September 7, 2021

Sent electronically

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Janet Yellen
Secretary
U.S. Department of the Treasury
1500 Pennsylvania Avenue, NW
Washington, DC 20220

The Honorable Martin Walsh
Secretary
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

Subject: CMS-9909-IFC, Requirements Related to Surprise Billing; Part I; Interim Final Rule with Comment Period, Federal Register (Vol. 86, No. 131), July 13, 2021

Dear Secretaries Becerra, Yellen, and Walsh:

On behalf of our more than 400 member hospitals and health systems, the California Hospital Association (CHA) greatly appreciates the work the Departments of Health and Human Services (HHS), Labor, and Treasury (hereafter, tri-agencies) have done to protect patients when they receive care from out-of-network facilities in emergencies or from out-of-network providers at in-network facilities by developing regulations implementing the "No Surprises Act". We look forward to partnering with the tri-agencies and health plans to implement the No Surprises Act and realize our mutually long-held goal of removing patients from billing disputes that arise when care is provided in situations covered under the No Surprises Act.

Achieving the law's goal of protecting patients from surprise bills in covered situations requires the tri-agencies to make numerous technical decisions in a short period of time. CHA appreciates the

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opportunity to collaborate with the tri-agencies to help develop regulations that create a transparent process for resolving out-of-network bills in covered situations that protects patients financially and ensures their continued access to broad health plan networks. We greatly appreciate that the tri-agencies have clarified and reiterated the patient protections of "prudent layperson standard" when patients seek emergency care in the Interim Final Rule (IFR).

CHA supports efforts to reduce patients' out-of-pocket costs for health care. However, given the lack of detail about how the qualifying payment amount (QPA) will be used in the independent dispute resolution (IDR) process, we are concerned that the IFR — contrary to Congressional intent — explicitly attempts to drive down the QPA. This may financially benefit some patients who receive care under scenarios covered by the No Surprises Act in the short run. However, for the long term, CHA is deeply concerned the tri-agencies' efforts to reduce the QPA will ultimately induce health plans to narrow their networks and reduce commercially insured patients' access to in-network facilities and providers for non-emergent services[1]. While the extent of the QPA's role in the IDR process remains to be defined, it will play a significant role in ultimately determining the amount out-of-network health plans pay providers and facilities. And given that the QPA is a median, it creates a perverse incentive for health plans to exclude from their networks facilities and providers whose contracted rates are above the median. Unfortunately, CHA believes that the following provisions within the IFR exacerbate the risk of plans narrowing their networks to benefit financially from an artificially reduced QPA at the expense of reducing consumer access to care:

1) *QPA Calculation*: The QPA plays two key roles in the No Surprises Act. It will be used both to determine the patient's cost-sharing in qualifying out-of-network situations and as a factor that will be evaluated in the IDR process when out-of-network plans and facilities or providers cannot agree on payment for lifesaving services provided to a patient. Instead of calculating the QPA in a neutral manner, the IFR advantages plans in multiple ways. This includes:

    a. Failing to account for previous contracted relationships between plans and facilities or providers when determining the QPA
    b. Excluding — inappropriately — some contracted rates in the calculation of the QPA
    c. Failing to adequately account for different types of facilities
    d. Providing an inadequate inflationary update mechanism to adjust the median payment rate from the baseline year

    While the IFR places transparency requirements on health plans related to the calculation of the QPA, these are minimal and wholly inadequate for facilities and providers to determine if the median payment rate has been determined accurately. The current lack of disclosure related to the QPA calculation increases the likelihood that facilities and providers will be forced to resort to the IDR process to receive appropriate payment for lifesaving services provided to patients of an out-of-network health plan.

2) *Notice and Consent Process*: The IFR adds requirements that were not contemplated by Congress in the statute. Those requirements limit the instances where a patient will have the opportunity

[1] CHA appreciates that this concern is top-of-mind for the tri-agencies given the IFR's discussion of and safeguards related to instances where a plan has "sufficient information" in a year subsequent to 2019 to calculate a QPA.

to consent to receive care from an out-of-network facility or provider. This is of particular concern for care provided once the patient is stabilized, as the rule adds an undefined "reasonable distance" requirement and undefined considerations that physicians must evaluate when determining if the patient has the "capacity to consent" to receive care from an out-of-network facility or provider.

CHA generally supports these additional patient protections. However, we are concerned the IFR provides no framework or guidance for determining when these additional undefined considerations interfere with a patient's capacity to consent or how it should be documented that they were considered. The added considerations are highly subjective, raising the risk of inconsistent application when an attending professional makes a determination about a patient's capacity to consent to receive care from an out-of-network facility or provider. Finally, the rule adds operational requirements that California's hospitals are unable to meet related to a nonparticipating emergency facility providing notice and consent on behalf of a nonparticipating provider for post-stabilization services.

Unless the tri-agencies address these issues, CHA is concerned the IFR will harm patient access to in-network non-emergent care and increase wait times for services. As currently written, the issues outlined in items one and two above create a regulatory environment that rewards health plans for narrowing their networks. While in emergency situations, health plan members will be able to access all facilities and providers at in-network cost-sharing amounts, in non-emergency situations health plan members may face limited access and choices for non-emergent care. This will likely increase wait times, resulting in poor outcomes and reduced patient satisfaction.

Finally, CHA appreciates the IFR's discussion of the factors the tri-agencies evaluated when considering whether to delay implementation of the provisions of the No Surprises Act. In light of the short time frame and paucity of crucial information necessary to operationalize the Act's requirements, CHA does not believe it is possible for plans, providers, facilities, and states to make the necessary changes to their information systems and operational processes to fully comply with the requirements by January 1, 2022. Given the lack of necessary information and IT infrastructure to implement the No Surprises Act, it is likely that all stakeholders will incur significant costs associated with manual processes until key processes can be automated and then incur rework costs as the tri-agencies clarify previously released regulations[2]. These additional costs will be translated into higher insurance premiums for consumers. Therefore, CHA asks the tri-agencies to protect patients from confusion and consumers from higher premiums, resulting from a rushed implementation of No Surprises Act, by providing additional enforcement discretion.

Following are CHA's specific comments on the provisions included in the IFR.

[2] CHA appreciates that Centers for Medicare and Medicaid Services Center for Consumer Information and Insurance Oversight (CMS-CCIIO) recently issued an FAQ deferring enforcement of the Good Faith Estimate and Advanced explanation of benefits (EOB) requirements related to insured individuals seeking to file a claim for services due to technical issues related to data exchange. However, as discussed in detail in these comments, there are other provisions of the No Surprises Act that call for enforcement to be deferred while all stakeholders develop the technical data exchange infrastructure necessary to operationalize the requirements.

Determination of the Cost-Sharing Amount and Payment Amount to Providers and Facilities

In accordance with the No Surprises Act, the IFR requires health plans to send an initial notice of denial of payment or initial payment no later than 30 calendar days after a nonparticipating provider or facility submits a "clean claim" for the protected services. The tri-agencies interpret an initial payment to be the intended payment in full prior to the start of an open negotiation period rather than some type of payment installment. The facility or provider, in covered situations, may accept the payment, or the final amount will be determined based on an all-payer model, a methodology defined in an applicable state law, or through negotiation and the IDR process.

CHA appreciates the Centers for Medicare & Medicaid Services (CMS) confirming the timeline for plans to either provide payment or issue a denial. Further, we agree with the tri-agencies decision to toll the payment/denial notice requirement based on a plan's receipt of a clean claim. However, given that some health plans unilaterally modify their definitions of what constitutes a clean claim, we ask that the tri-agencies focus on this area for compliance monitoring. Further, we ask the tri-agencies to publish a draft framework that it will use to monitor plans' compliance with the Act's requirement to send an initial notice of denial of payment or initial payment no later than 30 calendar days after a nonparticipating provider or facility submits a "clean claim" for the protected services so that hospitals and providers may offer feedback on it.

The IFR also provides technical requirements for calculating the QPA. However, it is difficult for CHA to provide comprehensive comments in response to the technical requirements for calculating the QPA until the details of the IDR process are made available. Therefore, we ask the tri-agencies to release the IDR regulations as soon as possible so that CHA and other stakeholders can consider both the QPA and its use in the IDR process together.

The regulations for calculating the QPA are explicitly intended to drive it down in an effort to reduce patient cost-sharing in out-of-network situations. We are strongly supportive of efforts to limit what patients are required to pay out-of-pocket for their care. **However, given that the QPA will likely be substantially below commercially reasonable rates, we strongly encourage the tri-agencies to clarify that the QPA is not intended to be used as the initial payment from health plans to facilities or providers in covered situations, and the QPA should not be overweighted in deliberations during the IDR process.**

Using an artificially depressed QPA as both the initial payment rate and a de facto benchmark in the IDR process, coupled with the IFR's limitation on when the notice and consent process can be used by patients to choose an out-of-network provider or facility, will reward health plans for narrowing their networks. These unintended consequences will harm access for patients who require non-emergent services, increasing their wait times and the distance they may have to travel for an in-network facility or provider.

