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September 7, 2021

Xavier Becerra, Secretary
Department of Health and Human Services
Attention: CMS–9909-IFC
P.O. Box 8016
Baltimore, MD 21244–8016

RE: CMS–9909–IFC - Requirements Related to Surprise Billing; Part I; published at Vol. 86, No. 131 Federal Register 36872-36985 on July 13, 2021

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

Dear Secretary Becerra,

UnityPoint Health appreciates this opportunity to provide comments on this Interim Final rule with request for Comments (IFC) related to Surprise Billing, Part I. UnityPoint Health is one of the nation's most integrated healthcare systems. Through more than 33,000 employees and our relationships with more than 480 physician clinics, 40 hospitals in urban and rural communities and 14 home health agencies throughout our 9 regions, UnityPoint Health provides care throughout Iowa, central Illinois and southern Wisconsin. On an annual basis, UnityPoint Health hospitals, clinics and home health provide a full range of coordinated care to patients and families through more than 8.4 million patient visits.

In addition, UnityPoint Health is committed to payment reform and is actively engaged in numerous initiatives which support population health and value-based care. UnityPoint Accountable Care is the ACO affiliated with UnityPoint Health and has value-based contracts with multiple payers, including Medicare. UnityPoint Accountable Care is a current Next Generation ACO, and it contains providers that have participated in the Medicare Shared Savings Program (MSSP) as well as providers from the Pioneer ACO Model. UnityPoint Health also participates in a Medicare Advantage provider-sponsored health plan through HealthPartners UnityPoint Health.

UnityPoint Health appreciates the time and effort of the Office of Personnel Management; the Internal Revenue Service, Department of the Treasury; the Employee Benefits Security Administration, Department of Labor; and the Centers for Medicare & Medicaid Services, Department of Health and Human Services in developing this IFC. As a member of the American Hospital Association (AHA) and the Healthcare Financial Management Association (HFMA), we are generally supportive of comment letters

submitted by those organizations. In addition, UnityPoint Health has reviewed this IFC and respectfully offers the following comments:

OVERVIEW

Surprise medical billing describes a situation when an insured patient unknowingly receives care from an out-of-network provider and then is presented with a bill for services and payment obligation beyond what the patient's insurer will cover. Under the IFC, group health plans and insurers and providers (including hospitals, facilities, individual practitioners and air ambulance providers) are prohibited from billing patients more than in-network cost-sharing amounts in specified circumstances. The prohibition applies to both emergency care and certain non-emergency situations where patients do not have the ability to choose an in-network provider.

Comment: UnityPoint Health believes the intent of the IFC is appropriate. This should be a consumer-facing rule granting consumer protections for patients seeking emergency care. Ultimately it is the payers who hold the contractual relationship with patient and determine whether providers are in or out of network for a particular health plan. We support, and payers should: (1) Disclose to nonparticipating providers the Qualifying Payment Amount (QPA) for each item or service and provide additional information upon request; (2) act timely in issuing initial payment or notice of denial of payment; and (3) Not limit emergency services coverage based on the final diagnosis code alone or general policy exclusions. Although we are supportive of the spirit of the IFC, this rule does shift a significant number of administrative duties and burdens to hospitals and providers, some of which may be avoided or lessened.

Given the breadth of the IFC (including the CMS phased approach with releasing companion rules), **UnityPoint Health requests that CMS delay implementation no earlier than January 1, 2023.** The current year end date poses the following challenges:

- Short turn-around time to operationalize. While CMS-9909-IFC was released on July 1 with a short comment period, CMS has signaled that the notice and comment periods for the audit process rule will begin in October and the independent dispute resolution (IDR) rule will begin late December. Without understanding the complete regulatory picture, it is not only difficult to appropriately comment on the impact of the underlying IFC, but it hampers the ability of organizations (both payers and providers alike) to institute relevant policy and procedures, embed workflows, and train staff – not to mention hiring vendors to create health information technology solutions.
- Rule complexity and unknowns. The underlying IFC itself is complex and has numerous uncertainties that will be difficult to operationalize by the end of the calendar year. For instance, EHRs will need to be revised to standardized bill claims forms to indicate whether surprise billing protections apply. Likewise, EHRs will need to contain the signed notice and consent forms as well as software builds to assure this information was requested. Another area of time and effort concern are workflows generally and HIT applications for exceptions, such as those for pain management services.
- National pandemic and health care workforce shortage. As a health care provider, the timing for the IFC rule adds another stressor to a health care workforce that is overburdened and in the midst of the national pandemic. At the time of this letter, UnityPoint Health is experiencing a

significant upswing in the number of hospitalized COVID-19 patients due to the Delta variant, and we have upwards of 1,500 position vacancies across our three-state footprint. Time spent to operationalize the IFC diverts resources from direct patient care.

