minimum standard benchmark payment amount as Congress chose not to and this amount would**

[1] Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials, 2018, Report (OEI-09-16-00410), https://oig.hhs.gov/oei/reports/oei-09-16-00410.asp

become the de facto benchmark—there is no approach to establishing a minimum payment amount that would result in fair and appropriate reimbursement in all instances.

Qualified Payment Amount (QPA)
The QPA will be used to calculate patient cost-sharing (except in instances where billed charges are less than the QPA) and to act as one of the factors for consideration by the arbiter in the independent dispute resolution process (which has not yet been established in regulation). The statute defines the QPA as the issuer's median in-network rate for 2019 trended forward and directs the Secretary of HHS to develop a methodology for calculating the QPA.

Trinity Health strongly believes the QPA is not an appropriate starting point for reimbursement for out-of-network care, as it is outlined in the rule. Given that the QPA will likely be substantially below a commercially reasonable rate, **we urge the Departments not to weigh the QPA in the Independent Dispute Resolution (IDR) process and clarify that the QPA is not to be used by plans and issuers as the initial payment rate unless both the plan or the issuer and the provider of facility agree to it through negotiation.** In addition, the regulations are drafted in a way that drives the QPA down. **We recognize the value in that for purposes of patient cost-sharing, though we urge the Departments to clarify that the QPA is not intended to be used as the initial payment from the plan to providers.**

Plans must provide a statement that the QPA was calculated consistent with regulations; however, they are not required to give providers meaningful information on how the QPA was calculated. As drafted, the regulation provides no way for providers—or the Departments—to know if plans truly calculated the QPA in accordance with the regulation. **Trinity Health urges the Departments to require plans share the data used to calculate the QPA with providers at the time the QPA is conveyed to the provider and conduct frequent oversight of the plan's calculation of QPA. Further, regulations must clearly state health plans are responsible for any consequences resulting from inaccurate calculations of the QPA, including making patients whole for any excess cost sharing, and the IDR process must have a mechanism for revisiting decisions that took into account a QPA that was later found to be inaccurately calculated. In addition, we urge the Departments to delay implementation of these provisions until regulations establishing the IDR process have been released.**

Interaction with State Law
The regulations state that these provisions apply to all forms of commercial coverage except in instances where states have surprise medical billing protections in place for state-regulated plans. In those instances, the state law and processes would apply.

The interaction between federal requirements and state law is very complicated. **Given the importance, we recommend the Departments clarify when state law applies and provide more examples in the final rule. In addition, the Departments need to work with the National Conference of State legislatures, the National Governors Association, and the National Association of Insurance Commissioners to develop guidance on the interaction between federal and state laws, including a cross-walk of state law and the federal provisions. Until these interactions are clear, we urge enforcement discretion on questions about jurisdiction between state and federal laws. In addition, we recommend CMS work with states to ensure that state law cannot include provisions that would lead to providers not receiving any payment for out of network emergency services, as patients should have freedom of choice in an emergency.**

In addition, it will be incredibly burdensome for providers to have to track different state laws and identify which applies for which patients---we don't know if a patient is on an insured plan or an ERISA plan. **Trinity Health urges the Departments to require plans to inform providers which applies for a particular patient and whether the ERISA plan has opted into requirements. We strongly suggest plans be**

required to furnish this information during eligiblity transactions as a new data point and keep track of this information on a continuing basis.

Oversight Complaint Process
The regulations establish a single process through which the departments can collectively receive complaints about potential violations of all of the consumer protection and balance billing requirements. This process will apply to health plans, providers, facilities, and providers of air ambulance services.

Trinity Health is concerned the proposed oversight mechanisms will not be able to monitor plan behavior. **We urge the Departments to develop an oversight mechanism that will allow providers to file complaints regarding health plan abuses of these provisions. In addition, the Departments will need to identify a way to filter complaints as there may be complaints that are unrelated to surprise billing protections.**

The Departments ask whether there should be a statute of limitations whether there should be a statute of limitations on the timeframe for submitting complaints. **Given record keeping requirements, Trinity Health recommends a statute of limitations of 3 years.**

Conclusion
Trinity Health strongly supports protecting patients from unexpected medical bills and we are available to discuss our comments. If you have any questions, 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