In defining the No Surprises Act's patient protections, CHA appreciates the IFR confirming they extend to high-deductible and catastrophic health plans. However, we are deeply concerned the IFR does not clearly define when the Act applies and when a state law with similar protections applies. This is further exacerbated by allowing health plans to opt into state law in instances where a state law may apply and

will likely create confusion for patients and increase administrative burden for facilities, providers, and health plans.

Below please find our recommendations for calculating the QPA in a manner that will not risk reducing patient access to care.

Methodology for Calculating the Qualifying Payment Amount

The IFR defines the calculation of the QPA. Given these dual uses of the QPA (as discussed above), CHA is concerned that the framework outlined in the IFR for calculating the QPA will encourage plans to narrow their networks, thereby harming patient access to care for services not subject to the No Surprises Act.

Median Contracted Rate

The IFR calculates the median contracted rate for an item or service by arranging in order from least to greatest the contracted rates of all plans of the plan sponsor (or of the administering entity, if applicable) or all coverage offered by the issuer in the same insurance market for the same or similar item or service that is provided by a provider in the same or similar specialty or facility of the same or similar facility type and delivered in the geographic region in which the item or service is furnished, and selecting the middle number. In determining the median contracted rate, the amount negotiated under each contract is treated as a separate amount. If there are an even number of rates, it is the average of the two middle amounts. If the same amount is paid in two or more contracts, they are considered their own separate amounts and included in the array determining the median.

CHA strongly disagrees with this methodology to calculate the QPA. The QPA as a median payment amount will result in 50% of facility or provider rates being above it. Therefore, it is likely that some health plans may not contract with facilities or providers at rates above the median — which the tri-agencies briefly discuss as an unintended consequence in the IFR — if plans believe they can avail themselves of a lower payment rate through the IDR process.

We strongly encourage the tri-agencies to resolve this flaw in the current QPA calculation methodology and remove the incentive for health plans to narrow their networks. Where a recent previous contract between a health plan and a facility or provider exists, CHA asks HHS to use it to calculate the QPA. In instances where a previous contractual relationship has not existed with a facility or provider, CHA asks the tri-agencies to adhere to congressional intent and calculate the QPA using a methodology that incorporates all contracted rates.

Calculating the QPA When a Previous Contracted Rate Exists

Several states that have adopted surprise billing laws similar to the No Surprises Act have included provisions in statute designed to ensure their laws do not create incentives for health plans to narrow their networks and reduce patient access to in-network non-emergent care. In instances where a health plan had a contract in effect with a facility or provider but the contract recently expired, the QPA is the last contracted rate in effect between the health plan and the facility or provider, increased by a percentage (between 8% and 25%) to encourage health plans and facilities or providers to contract with one another to ensure access to in-network facilities and providers for members requiring non-emergent services, and adjusted for inflation to the current year using the Consumer Price Index for Medical Care

Services (CPI-M). Examples that CHA is aware of include Nevada (between 108% and 115% of the prior contracted amount[3]) and New York (125% of the prior contracted amount, adjusted for inflation[4]).

CHA believes this is a reasonable approach to prevent the No Surprises Act from negatively influencing network access for patients who require non-emergent services. We encourage the tri-agencies to protect patient access to in-network facilities and providers by incorporating a similar mechanism for calculating the QPA where a previous contract between the health plan and facility or provider existed.

The Tri-Agencies Should Include All Contracted Rates in QPA Calculation

Rates for services negotiated between health plans and in-network providers or facilities take into consideration a variety of factors that are not accounted for where a health plan and facility or provider have been unable to negotiate a mutually agreeable contract. Common factors tend to include situations where an in-network facility or provider offers a health plan deeper per-unit price discounts based on the number of covered lives they will have the opportunity to provide care for under a given contract and streamlined administrative processes. In addition to these considerations, in-network facilities or providers frequently offer discounts to health plans that are willing to partner with them on initiatives to improve the overall health of the population covered by the contract.

Single case rates are typically negotiated between health plans and providers or facilities when a health plan's network is inadequate to provide the care required by the plan's members. Those contracted rates effectively extend a plan's network under certain circumstances. The IFR acknowledges this by stating, "… a plan or issuer may negotiate an ad hoc arrangement with a nonparticipating provider or facility to *supplement*[5] *the network of the plan or coverage* for a specific participant, beneficiary, or enrollee in unique circumstances[6]."

The tri-agencies further acknowledge that services paid for under a single case rate are effectively in-network services in describing the scope of the Act's protections and for defining in-network health care facilities. They state that a single case agreement is typically, "… used to address unique situations in which a participant, beneficiary, or enrollee requires services that typically occur out-of-network constitutes a *contractual relationship*[7] for purposes of this definition, and is limited to the parties to the agreement with respect to the particular individual involved" and, "it is reasonable that an individual would expect items and services delivered at a health care facility that has a single case agreement in place with respect to the individual's care to be delivered on an in-network basis."[8] Because the individual patient recognizes all care delivered to be provided on an in-network (contracted) basis, the patient also accepts the cost-sharing based on the single case rate as reasonable.

Despite recognizing that a single case rate constitutes a contracted rate for the purpose of defining in-network health care facilities, the IFR does not include single case rates in the calculation of the QPA.

[3] https://www.leg.state.nv.us/NRS/NRS-439B.html#NRS439BSec748
[4] https://www.nysenate.gov/legislation/laws/FIS/605
[5] Emphasis added
[6] IFR, Display copy pg. 66.
[7] Emphasis added
[8] IFR, pg. 40 display version.

CHA believes this inconsistent treatment of single case agreements is contrary to Congress' intent in defining the QPA. Throughout the No Surprises Act, the QPA is defined as[9]:

> *… for an item or service furnished during 2022, the median of the contracted rates recognized by the plan or issuer, respectively (determined with respect to all such plans of such sponsor or all such coverage offered by such issuer that are offered within the same insurance market (specified in subclause (I), (II), (III), or (IV) of clause (iv)) as the plan or coverage) as the total maximum payment (including the cost-sharing amount imposed for such item or service and the amount to be paid by the plan or issuer, respectively) under such plans or coverage, respectively, on January 31, 2019 …*

As the IFR notes, single case rates represent a "contracted rate recognized by a plan or insurer" for purposes of creating an in-network relationship when a health plan's network is inadequate. **If a single case agreement creates a "contracted rate" negotiated with and "recognized by the plan or issuer" — even if for a single case — CHA believes that, per the statute, it must be included in the calculation of the QPA. Therefore, we ask the tri-agencies to revise the instructions for calculating the QPA and require health plans to include single case agreements.**

Given the prominent role the QPA plays in the IDR process as one piece of evidence considered by the arbitrators, we are concerned that omitting single case rates will only encourage some health plans to further limit their networks, reducing access to highly trained specialists and tertiary and quaternary facilities.

The IFR notes that the tri-agencies also are interested in comments on the impact of "large, consolidated health care systems" on contracted rates and whether the contracting practices of such systems could inflate the QPA and, therefore warrant an adjustment to the methodology. **CHA strongly opposes any such adjustment to the QPA. The section of the statute cited above does not allow HHS to make such an adjustment.**

The use of "all such plans or all such coverage" makes it clear that Congress intended that all applicable contracts with all providers and facilities — including allegedly large, consolidated health care systems — be included in the calculation of the QPA. Therefore, we do not believe the statute allows HHS to pick and choose which types of providers and facilities should be included in the calculation of the QPA any more than the statute allows HHS to require large, consolidated health plans with dominant market share[10,11,12] to use a third-party database to calculate its QPA despite it having "sufficient information."

Facility of the Same or Similar Type Facility

The IFR allows for different QPAs based on whether an emergency department is freestanding or hospital-based if the plan has separate contract rates for each type of facility. However, the IFR does not

[9] Section 2799A-1(a)(2)(E)(1) of 42 U.S. Code 300gg
[10] https://www.kff.org/private-insurance/state-indicator/market-share-and-enrollment-of-largest-three-insurers-individual-market/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D
[11] https://www.kff.org/other/state-indicator/small-group-insurance-market-competition/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D
[12] https://www.kff.org/other/state-indicator/large-group-insurance-market-competition/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

require plans to separately calculate a median contracted rate based on other characteristics of facilities that might cause contracted rates to vary, such as whether a hospital is an academic medical center or teaching hospital.

CHA asks the tri-agencies to reconsider the decision to not require plans to calculate separate rates for other types of facilities. We are particularly concerned about the impact of this decision on access to tertiary and quaternary care. Given that many tertiary and quaternary hospital patients are admitted through the emergency room or transferred from other hospitals that cannot provide an adequate level of care, this could create an unintended incentive to drop tertiary and quaternary hospitals from some networks to secure an artificially depressed payment rate through the IDR process. This is a very real concern given the significant, additional limitations the IFR places on using the notice and consent process (as discussed below) to appropriately bill for the cost of providing post-stabilization care.

One way to address this issue would be to instruct health plans to remove non-tertiary and non-quaternary hospitals from the dataset used to calculate the QPA for out-of-network services provided by a tertiary and quaternary hospital. If the tri-agencies do not address this issue, CHA is deeply concerned that plans will exclude tertiary and quaternary hospitals from their networks, decreasing access to lifesaving specialty care services in non-emergent situations such as cancer care or organ transplantation.