- Other federal rules. This IFC added to a cadre of other CMS regulations. As mentioned, CMS has still to release No Surprises rules on IDR, patient-provider dispute resolution, and the price comparison tools. All regulations will require similar yet different work effort, HIT builds, and training. Outside of surprise billing, hospitals are responsible for price transparency and 21st Century Cures information blocking rules. Aside from our providers in emergency medicine and hospitalists, many of the same Revenue Cycle, IT, Compliance, Legal, and Patient Experience personnel are tapped to implement each of these.

As an integrated health system, we would suggest that the above concerns are magnified for independent providers (in network or out of network) that practice at our facilities. It is our impression that many independent providers are unaware of this (and other rules) and that the growing regulatory burden in health care will further strain our condensed workforce. **We urge CMS to engage in an outreach campaign targeting individual providers.** We do not agree that hospitals/facilities should be responsible for provider outreach.

Finally, as a consumer protection initiative, this complex process does not necessarily support an improved patient care experience. **While UnityPoint Health supports guardrails on surprise billing, the process to achieve this should not negatively impact patient experience nor detract health care resources from care delivery.** As proposed, providers seeking reimbursement for services provided are charged with identifying the contractual relationship between payers and consumers. The IFC does simplify the determination of how patients will be treated – whether coverage exists, and which providers (facilities, individual providers, services) are in or out of network. UnityPoint Health supports a process to assure the sustainability of access to emergency services maintained through adequate payment.

QUALIFYING PAYMENT AMOUNT (QPA)

Th IFC establishes the methodology for calculating the QPA, including further defining the similar items and services, providers and facilities, and geographic regions that will be used for calculating a median rate, and the methodology for arranging contracted rates to determine a median amount. The IFC adds new methodologies for calculating the QPA for air ambulance and anesthesia services.

Comment: UnityPoint Health urges CMS to simplify the IFC. Under the IFC, QPA is generally the median contracted rate recognized by the plan as provided in 2019 for the same or similar item or service by a similar provider in the same geographic region. This calculation is complex, and results will be multilayered as bounded by item/service, provider, and geographic area within a plan. From an operational perspective and to improve transparency, we would recommend that CMS require payers to develop and post QPA schedules in advance of the CY. Advance posting will streamline this process and enable timely response.

In terms of the calculation itself, UnityPoint Health would alternatively suggest that CMS consider a standard rate based on a mark-up from Medicare rates. The establishment of a fee schedule would promote clarity and simplicity over the administratively burdensome QPA formula being proposed. As proposed, we do not support a QPA based on average contracted rates, as these do not reflect payment and actualized reimbursement. This approach does not adequately capture the true cost of care and may

place too strong an emphasis on contracted rates that are agreed to based on a wide range of factors. A reliance on contracted rates falsely assumes that rates for individual services have been specifically negotiated, when instead providers negotiating contracts more holistically. For instance, QPA calculations may be inflated for services when providers accept certain contract rates without negotiation for services they do not frequently or ever perform. Conversely, QPA calculations may be undervalued for contracted rates that take value-based arrangements and other quality payments into consideration. While a payer, upon request, must provide a statement that the payer's contracted rates include risk-sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments for the items and services involved that were excluded for purposes of calculating the QPA, this statement does not improve the accuracy of the QPA and may even dissuade providers from engaging in value-based arrangements.

The IFC squarely places the burden on providers to review, monitor, and audit the QPA calculation for numerous plan contracts, yet it will be difficult for providers to ascertain payer compliance from the limited information that providers may request. Providers will not have insight into the payers' calculation itself to confirm it is applied appropriately. Although we appreciate that payers must provide limited additional information, we are concerned that CMS is abdicating its regulatory compliance function to providers without adequate information or tools.

While the above includes some initial feedback on the proposed QPA calculation, **we would reserve other comments on QPA pending CMS's release of the independent dispute resolution (IDR) process**. The foreshadowed IDR process will require providers to add staff to track and administer this work, and we believe that CMS has underestimated the ongoing costs.

EMERGENCY SERVICES AND POST-STABILIZATION SERVICES

The IFC broadens the definitions of emergency services and emergency medical conditions and prevents payers from limiting coverage based on the final diagnosis code alone or general policy exclusions.

Comment: UnityPoint Health applauds the CMS directive that prevents payers from limiting coverage based on the final diagnosis code alone or general policy exclusions. This coverage limitation was being considered by some commercial payers for emergency room encounters earlier this summer, and we believe this action would have circumvented the intent of the No Surprises Act.