Non-Fee-for-Service Contractual Arrangements

The IFR excludes risk sharing, bonus, penalty, and other incentive-based and retrospective payments or payment adjustments from the calculation of the QPA. **CHA asks the tri-agencies to clarify that any "withhold" amounts used to fund quality bonuses must be added back to the contracted rates when a plan calculates its QPA.** If this is not clarified, CHA is concerned that it will serve as a disincentive for facilities and providers to participate in value-based payment models.

Same or Similar Service

The IFR defines "same or similar item or service" as a health care item or service billed under the same service code, or a comparable code under a different procedural code system. Service codes are those that describe an item or service, including a Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), or Diagnosis-Related Group (DRG) code. **For the sole purposes of calculating the QPA, CHA supports this definition of same or similar service.**

However, CHA does not believe this narrow definition of "same or similar item or service" should be used to define "like" items and services for the purposes of batching claims to submit to IDR entity. CHA strongly supports claims batching. If constructed appropriately, this will provide an effective means to avoid unnecessary administrative costs for all parties, reduce the potential for IDR entities to develop case backlogs, and accelerate payments to facilities and providers — particularly financially distressed facilities and providers — when they provide care to patients in situations covered by the No Surprises Act.

However, for batching to be effective, the regulation's criteria should be flexible enough to accommodate a wide range of clinical scenarios and payment methodologies. We believe that Congress appreciated this

complexity and gave the tri-agencies latitude to broadly define how "similar services" might be batched. Section 2799A–1(c)(3)(A) states:

> *IN GENERAL. — Under the IDR process, the Secretary shall specify criteria*[13] *under which multiple qualified IDR dispute items and services are permitted to be considered jointly as part of a single determination by an entity for purposes of encouraging the efficiency (including minimizing costs) of the IDR process. Such items and services may be so considered only if…*

CHA notes that Congress did not specifically instruct the tri-agencies to develop a single criterion for batching. Instead, it used the plural form, without qualification. CHA believes batching criteria should be broad enough to aggregate claims for "treatment of a similar condition" (e.g., emergency services that result in an inpatient admission). However, the statute does not explicitly define treatment of a similar condition as having homogenous resource utilization/costs (e.g., treatment of an acute myocardial infarction may be accomplished through medical means, mechanical intervention/percutaneous coronary intervention, or coronary artery bypass graft surgery). Therefore, we believe Congress intended for IDR entities to disaggregate batched claims for "treatment of a similar condition" and determine the appropriate payment amounts for sub-groups of claims. **We encourage the tri-agencies to use the flexibility afforded to them by Congress to create a broad set of criteria that facilities and providers can use to batch and submit claims to an IDR entity.**

Indexing

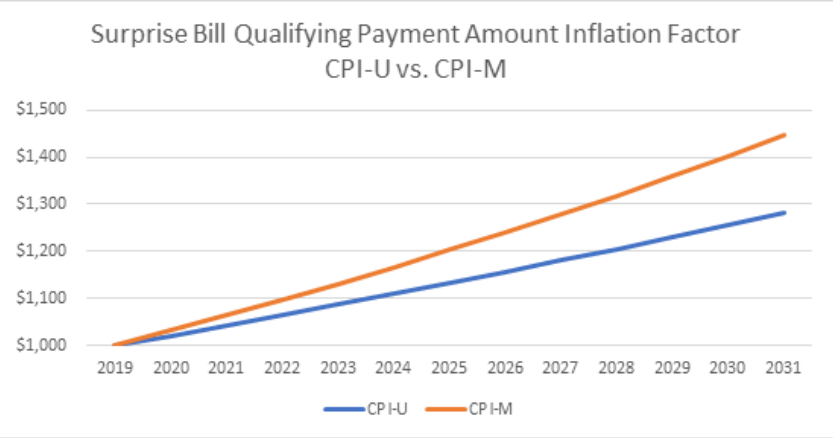
The IFR provides that the median contracted rate determined as of January 31, 2019, is indexed using the consumer price index for all urban consumers (CPI-U) for 2019, 2020, and 2021 to calculate the QPA for 2022. Thereafter, the amount is indexed annually using the CPI-U for the prior year. To ensure that all plans and issuers are adjusting the amounts in a uniform manner, the IFR requires all plans and issuers to use the percentage increase for any year based on the CPI-U published by the Bureau of Labor Statistics.

CHA believes the QPA should be adjusted for inflation using the CPI-M component of the CPI-U index. CPI-U is a broad index of inflation that includes an array of items (e.g., food, energy, transportation, medical care, recreation, housing, etc.), of which medical care is one component. Historically, the overall index has grown at a slower rate than medical care, as costs for key inputs to health care (e.g., pharmaceuticals) grow faster than the overall economy. Using the broader CPI-U index instead of CPI-M to adjust the QPA for input price inflation will, over time, result in an amount that fails to cover the cost to provide health care services to individuals in situations covered by the No Surprises Act.

Below is a graph that compares the estimated QPA in 2031, adjusted for inflation using the averages of CPI-U and CPI-M from 2016 through 2019[14], of a service with a QPA in 2019 of $1,000.

[13] Emphasis added.

[14] https://www.bls.gov/opub/ted/2020/consumer-price-index-2019-in-review.htm#:~:text=Medical%20care%20prices%20rose%204.6,percent%20from%202017%20to%202018.



The QPA calculated using CPI-U is $163 less than the QPA calculated using CPI-M. **CHA asks HHS to require health plans to adjust the QPA for inflation using CPI-M. Over the long term, this will benefit patients by promoting stable health plan networks.**

Eligible Databases

In cases in which a plan does not have "sufficient information" to calculate a median contracted rate, the Act directs the plan to determine the QPA through use of any database that is determined not to have any conflicts of interest and to have sufficient information reflecting allowed amounts paid to a health care provider or facility for relevant services furnished in the applicable geographic region. The IFR provides that state databases are categorically eligible, as they do not have any conflicts of interest and contain sufficient information reflecting allowed amounts.

The IFR also allows for third-party databases to be used if the following criteria are met:

- The database or the organization maintaining the database cannot be affiliated with, or owned or controlled by, any health insurance issuer, or a health care provider, facility, or provider of air ambulance services, or any member of the same controlled group as, or under common control with, any such entity.
- The database must have sufficient information reflecting in-network amounts paid by group health plans or health insurance issuers offering group or individual health insurance coverage to providers, facilities, or providers of air ambulance services for relevant items and services furnished in the applicable geographic region.
- The database must have the ability to distinguish amounts paid to participating providers and facilities by commercial payers, such as group health plans and health insurance issuers offering group or individual health insurance coverage, from all other claims data, such as amounts billed by nonparticipating providers or facilities and amounts paid by public payers.

CHA supports the IFR's requirements that a third-party database must meet for a health plan to use it to calculate the QPA in absence of sufficient information. CHA strongly encourages the tri-agencies to develop a certification process that third-party databases must complete for a health plan to use them to calculate the QPA. We further ask that HHS, on an annual basis, post a list of certified third-party databases that health plans may use so that facilities and providers are aware of which databases are eligible for use in calculating the QPA.

Additionally, CHA asks the tri-agencies to include a transparency requirement that third-party databases must meet to be considered eligible. **To meet this requirement, third-party databases would be required to post on a publicly available website the methodology they use to aggregate claims data and calculate QPAs for each service and market. On an annual basis, the third-party database would be required to be audited by an independent third-party entity to ensure that the claims data are aggregated and the QPA calculated in accordance with the methodology made publicly available.**

New Service Codes – Reasonably Related Service Codes

The IFR defines a "new service code" to mean a service code that was created or substantially revised in a year after 2019. New service codes occur when plans and issuers may be unable to calculate the QPA using the approaches discussed earlier, because the plan, the issuer, and any eligible databases do not have sufficient information about the new service code. In situations in which a plan is billed for a covered item or service using a new service code, the IFR requires the plan to identify a reasonably related service code that existed in the immediately preceding year. As an example, the IFR suggests that a reasonably related service code might be another service code within the same family of codes or involve services that represent similar relative value units. This related service code will be used to determine a ratio of the payment for the new service code to the relative service code, then multiplied by the relative service code, to calculate the QPA for the new service code.

The IFR seeks comment on whether additional rules are needed on how plans and issuers should be required to identify a reasonably related service code, and on whether a crosswalk methodology needs to be developed to identify related service codes for each new service code. **CHA strongly believes HHS should convene a panel of technical experts from health plans, facilities, and providers to develop an annual crosswalk of new service codes to the most relevant related service code that plans must use to calculate the relativity ratio for new service codes. Additionally, CHA strongly encourages the tri-agencies to use the notice and comment rulemaking process to develop a standard calculation for the relativity ratios used to determine the QPA for new service codes.**

Sufficient Information Obtained in Subsequent Year

The IFR requires that, when a plan or issuer initially does not have sufficient information but later gains such information, the plan or issuer must calculate the QPA using the median contracted rate for the first sufficient plan year — in the case of an item or service for which a plan or issuer does not have sufficient information in 2019, the first year after 2022 for which the plan or issuer has sufficient information to calculate the median of contracted rates in the year immediately preceding that first year after 2022. Where contracted rates for a year after 2019 are used to calculate the median contracted rate, a plan or issuer will be considered to have sufficient information if the plan or issuer has at least three contracted rates to calculate the median and the contracted rates account for at least 25% of the total number of claims paid for that item or service for that year. The 25% minimum claims volume requirement is intended to ensure that those network contracts represent a reasonable proportion of a plan or issuer's total claims and, therefore, are not designed to manipulate the QPA.

CHA appreciates the tri-agencies' concern about the potential for some health plans to attempt to manipulate the QPA via future contracting and network culling strategies. However, we do not believe this approach sufficiently addresses the potential risk for the QPA to be manipulated. Therefore, we ask the tri-agencies to rescind the regulations allowing plans to use data other than from 2019. The

one exception to this should be instances where the item or service in question is newly covered. **In instances where the lack of sufficient information is not the result of a newly covered item or service, CHA believes that health plans should be required to calculate the median payment rate for an item or service using a qualifying, independent database.**

Information to Be Shared About the QPA

The IFR requires health plans to share certain information about the QPA with out-of-network providers and facilities. Health plans must disclose:

1) The QPA for each item or service involved
2) A statement certifying that the QPA is the recognized amount (for purposes of patient cost-sharing) and was calculated in compliance with the methodology described in the IFR
3) A statement confirming the option for a 30-day open negotiation period to determine the total payment amount followed by initiation of the IDR process within four days of the end of the open negotiation period

Additionally, upon request of the provider or facility, the health plan or issuer must, in a timely manner, provide:

1) Information about whether the QPA includes contracted rates that were not set on a fee-for-service basis and if those items and services were determined using underlying fee schedule rates or a derived amount
2) Information to identify which related service code was used, if one was used, to determine the QPA for a new service code
3) Information to identify which database was used to determine the QPA (if applicable)
4) A statement that the plan's or issuer's contracted rates include risk-sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments for the items and services that were excluded for purposes of calculating the QPA

Given the implications for patient out-of-pocket payments and facility or provider payments based on the role of the QPA in the IDR, the health plan's methodology and data used to calculate the QPA should be readily transparent to all stakeholders. Instead of requiring facilities or providers to request items one through four above, health plans should be required to transmit this information to the facility or provider.

Additionally, health plans should be required to transmit the specific data points used to calculate the QPA to the patient, the facility or provider, and to the IDR entity when materials supporting the health plan's requested amount are submitted. The specific data points should include the de-identified array of payment rates used to determine the median payment amount and the names of facilities or providers whose rates were used to determine the median amounts to ensure the rates used are comparable. Further, the IFR allows self-insured plans to base the QPA on either their plan sponsor's or TPA's data. In this scenario, self-insured plans should also be required to identify which dataset was used to calculate the QPA. If CMS persists in requiring facilities and providers to request this information, CHA asks that

the agency define "in a timely manner" as requiring the plan or issuer to transmit this information to the facility or provider electronically within two calendar days of receiving the request[15].

The level of transparency described above will reduce the volume of claims submitted to the IDR process by ensuring a fair initial payment. And, when necessary, the transparency provided by adopting these recommendations will create a productive basis from which health plans and facilities or providers can negotiate the appropriate payment amount. Given the relatively short negotiating window contemplated in the IFR 30 days — it is essential that facilities and providers have information related to how the QPA was calculated so it can be factored into their negotiations with the plan about the appropriate payment amount.

Further, the tri-agencies should include a mechanism in the IDR process that provides more time before initiating the negotiation period and "triggering" the IDR process if the provider or facility has questions about the accuracy of the QPA calculation. Currently, facilities and providers have 30 days from when payment or a denial is received to initiate the negotiating period, and four days from the end of the negotiation period to "trigger" the IDR. **CHA asks that the IDR process allow, at the facility or provider's discretion, that the clock on the 30-day negotiation period not begin until the facility or provider is satisfied that the QPA is accurately calculated. However, during this period, plans and facilities or providers should be allowed to engage in negotiations designed to determine an appropriate payment rate for services provided to a patient who received out-of-network services.**

While transparency into the calculated QPA is necessary, it is not sufficient to ensure that it is accurately calculated in accordance with Congress' intent and this IFR. The IFR provides scant detail on the process the various agencies will use to audit the QPA of plans under their jurisdiction — save only that they will use their "existing processes." From the detail that is provided, CHA is concerned that this is insufficient to ensure that the QPA is calculated accurately. For example, in describing HHS' audit efforts, the IFR states that:

> *HHS has primary enforcement authority over issuers (in a state if the Secretary of HHS makes a determination that a state is failing to substantially enforce a provision (or provisions) of Part A or D of title XXVII of the PHS Act) and non-federal governmental plans, such as those sponsored by state and local government employers and expects to conduct no more than 9 audits annually.*

We strongly encourage the tri-agencies to put forth in regulation a comprehensive audit process ensuring the accuracy of the QPA given its role in both calculating patient out-of-pocket costs and serving as one piece of evidence considered in the IDR process. Given past instances where health plans have manipulated payment amounts calculated in a "black box" environment to their advantage, we do not believe this concern is unmerited or the request unreasonable[16]. Further, the audit regulations must hold health plans accountable when their QPA calculations are found to be inaccurate. This must include, but not be limited to, reimbursing patients for any excess cost-sharing based on an inaccurate

[15] This information should be mailed only if the facility or provider specifically requests it.
[16]https://www.mssny.org/MSSNY/Resources/Legal_Matters/Class_Action_Settlements/United_Healthcare_Settlement/MSSNY/Practice_Resources/Legal_Matters/Class_Action_Settlements/United_Healthcare_Settlement.aspx?hkey=52f280ad-c706-4fe9-92cd-26fb332d9860

QPA and increasing payments to facilities or providers in instances where an inaccurately calculated QPA was lower than it should have been. Plan responsibility for increased payments should apply to both the patient's cost-sharing — providing further protection for patients — and payments to facilities or providers stemming from IDR decisions based (in-part or wholly) on an inaccurately calculated QPA.

Applicability of the No Surprises Act's Protections to High-Deductible and Catastrophic Health Plans

The IFR clarifies that where the surprise billing protections apply and the out-of-network rate exceeds the amount upon which cost-sharing is based, a plan or issuer must pay the provider or facility the difference between the out-of-network rate and the cost-sharing amount, even in cases where an individual has not satisfied their deductible. Further, HHS clarifies that it interprets the No Surprises Act as permitting catastrophic plans to make payments required by sections 2799A-1 or 2799A-2 of the Public Health Service (PHS) Act without losing their status as catastrophic plans. Therefore, the IFR specifies that a catastrophic plan must provide benefits as required under sections 2799A-1 and 2799A-2 of the PHS Act and their implementing regulations, or any applicable state law providing similar surprise billing protections to individuals.

CHA thanks the tri-agencies for these clarifications and strongly agrees with their interpretations of the PHS Act as it relates to the consumer protections in the No Surprises Act and high-deductible and catastrophic health plans. We believe these clarifications are necessary to ensure patients with high deductibles and those who have chosen catastrophic plans are removed from billing disputes between providers and/or hospitals and out-of-network health plans as Congress intended when it passed the No Surprises Act.

Specified State Law

The IFR defines a specified state law as one that provides a method for determining the total amount payable under a group health plan or group or individual health insurance coverage to the extent the state law applies. This includes instances where the tri-agencies have interpreted this term to include state laws where the state law applies because the state has allowed a plan that is not otherwise subject to applicable state law an opportunity to opt into a program established under state law, subject to section 514 of the Employee Retirement Income Security Act (ERISA), for an item or service furnished by a nonparticipating provider or nonparticipating emergency facility.

CHA notes that the interactions between specified state laws (where they exist) and federal laws are incredibly complex. If not clearly understood by health plans, providers, facilities, and state/federal regulators, these interacting laws will be a source of confusion for all stakeholders and negatively impact patients. **Therefore, CHA greatly appreciates the example scenarios provided in the IFR to help demonstrate the circumstance where a specified state law applies.**

However, the IFR notes that as of February 5, 2021, 33[17] states have enacted legislation that provides some protection for consumers with regard to balance bills. Given the diversity of state laws, CHA is concerned that the four examples provided in the rule do not adequately address each state law's unique relationship with the No Surprises Act and the related implementing regulations. **Therefore, CHA**

[17] https://www.commonwealthfund.org/sites/default/files/202103/Hoadley_state_balance_billing_protections_table_02052021.pdf -

strongly encourages the tri-agencies to work with the National Conference of State Legislatures, National Governors Association, and the National Association of Insurance Commissioners to provide guidance to states, plans, self-insured plans, providers, and facilities as to the specific interaction between each state's law and the No Surprises Act.

Further, CHA strongly opposes allowing ERISA plans to opt into a specified state law. We believe doing so will increase the risk of confusion for patients about the out-of-pocket amount they are required to pay and significantly increase the administrative burden for facilities, providers, and health plans. The following scenario — adapted from the IFR — provides one such example of a situation that will both confuse the patient and increase the administrative burden.