Generally, **UnityPoint Health does not support the inclusion of post-stabilization services (PSS) within the IFC**. Under Emergency Medical Treatment & Labor Act (EMTALA), participating hospitals must provide a medical screening examination, stabilize patients with an emergency medical condition, and transfer or accept appropriate patients as needed. While a "no surprise billing" restriction targeting emergency services appears to align with EMTALA practices, PSS blurs emergency and outpatient services and requires patient attestations that create unnecessary complexity and confusion. From a patient perspective, this adds another documentation request and more administrative burden to a situation where patients commonly express form/documentation fatigue. Once a patient is able to be discharged, requesting PPS attestations will likely create confusion between emergency services already provided and scope of future post-stabilization services. In terms of the proposed notice itself, we request CMS to develop talking points as it will be an uphill battle to convince patients to sign a document that indicates their agreement to pay more than they would otherwise be obligated to pay for these services.

We also have operational concerns related to PSS as this drastically changes the scope of QPA and

notices/disclosures. We interpret the IFC to prohibit a provider from balance billing a post-stabilization patient in instances where the patient both declines to be transferred and declines consent to be balance billed. If this is the correct interpretation, we request that CMS clarify the process by which hospitals and providers will be reimbursed for PSS. In addition, we urge CMS to provide more guidance related to the circumstances under which this applies or does not apply. For instance, how is "reasonable travel distance" defined? This will differ depending upon geographic area as availability of service providers. We also seek clarity as to whether PSS requirements supersede existing health plan coverage for out-of-network services.

METHODOLOGY FOR DETERMINING COST SHARING

The IFC clarifies that consumers' cost sharing will be based on an all-payer model agreement amount. If this amount is not available, cost sharing will be determined by existing state law, then by the lessor of the billed charge or the Qualifying Payment Amount (QPA).

Comment: While **UnityPoint Health appreciates that consumers/patients should not receive surprise bills for emergency services reasonably anticipated to be in-network**, we are not convinced that the IFC strike the correct balance.

PAYER DISCLOSURES: SURPRISE BILLING REQUIREMENTS AND QUALIFYING PAYMENT AMOUNT

The IFC requires payers to disclose to nonparticipating providers the Qualifying Payment Amount (QPA) for each item or service involved and, upon request, information regarding whether the QPA was based on an underlying fee schedule or derived amount, any alternative service codes or eligible databases, and whether any contracted rates were not set on a fee-for-service basis.

Comment: UnityPoint Health agrees that this disclosure requirement is the sole responsibility of the payer and not hospitals. We support the requirement that the payer must disclose to nonparticipating providers the QPA for each item or service. In addition, we support that providers may also request information from payers about the QPA calculation. It is crucial that payer responses contain sufficient detail for providers to effectively evaluate rates. We encourage CMS to consider providing further guidance for providers on what constitutes sufficient detail within responses related to market, contracted rates in order of utilization, and the specific procedures/coding used to generate the rates. If CMS requires advanced publication (as suggested in our narrative under "Qualifying Payment Amount (QPA)", CMS may also want to consider having the payer proactively address these issues in that posting.

INITIAL PAYMENT AND NOTICE OF DENIAL OF PAYMENT

The IFC requires payers to act in a timely fashion in issuing an initial payment or notice of denial of payment. The initial payment must reflect what the payer considers to be payment in full. The notice of denial of payment does not include denials due to adverse benefit determinations.

Comment: UnityPoint Health supports the requirement for payers to act timely in issuing initial payment or notice of denial of payment. We would suggest that CMS consider providing guidance related to what constitutes a timely based on "clean claim" and that the initial payment should represent payment in full. If CMS were to establish a minimum rate, for simplicity we would suggest that CMS consider a multiplier based on Medicare rates.

PROCESSES FOR RECEIVING CONSUMER COMPLAINTS

The IFC begins to outline the consumer complaint processes for reporting payer and provider violations and notes that these processes may be expanded.

Comments: The IFC leaves many questions unanswered. It is unclear how consumers may go through the process of filing a complaint, whether consumers will be notified of the investigation results, how long it will take to conduct and conclude an investigation, and what consequences may arise if a payer or provider is found to have violated the Act. With a focus on consumer complaints, it is also unclear if CMS intends to include both payers and providers within a "universal" complaint system. Although the IFC references that payers may submit complaints against providers, it does not address whether providers may use the system to submit complaints against payers. **These details are crucial for operationalizing this IFC, and further supports our request for CMS to delay implementation until January 1, 2023.**

CMS has proposed time limit for document retention, and based on this, **UnityPoint Health supports CMS implementing a time limit for consumer complaints.** We await future rulemaking that details the complaint process generally before providing further input.

PROVIDER NOTICE AND CONSENT

The IFC establishes the content, language, and timing standards related to notice and consent forms and how these forms must be delivered. There was no expansion of exceptions to providing notice and consent.