> *Facts.* An individual receives emergency services at a nonparticipating hospital located in State A. The emergency services furnished include post-stabilization services, as described in 26 CFR 54.9816-4T(c)(2)(ii), 29 CFR 2590.716-4(c)(2)(ii), and 45 CFR 149.110(c)(2)(ii). The individual's coverage is through an employer-sponsored ERISA plan, and the coverage includes benefits with respect to services in an emergency department of a hospital. State A has a law that prohibits balance billing for emergency services provided to an individual at a nonparticipating hospital located in State A and provides a method for determining the cost-sharing amount and total amount payable in such cases. The law applies to issuers licensed in State A and allows ERISA plans to opt in. However, State A's law has a definition of emergency services that does not include post-stabilization services.
>
> *Conclusion*. In this example, State A's law – which the patient's ERISA plan has opted into – would apply to determine the cost-sharing amount and out-of-network rate for the emergency services, as defined under State A's law. State A's law would not apply for purposes of determining the cost-sharing amount and out-of-network rate for the post-stabilization services for the ERISA plan. Instead, the lesser of the QPA or billed amount would apply to determine the recognized amount, and either an amount determined through agreement between the hospital and issuer or an amount determined by an IDR entity would apply to determine the out-of-network rate, with respect to post-stabilization services.

From a clinical care standpoint, there is no bright line between pre- and post-stabilization services in many instances. And from a methodology standpoint, in many payment systems commonly used by health plans, the pre- and post-stabilization services are bundled together to calculate one payment for the episode of care. Therefore, it will not be possible to piecemeal unbundle the services and calculate separate cost-sharing for items and services provided before and after the patient is stabilized. And in instances where it is possible, providers, facilities, and health plans will incur additional IT system costs for specific ERISA plans (which may change year-to-year) based on whether the health plan opts in for a given plan year so they can accurately determine which items and services are covered under the No Surprises Act and which are covered under the specified state law. In instances where it is possible to calculate the cost-sharing on a piecemeal basis, from a patient perspective, this is likely to create confusion and dissatisfaction. While the patient experienced one episode of care, there are two different cost-sharing methodologies they need to understand to ensure that their out-of-pocket amount was calculated accurately.

CHA strongly encourages the tri-agencies to prohibit ERISA plans from opting into a specified state law to avoid this situation. Beyond the confusion this will create for patients, it may not be operationally possible — as discussed above — for a plan to calculate separate cost-sharing for the services provided pre-and post-stabilization. This concern also extends to state regulated plans. To address this issue, we would strongly encourage the tri-agencies to only allow a state-specified law to take precedence over the No Surprises Act for state regulated products if the law covers the exact same items and services as the No Surprises Act.

Additionally, under the IFR, a self-insured plan that opts into a state law must prominently display in its plan materials on coverage for out-of-network services, a statement that the plan has opted into a specified state law; identify the relevant state; and provide a general description of the items and services provided by nonparticipating facilities and providers that are covered by the specified state law. **If the tri-agencies allow ERISA plans to opt into a state-specified law, CHA strongly supports the requirement that plans prominently state they have done so in all related "plan materials."**

We ask that the tri-agencies clarify that "plan materials" include, but are not limited to, the member's insurance identification card, responses to "eligibility"[18] requests from the facility or provider, and electronic remittance advice[19] (including denial notices) sent to the facility or provider. Specifically related to remittance advices, we ask that payers include a clear remittance "remark" message that indicates if the covered service is subject to the No Surprises Act or a specified state law. And we strongly believe that this should extend to all products — not just ERISA plans that have opted into a specified state law.

CHA believes this clarification — which should apply to all plans and issuers — is essential. Requiring the use of electronic exchange of eligibility and payment data will provide the real time information necessary to ensure that facilities and providers can meet the requirements of the No Surprises Act. At the front end of the revenue cycle when a patient schedules a service, having this information in real time will allow facilities or providers to easily identify patients whose health plan is out-of-network to determine if the care they seek is covered by the No Surprises Act (or an applicable state law) so that the patient can be educated about their rights, and the notice and consent process can be administered in a timely manner (if appropriate).

Once payment or a denial notice is received, including specific remarks on the remittance advice will allow the facility or provider to confirm the appropriate cost-sharing to bill the patient based on whether the patient consented to receive services from an out-of-network facility or provider. Further, requiring that this information be provided at each stage of the revenue cycle in an electronic format will reduce the administrative burden for plans, facilities, and providers by allowing them to develop automated processes for identifying which patients the protections of the No Surprises Act (or applicable state law) apply to. **Given the importance of this information to ensuring hospitals can comply with the Act, CHA believes that plans failing to provide the information described above in an electronic format should be subject to civil monetary penalties.**

[18] Eligibility information includes the member's eligibility for benefits, whether the facility or provider placing the inquiry is in-network for the service/procedure in question, and if the plan is using a "pass-through" network. Further, plans should be required to supply eligibility information electronically, in real time.
[19] This requirement should extend to paper remittance advices in instances where a plan still uses them.

Scope of the New Surprise Billing Protections

The IFR provides further detail on the scope of No Surprises Act's balance billing protections. Specifically, the rule reinforces the prudent layperson standard, which CHA strongly supports. The rule also further defines post-stabilization services. While additional clarity is generally appreciated, the IFR expands the definition beyond what Congress initially intended in the statute. It adds both an undefined distance requirement for in-network facilities, which must be met for a patient to be eligible to consent to be balance billed when their health plan's network is inadequate and there are highly subjective requirements related to the patient's capacity to consent.

The IFR also relies on state law to determine who can provide consent on behalf of a patient. While CHA appreciates this reliance on state law, we ask that the tri-agencies provide additional guidance. California state law is unclear on this issue. Finally, as discussed below, there are instances where a patient needs to be transferred to another facility and has the choice of an in-network or out-network facility, but it is unclear how the No Surprises Act (or applicable state law) would apply in these situations. We ask the tri-agencies for additional guidance on instances where the patient chooses an out-of-network facility.

Definition of Emergency Services – Prudent Layperson Standard

The IFR notes the tri-agencies are aware that some commercial health plans have implemented policies that restrict coverage for emergency services that are inconsistent with the prudent layperson standard. For example, the rule states that some plans have implemented policies to deny coverage based on the patient's final diagnosis or using general plan coverage exclusions. The IFR clarifies these policies are inconsistent with the requirements of the No Surprises Act, as well as the prudent layperson standard established by the Affordable Care Act.

CHA strongly supports this clarification and appreciates the tri-agencies taking this opportunity to protect Americans who are experiencing an emergent health care event by confirming the requirements of the prudent layperson standard. CHA is also aware that in some instances health plans have implemented policies that, instead of outright denying claims for emergency services based on the final diagnosis, down-code the emergency room visit based on the final diagnosis. **CHA asks that the tri-agencies protect patients further by confirming that policies of this nature are also inconsistent with the prudent layperson standard.**

Post-Stabilization Services

The IFR's definition of post-stabilization services for purposes of using the notice and consent process includes the following four components:

1) *Patient Is Stable*: The attending physician, considering all relevant factors, determines the patient can travel a "reasonable distance" to an in-network facility using non-emergency transportation.
2) *Patient Has Capacity to Consent*: The attending physician determines that the patient (or their representative) is capable — based on a set of holistic factors — of providing informed consent.
3) *Conditions of the No Surprises Act Are Met*: All the other conditions included in the No Surprises Act, as defined by the tri-agencies, are met by the facility or provider.
4) *Relevant State Laws Followed*: Facilities and providers comply with any state laws relevant to balance billing.

As discussed below, CHA has specific concerns with how the tri-agencies have defined when the patient is stable and has capacity to consent. Further, we seek clarity as to how the No Surprises Act applies to common patient transfer scenarios.

Patient Stabilized
The attending physician must determine that the patient meets the Emergency Medical Treatment and Labor Act (EMTALA) definition of stable. **CHA supports the tri-agencies' approach in placing the responsibility to determine when a patient is able to provide consent with the treating provider.**

In addition, the patient must be able to travel a "reasonable distance" to an in-network facility. The tri-agencies seek comment on the definition of "reasonable travel distance" and whether standards are needed to describe an unreasonable travel burden. The distance a patient must travel to seek medical care is often impacted by network adequacy. If a patient is enrolled in a plan that utilizes a narrow network of facilities and providers, then access to an in-network provider or facility for needed care could be challenging. A sufficient number of facilities and qualified health care providers is necessary to ensure members have access to covered services within a reasonable distance. When plans do not have sufficient numbers or types of facilities and providers, patients are forced to forego, wait for, and/or travel long distances for medically necessary care. This can negatively impact plan members' health outcomes and result in consumers seeking care at local but out-of-network facilities or providers to receive the services necessary to ensure positive outcomes in a timely manner.

CHA believes that the definition of a "reasonable distance" to travel to receive in-network care will vary by the location of the hospital in which the patient was first stabilized. CMS recognized the relativity of the concept of "reasonable distance" to travel to receive care when it set different distance requirements to determine network adequacy for Medicare Advantage plans for patients located in urban, suburban, rural and super-rural areas (85 FR 33905)[20]. **CHA strongly encourages the tri-agencies to adopt a similar framework — as opposed to a one-size-fits-all standard — to determine the "reasonable distance" requirement.** Additionally, networks should be required to have a sufficient number of providers and facilities to allow adequate access for patients. A minimum requirement ensures that plans have a contracted network that is broad enough to provide beneficiaries access to covered services. CHA notes the majority of plans regulated under the No Surprises Act and this IFR are ERISA plans. ERISA does not mandate that plans meet any specific network adequacy requirements. This leaves the majority of commercially insured patients exposed to the risk of having limited access to an adequate network of health care facilities and providers.

Capacity to Consent
The IFR states that, in order to balance bill for emergency services by a non-participating provider or facility, the emergency physician or treating provider must determine, using appropriate medical judgment, that the patient (or authorized representative) is in a condition to receive the information in the notice and provide consent. The preamble mentions various factors, including the patient's emotional state, alcohol/drug use, pain, mental disorder, and cultural and contextual factors for members of underserved communities. For both emergency services provided by a non-participating provider or facility, and to be treated by a nonparticipating provider in a participating facility, the consent must be

[20] https://www.govinfo.gov/content/pkg/FR-2020-06-02/pdf/2020-11342.pdf

provided voluntarily, meaning the individual is able to consent freely without undue influence, fraud, or duress.

The IFR solicits comments on the conditions described above, and on what guidelines, beyond state laws regarding informed consent, may be needed to determine when an individual is in a condition to receive the written notice and provide consent. For example, are standards needed to account for individuals who are experiencing severe pain, intoxication, incapacitation, or dementia after being stabilized following an emergency medical condition?

California has no statute or regulation specifying when an individual is in a condition to provide informed consent. CHA is not aware of any common law on this topic either; if there is any, the holding would necessarily be limited to the specific facts and circumstances facing the individual involved in the legal matter. Specific objective guidelines and standards must be included in regulations related to the No Surprises Act so that facilities, providers, patients, and authorized representatives know when an individual may provide informed consent and when they may not (and in the latter case, may not be able to access the nonparticipating facility or provider of their choosing).

In particular, the subjective factors listed in the IFR preamble must be carefully defined. Although physicians presumably learn how alcohol and drugs are likely to impact a patient's decision-making abilities, they are not taught in medical school how to determine when a parent is too emotional to make a rational decision about paying for out-of-network care for their injured child. Likewise, medical school does not impart any information about how much influence is "undue": if a physician sincerely believes that a particular out-of-network specialist is the best provider to treat a patient's condition and so informs the patient, does this constitute undue influence? Finally, the suggestion in the preamble that a physician should expect that some members of underrepresented communities may be unable to make a voluntary, knowing decision about consenting to out-of-network care due to a lack of trust or other historical inequities is concerning. These factors must be fully defined and objectively measurable so that every patient has the opportunity to exercise his or her right to obtain care from a nonparticipating provider or facility if desired.

Determining the Patient Representative

The IFR states that:

> *… an authorized representative is an individual authorized under State law to provide consent on behalf of the participant, beneficiary, or enrollee, provided that the individual is not a provider affiliated with the facility or an employee of the facility, unless such provider or employee is a family member of the participant, beneficiary, or enrollee. (45 CFR §§149.410(b)(3) and 149.420(c)(2))*

This language presumes that each state clearly defines who may provide consent on behalf of an incapacitated patient. This is not the case in California for most adult patients lacking capacity, as discussed further below. In addition, the regulatory language fails to specify whether the patient representative must be authorized under state law to: (1) consent to health care services and procedures on behalf of the patient, or (2) bind the patient to financial obligations, or (3) both. In California, to the extent there are state laws on these topics, a person who may consent to health

care services may or may not have the ability to bind the patient to financial obligations, and vice versa.

California has no statute or regulation specifying who may consent to health care services or procedures on behalf of an adult patient who lacks the requisite mental capacity to do so, with two exceptions (both of which have complications in the context of this regulation):

1. A patient who has executed a written Advance Health Care Directive. The agent named in an advance directive may consent to health care services for the patient. State law, however, does not explicitly allow the agent to bind the patient to financial obligations. It is possible that state courts will determine that such an agent has this authority — analogously, state appellate decisions have held that such an agent can bind the patient to arbitration with a health care facility unless the advance directive contains a restriction to the contrary. (*Garrison v. Superior Court,* 132 Cal.App.4th 253 (2005); *Hogan v. Country Villa Health Services, Inc.*, 55 Cal.Rptr. 3d 450 (2007)) However, state law is not clear at this time.

2. A patient under a court-ordered Probate Code conservatorship that specifically grants the conservator the authority to make health care decisions. A health care facility must review the letters of conservatorship to determine the scope of the conservator's authority — that is, whether the conservator can make health care decisions on behalf of the patient, financial decisions, or both. In the absence of this documentation (which most patients do not carry with them), the hospital does not know who can provide consent. To add an additional complication, California has a separate type of conservatorship for patients who need mental health services. The Probate Code conservatorship mentioned above does not allow a conservator who may make "physical" health care decisions for a patient to consent to placing the patient in a mental health treatment facility. Instead, placement in a mental health treatment facility requires a "Lanterman-Petris-Short Act" conservatorship, which does not confer the ability to make financial decisions on behalf of the patient.

The above situations are complicated enough, but the vast majority of patients have not executed an advance directive and are not under a conservatorship. In those cases, health care providers are left with almost no legal guidance as to who is authorized to make health care decisions for an adult patient who lacks the capacity to do so. There is no statute or regulation that sets forth a hierarchy of potential decisionmakers or even a list of acceptable decisionmakers. Instead, health care providers rely on common law (court decisions), which also does not specify a hierarchy or list of acceptable decisionmakers. California courts have ruled in various contexts that health care providers may rely on close family members and friends to consent to health care services on behalf of incapacitated patients, with no further specificity. However, the courts have also ruled that this authority is limited to consent to health care service and does not, for example, extend to binding the patient to arbitration. (*Pagarigan v. Libby Care Center, Inc.,* 99 Cal.App.4th 298 (2002); *Goliger v. AMS Properties*, Inc., 123 Cal.App.4th 374 (2004); *Flores v. Evergreen at San Diego, LLC*, 148 Cal.App.4th 581 (2007)) It is far from clear whether close family members or

friends can bind a patient to a financial obligation. This regulation should make this clear for balance billing purposes.

As a practical matter, health care providers typically look to parents, spouses, adult children, siblings and the "significant others" of incapacitated adults to consent for health care services. Of these individuals, typically none but a spouse is responsible for paying the bill, and it is not clear that any can legally bind the patient to a financial obligation.

Similarly, there are complex situations with minor patients. Some minors have the legal authority to consent to their own health care services; are these minors also permitted to sign the balance billing consent under this regulation? Is there an age requirement? For example, can a 13-year-old pregnant patient consent to balance billing related to her pregnancy care? Or, with a slightly different twist, can a 13-year-old mother be considered to be an authorized representative to sign a balance billing consent related to care for her infant? In both cases, state law permits the teen to consent to the health care services. It would appear that the language of this regulation would permit her to consent to balance billing, but clarification on this point would be appreciated.

The language of the regulation should also address ostensible agency. For example, under California law, a stepparent is not authorized to consent to health care services for a minor patient (unless a parent has signed a document granting this authority). However, it is very common for stepparents to bring children to a hospital for services acting as their parent — that is, to not disclose the stepparent relationship — and sign consent forms for the services. If, for example, a stepmom does this and signs the balance billing consent, this should be valid under an ostensible agency theory if the health care provider has no reason to know she is not a legal parent.

CHA urges the agencies to adopt more specific language at 45 CFR §§149.410(b)(3) and 149.420(c)(2), as follows:

> … an authorized representative is an individual authorized under state law to provide <u>consent to health care services</u> on behalf of the participant, beneficiary, or enrollee, <u>or to bind the participant, beneficiary, or enrollee to financial obligations,</u> provided that the individual is not a provider affiliated with the facility or an employee of the facility, unless such provider or employee is a family member of the participant, beneficiary, or enrollee. <u>An authorized representative shall include, but is not limited to, any individual who is, or holds himself or herself out to be, a family member, conservator, or agent of the participant, beneficiary, or enrollee.</u>

All Conditions Satisfied

The statute and IFR prohibit the patient from using the notice and consent process to elect to receive care from an out-of-network facility and be balanced billed if they are unable to travel to an in-network facility using nonmedical transportation. If the individual requires medical transportation to travel, including transportation by either ground or air ambulance, the balance billing prohibition continues to apply to post-stabilization services provided in connection with the visit for which the individual received emergency services. However, there are common patient transfer scenarios where the patient may not

satisfy the requirements of the No Surprises Act to receive notice and provide consent, but they still actively choose to receive care from an out-of-network facility. CHA asks the tri-agencies for guidance as to how the Act would apply to the common scenarios discussed below.