Comment: UnityPoint Health believes that this process raises more questions than answers, and we strongly echo the feedback of the American Hospital Association on this requirement. In addition, UnityPoint Health would highlight the following:

- Content. CMS has issued a model disclosure notice in English that providers and facilities may use to post on websites and provide enrollees. Despite providing this "model disclosure," CMS encourages providers to use plain language for the notices. It seems odd that CMS would not provide a model form in plain language and prioritizing health literacy. Before publishing, we request that CMS revisit and revise any model forms for plain language and health literacy concerns so that providers are not saddled with this additional duty and expense.

  For the post stabilization services form, it indicates that a provider may refuse to treat. This seems at odds with the substantive requirements. As we stated in our response under *Emergency Services and Post-Stabilization Services* narrative, we interpret the IFC to prohibit a provider from balance billing a post-stabilization patient in instances where the patient both declines to be transferred and declines consent to be balance billed. We request that CMS revisit this form and provide clarification as to when this statement is applicable.
- Language. The IFC requires the notice and consent be available in 15 languages. We are puzzled that CMS would choose to require a specific number of languages, rather than enabling each provider to target prevalent languages in their service area. For instance, the 510(R) requirement refers to forms in languages that cover 95 percent of primary and secondary areas. We urge consistency among language diversity, equity, and inclusion requirements. Also, we urge CMS to develop and provide these preprinted forms on a website that is electronically downloadable. It would be more cost effective and process efficient for CMS to standardized forms and make them readily available to all providers instead of having providers individually incur this time and

expense to assure forms are translated accurately.

- Format: As proposed, the disclosure for individuals who are enrollees of a health plan offered by a health insurance issuer must be only one page, in font no smaller than 12 point, and may be provided through mail or email as selected by the enrollee. Providers must provide this disclosure to the patient at the time payment is requested (e.g. financial clearance, point of service payment) or, if no payment is requested in advance, provide this disclosure to the patient no later than when the provide submits the claim to the payer/issuer. Not only will providers need to revise workflows to accommodate this disclosure requirement, but the disclosure documentation will necessitate an EHR build for a field to reflect the date/time provided.
- Timing. The pre-72-hour and post-72-hour timeframes seem arbitrary and lack flexibility needed to implement this on a timely basis. These requirements are going to force providers to staff this requirement seven days a week and create artificial deadlines. For instance, for procedures that are scheduled at least 72 hours in advance, this would create expedited documentation turn-around of less than 24 hours for procedures scheduled four days (96-72 hours) in advance. If a procedure was scheduled 75 hours in advance, this would require a three-hour window to produce and provide a disclosure, which may be less than the same-day window for less than the 72-hour timeframe. Windows less than 24 hours are challenging, assume that the information needed for the disclosures are readily available, do not consider volume of and need for services, and do not account for face-to-face requests versus electronic/remote requests.
- Exceptions. While CMS has provided particular special rules for air ambulance and services and anesthesia services, there is not a specific exception for pain management services. We are uncertain whether this omission signals a deliberate exception and request that CMS clarify whether the notice and consent requirements apply to pain management.

ALL-PAYER CLAIMS DATABASES & DEFAULT DATABASES

The IFC provides states wide discretion in implementing All-Payer Claims Databases. These databases will be considered categorically eligible to serve as a resource for calculating the Qualifying Payment Amount.

Comment: UnityPoint Health has historically been supportive of all-payer claims databases. Comprehensive information on disease incidence, treatment costs and health outcomes is essential for informing and evaluating state health policies and population health initiatives, but it is not readily available. Some states have adopted legislation that requires all-payor databases to collect and make available unidentified patient data to government and providers through a centralized database. For example, Minnesota has enacted a system that securely collects medical claims, pharmacy claims, and eligibility and provider files from all private and public payors. The system enables data analytics to be performed by authorized users that can show health and cost trends by location of service, variations in service lines, quality and costs, information on chronic health conditions, and cost transparency.

UnityPoint Health finds value in all-payer databases that would collect information from all private and public payors to promote transparency and increase the quality of health care provided to the patients we serve. If such a database could be used to provide more visibility and accountability for Qualifying Payment Amount calculations, this would just be another reason to urge states to implement these databases.

DEFINITIONS

The IFC proposes to define key terms that are specific to the requirements and implementation of the IFC.

Comment: UnityPoint Health is concerned that CMS is choosing to maintain separate key terms shared with EMTALA but with different definitions. **We urge CMS review the No Surprises definitions and utilize existing EMTALA definitions when appropriate.**

The IFC defines payers as both "group health plan or plan" and "health insurance issuer or issuer" in reference to 5 U.S.C. 8901. We would request that CMS clarify that these definitions exclude Christian Healthcare Ministries, which effectively remove Christian Healthcare Ministries from complying with the IFC.

We are pleased to provide input on this IFC and its impact on our health system, our patients and communities served. To discuss our comments or for additional information on any of the addressed topics, please contact Cathy Simmons, Executive Director, Government & External Affairs at cathy.simmons@unitypoint.org or 319-361-2336.

Sincerely,

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