Interaction with EMTALA

The IFR does not contemplate a scenario where a health plan enrollee requires emergency services and is initially taken to a hospital that cannot provide the appropriate level of care. In this situation, the patient needs medical transport to another facility. The health plan wants them to go to a participating facility, located within a "reasonable distance" of the patient, that provides the necessary services, but the patient wants to go to a "better" hospital that is out-of-network. Under EMTALA, the "better" out-of-network hospital must accept the patient (if the hospital has capacity/capability). In this relatively common situation, how would the No Surprises Act apply? **In this and similar scenarios where EMTALA applies and the patient actively chooses to receive care for covered services from an out-of-network facility, CHA asks the tri-agencies to confirm that the health plan is still required to follow the No Surprises Act's requirements related to patient cost-sharing and facility payment.**

Affecting Timely Transfers Post-Stabilization

CHA believes a health plan has the responsibility to affect the timely transfer of its members to an in-network hospital once the patient is clinically stable. This responsibility is delineated in California state law Assembly Bill (AB) 1203[21]. AB 1203 requires hospitals to contact an out-of-network patient's health plan once they are stable if additional services are required. Health plans are required to respond within an allotted time frame to either authorize coverage of post-stabilization care or inform the out-of-network hospital that the health plan will arrange for the prompt transfer of the patient to an in-network hospital. If the plan either fails to respond in a timely manner or fails to arrange for a transfer of the patient to an in-network hospital in a timely manner, the health plan is required to pay charges for its members' care. Patient cost-sharing is limited to the in-network amount in these instances for the patient. **CHA encourages the tri-agencies to confirm that, for state regulated plans, AB 1203 would apply for emergency services provided by a hospital instead of the No Surprises Act. Further, we ask the tri-agencies to include a similar requirement for health plans subject to the Act.**

Application of the No Surprises Act When Patient Refuses Transfer to In-Network Facility

CHA asks the tri-agencies to clarify how the prohibition on balance billing applies in the following situation:

> A patient receives emergency care at an out-of-network hospital. The patient's physical condition is stable such that they can be transported to an in-network facility via non-medical transportation, the attending physician determines they are mentally competent to provide consent to receive post-stabilization services, and there is an in-network facility within a "reasonable distance." The patient refuses to be transferred to the in-network facility and to provide consent to be balance billed.

In this situation, CHA recommends that the patient's health plan should be responsible to pay for all services (including post-stabilization services) provided to the patient through discharge.

[21] http://www.leginfo.ca.gov/pub/07-08/bill/asm/ab_1201-1250/ab_1203_bill_20080930_chaptered.html

Notice and Consent Exception to Prohibition on Balance Billing

The IFR establishes detailed requirements for facilities and providers to deliver notice and receive consent from patients to balance bill them in situations where the patient seeks to receive care from an out-of-network provider or facility. CHA is concerned that one of the conditions (discussed further below) that a nonparticipating hospital must satisfy to execute a valid notice is operationally not possible. Further, this requirement conflicts with California law as it relates to nonparticipating physicians providing post-stabilization services to members of state regulated plans. Therefore, in certain situations this requirement — if maintained — precludes both hospitals and physicians from using the notice process to obtain consent from patients who wish to receive post-stabilization services from a facility or provider a health plan has refused to contract with, which is contrary to Congress' intent in the No Surprises Act.

The IFR also allows the patient to revoke consent prior to the start of services. CHA believes that HHS needs to provide additional clarity around when the patient may revoke consent. Further, CHA strongly encourages HHS to reduce the administrative burden related to notifying health plans that the patient has consented to receive (and be balance billed for) services from an out-of-network facility or provider. While CHA appreciates the patient protections provided by allowing the plans to determine when notice was not properly provided and consent to balance bill a patient was not properly received, we ask the agencies to provide additional details for how these disputes should be resolved. And finally, we appreciate HHS' question about ensuring access to specialists for patients whose health plan's network is inadequate.

Below please find CHA's detailed comments on each of these areas.

Standard Notice and Consent Document

The IFR requires facilities and providers to use the standard form created by HHS with only minimal modification. The form must be provided separately from other documents and include such information as: the name of the out-of-network provider or facility, the provider's contact information, a good faith estimate of charges, information on any care management limitations that may be imposed by the patient's health plan/issuer, and the contact information for appropriate state and local agencies to report any potential violations. The notice and consent form must be available in the 15 most common languages spoken in the state or geographic region. In cases where the notice is provided for post-stabilization services by a nonparticipating provider within a participating emergency facility, a list of any participating providers at the facility that are able to furnish the items or services is required. Finally, the regulations require separate signatures at the time the notice was provided and again when consent is given by the patient.

CHA appreciates HHS' efforts to develop a model form. **However, we ask that HHS allow hospitals and providers the flexibility to create and use their own forms as long as these forms contain the core data elements outlined in the IFR.** Our members believe this is necessary so the notice and consent document can be incorporated into existing patient care and administrative workflows. CHA notes that requiring all hospitals subject to the No Surprises Act to translate the notice and consent document into their state or geographic region's 15 most frequently spoken languages creates significant, unnecessary administrative cost for facilities and providers. Therefore, we ask the agency to make translations of the CMS-10780 Standard Notice and Consent document publicly available via an HHS website in the 100

most commonly spoken languages in the United States. This would reduce the overall administrative cost of using the standard notice and consent — thereby encouraging more facilities and providers to do so — and ensure a high-fidelity translation of the original document.

CHA asks HHS to define what "separately" means in the context of when a patient elects to receive their notice and consent document electronically. Typically, when patients complete registration or pre-registration documents electronically, they review multiple individual documents that, after being signed, are then provided in a single electronic (or printed) packet. **CHA believes a process similar to what is described above would still meet the HHS requirement to provide the document "separately," but we ask for further clarification and examples of what would and would not meet the "separately" requirement.**

CMS-CCIIO recently issued FAQs that defer the enforcement date of the good faith estimate requirement for insured individuals who will submit a claim for services to their health plan[22] until implementing regulations can be promogulated. The FAQs state that the enforcement deferral will allow sufficient time for health plans and providers or facilities to develop the information exchange infrastructure necessary to transmit the information related to the good faith estimate. **We thank CMS-CCIIO for understanding the technical information exchange challenges inherent in this requirement and appreciate the deferral of enforcement. CHA asks the tri-agencies to clarify that the enforcement deferral of the good faith estimate requirement provided by the August 20, 2021, CMS-CCIIO FAQs extends to the requirement to include a good faith estimate in the notice and consent.** CHA notes that the patients who will receive the good faith estimate in this instance are insured and intend to submit a claim for services they receive from an out-of-network provider or facility to their health plan for payment. Further, the IFR currently requires the provider or facility to transmit the Notice and Consent form to the health plan.

Specific to the requirement that a hospital provide a patient with a list of in-network providers who practice at the facility, California hospitals do not employ physicians. This is prohibited by California state law (Business and Professions Code section 2400). Therefore, it will not be possible for in-network emergency facilities to include a list of alternative in-network providers at the facility who may provide post-stabilization services to patients. Hospitals currently do not collect this information as part of the credentialing process. Even if they started collecting this information, the administrative burden would be overwhelming, and it would not be possible to ensure the accuracy of any list of in-network providers. As HHS is aware, there is no standard contract renewal date between health plans and providers. And while this could be collected and tracked, that would still not be sufficient to ensure accuracy. Plans and providers terminate contracts before their renewal date frequently and do so for a host of reasons. Conversely, previously nonparticipating plans and providers frequently enter into new contracts, thus changing network participation status.

Even if, despite the significant administrative burden, a hospital established a monthly process to update its participating provider lists, some information would be inaccurate despite a hospital's best efforts. However, the patient's health plan should know with 100% accuracy which providers participate in their networks at any given moment. **Therefore, CHA believes health plans are the most accurate source of information for a patient to determine which providers are in-network.** Further, CHA notes that the

[22] https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-49.pdf

CMS-10780 Standard Notice and Consent form currently has multiple prompts for the patient to contact their health plan to identify in-network providers.

Given the risk of a hospital — despite its best efforts to provide a patient with accurate information on in-network providers who can deliver post-stabilization services — providing a patient with inaccurate information, we ask that HHS replace the requirement that hospitals provide a specific list of providers who participate in the patient's health plan at their facility with a prompt to either call their health plan or consult their health plan's online provider directory. If HHS persists in requiring the in-network hospital to provide this information, we ask that HHS hold hospitals harmless if the information is inaccurate.

Finally, CHA notes that the required CMS-10780 Standard Notice and Consent form includes one signature line. There is not a separate line to capture the patient's signature at the time consent is provided, as currently required. **CHA encourages CMS to correct the standard document by adding a second signature line to capture the patient's consent to be balance billed for services delivered by an out-of-network facility or provider, as is currently required.**

Timing of Notice

The regulations require that a patient receive the notice with the request for their consent to be balance billed at least 72 hours before the service or treatment is to be delivered. For same-day services, the notice must be provided at least three hours prior to receiving the service or treatment. The explanatory text accompanying CMS form-10780 (Standard Notice and Consent form) states that the time required to complete this information collection is estimated to average 1.3 hours per response.

CHA has multiple concerns with requiring a patient who wishes to receive care from an out-of-network facility or provider to wait over four hours (three-hour mandated period plus an additional hour to complete the document) before they can receive the care they require. First, the requirement will interrupt clinical care processes, which could negatively impact patient outcomes and patient satisfaction with their overall process of care. Second, given the current COVID-19 public health emergency and the need for social distancing, CHA questions the wisdom of requiring a patient wishing to receive care from an out-of-network facility or provider to wait unnecessarily at a hospital for at least four hours for care. CHA believes there is an opportunity to balance ensuring that a patient doesn't feel "pressured" to provide consent with the need to not interrupt clinical care for patients who require post-stabilization services. **CHA recommends that after the patient has been educated about their rights under the No Surprises Act, the tri-agencies provide the patient an opportunity to waive the currently required waiting period to receive notice and provide consent.**

Content of Notice

The IFR requires the notice to state that the health care provider furnishing the items or services is a non-participating provider, or that the health care facility furnishing the items or services is a nonparticipating emergency facility, as applicable, with respect to the health plan or coverage. The notice must include the good faith estimated amount that such non-participating provider or non-participating emergency facility may charge the individual for the items and services involved, including any item or service that the non-participating provider reasonably expects to provide in conjunction with such items and services.

Non-participating providers who are delivering this notice are required to provide a good faith estimate for only the items or services that they will furnish and are not required to provide a good faith estimate for items or services furnished by other providers at the facility. **CHA appreciates and strongly supports this provision. Facilities and providers, in most if not all cases, cannot know which other provider(s) (or facilities) are in a given health plan's network or what other nonparticipating providers (or facilities) charge for a service or item that may be provided in conjunction with a visit that is covered under the No Surprises Act.**

Related to post-stabilization services, the IFR requires non-participating emergency facilities to include in the written notice the good faith estimated amount that the patient may be charged for items or services furnished by the non-participating emergency facility or by nonparticipating providers with respect to the visit at such facility (including any item or service that is reasonably expected to be furnished by the nonparticipating emergency facility or nonparticipating providers in conjunction with such items or services). To the extent that the non-participating facility omits from the good faith estimate information about items and services provided by a non-participating provider, the notice and consent criteria will not be considered met for items and services furnished by that provider, and the requirements in 45 CFR 149.410(a) (and the corresponding requirements on plans and issuers) would apply.

CHA strongly objects to the requirement that non-participating emergency facilities provide the notice and consent document, including a good faith estimate for items and services provided by a nonparticipating provider, related to services provided once the patient has been stabilized. First, hospitals do not have access to the charge and network participation information for providers they do not employ. And, as described above, California hospitals are prohibited by California state law from employing physicians. Therefore, hospitals in California do not have access to the charge and network participation information for the physicians who may deliver post-stabilization services in their facility and cannot deliver a good faith estimate and notice and consent on their behalf.

Second, beyond the significant barriers described above, in certain situations California state law prevents hospitals from providing notice and consent on behalf of an out-of-network physician. California Health and Safety Code (HSC) §1371.9 prohibits nonparticipating providers from balance billing patients for non-emergency services. The definition of emergency services at HSC §1317.1 is incorporated into §1371.9 by reference and does not include post-stabilization services.

Like the No Surprises Act, HSC §1371.9 does allow a patient to choose to receive care from an out-of-network physician by consenting to be balance billed. However, HSC §1317.9(c)(2) prohibits a facility from obtaining consent on behalf of the provider. Specifically, HSC §1317.9(c)(2) states:

> *The consent shall be obtained by the noncontracting individual health professional in a document that is separate from the document used to obtain the consent for any other part of the care or procedure. The consent shall not be obtained by the facility or any representative of the facility*[23].

Therefore, in situations where a patient's health plan is regulated by the state and is out-of-network for both the facility and provider delivering post-stabilization services, the IFR sets up a conflict between

[23] Emphasis added.

state and federal law. Currently, the IFR appears to require the non-participating facility to deliver the notice and consent document on behalf of the non-participating provider. However, state law requires that the non-participating provider deliver its own notice and obtain consent for the services provided to a patient who wishes to receive care from a provider not included in the health plan's network. **Given the operational impediments and conflict with state law in certain circumstances, CHA asks HHS to remove the requirement that non-participating facilities provide notice and obtain consent to balance bill for any non-participating providers who may be involved in delivering post-stabilization services.**

If the tri-agencies persist in requiring non-participating facilities to deliver the notice and consent — including the good faith estimate — on behalf of non-participating providers, **CHA asks that when a non-participating facility omits (due to not having the charge information or network participation status necessary for non-participating providers to complete the good faith estimate as discussed above) a non-participating provider from the good faith estimate, that the requirements in 45 CFR 149.410(a) would only apply to the omitted non-participating provider.** In this scenario, if the patient chooses to receive services from a non-participating facility and provides consent, the facility could balance bill the patient for post-stabilization services delivered. However, the nonparticipating provider(s) omitted from the notice and consent and good faith estimate will not be able to balance bill the patient, as consent was not obtained.

The IFR also requires the notice and consent document to provide information about whether prior authorization or other care management limitations may be required in advance of receiving such items or services at the facility or from the provider. CHA appreciates that HHS recognizes the challenges non-participating facilities and providers will face when trying to identify an out-of-network plan's prior authorization or care management limitation requirements. When a non-participating facility or provider does not have a contract with a health plan, that facility or provider does not have a list of items and services subject to the health plan's care management limitations. **Therefore, we strongly support the provision in the IFR that allows providers and facilities to satisfy this requirement by providing "general information."** CHA believes the "general statement" concerning care management limitations included on CMS-10780 Standard Notice and Consent strikes the right balance between notifying patients about potential care management limitation requirements and the level of detailed information a hospital or provider can offer related to those requirements for an out-of-network plan.

Revocation of Consent

The IFR allows a participant, beneficiary, or enrollee to revoke consent by notifying the provider or facility in writing prior to furnishing the items or services. If an individual revokes consent, the balance billing protections apply to applicable items or services provided after the revocation as if consent was never provided. **CHA agrees with HHS that the option to revoke consent *prior to the initiation of care* is a critical safeguard to ensure that balance billing protections are waived only when individuals knowingly, purposefully, and freely provide informed consent.** We ask that HHS clarify that a patient may only revoke consent if they provide notice of revocation 24 hours prior to the initiation of care. From the perspective of providing safe and effective care, if a patient revokes consent immediately before a service or in the middle of receiving care, it is unlikely that the specialist or facility will (or can) discontinue care and refer the patient to an in-network facility or provider for the services. Given this, CHA is concerned that if a provider or facility schedules (or initiates) care on the good faith belief that it

has received consent to balance bill the patient, and the patient subsequently revokes consent within 24 hours prior to the service, it will limit a provider or facility's willingness to offer nonemergent services to out-of-network patients.

Further, related to multi-stage care processes, many health plans pay for services using methodologies that provide a fixed amount per discharge or case (examples include but are not limited to MS-DRGs or APR-DRGs for inpatient services, and APCs or APGs for outpatient services). In some instances, it may not be possible to segregate the payment (and therefore patient cost-sharing) for the services provided prior to revocation of consent from those services provided after revocation. **If HHS does allow a patient to revoke consent during the middle of a care process, we believe that agency needs to develop a framework for case rate payment methodologies to determine what amount the facility or provider may balance bill the patient for the services provided prior to revocation of consent.**

Requirement to Notify Plan or Issuer

The IFR requires that providers and facilities notify plans/issuers when the balance billing protections apply. **Given that health plans know who participates in their networks and for what services, CHA questions the need for a facility or provider to notify the health plan when the No Surprises Act applies. Not only will the plan know which facilities and providers participate in their network, but the plan will know whether the Act or an applicable state law applies. Therefore, we ask the tri-agencies to reduce facilities' and providers' administrative burdens by eliminating this requirement.** If the tri-agencies do not remove this requirement from the regulations related to the No Surprises Act, we ask the tri-agencies to provide a thorough explanation of why it is necessary for a facility or provider to notify the plan about when the protections of the No Surprises Act (or applicable state law apply).

Additionally, the provider or facility must send a copy of the signed notice and consent document to the plan/issuer. **Given that there isn't a consistently used claims attachment standard, CHA strongly encourages the tri-agencies to rescind the requirement that providers and facilities transmit a copy of the notice and consent form to the health plan. Instead, CMS should create and require the use of a new modifier that indicates services for which the patient received notice, elected to receive care from an out-of-network facility or provider, and provided consent to be balance billed.** Using a modifier will eliminate the real risk that a patient's cost-sharing is miscalculated by the plan when a claim billed electronically is not reconciled to a notice and consent form submitted via the plan's web portal, fax, or mail. We also believe this will reduce the administrative burden on plans, facilities, and providers by eliminating the potential for some plans to require the notice and consent form be sent as an electronic claims attachment, others to require it be sent by web portal or fax, and still others by mail.

Plan or Issuer Believes Notice and Consent Was Not Properly Given

The IFR requires a plan that believes the notice was not properly given and consent received by the facility or provider to apply the cost-sharing and other requirements set forth in the IFR and applicable state law. Plans may reprocess any claims that were not processed consistently with the cost-sharing requirements in the No Surprises Act or applicable state law. **CHA requests the tri-agencies provide examples of what would and would not constitute an appropriate situation for a plan, contrary to a facility or provider's assertion that it has provided a valid notice and received consent to process (or reprocess) a claim under the protections of the No Surprises Act. Further, CHA asks the tri-agencies**

to clarify that plans may not use an improperly delivered notice and consent as the basis to deny payment for services subject to the requirements of the Act.

Surprise Billing Complaints

The No Surprises Act requires a process for the tri-agencies to receive complaints about violations of the QPA requirements by plans and issuers. The IFR extends the process beyond QPA requirements to all the consumer protections and balance billing requirements of the No Surprises Act. In addition, the statute directs the tri-agencies to establish a process to receive consumer complaints regarding violations of the Act by providers, facilities, and providers of air ambulance services.

Under the IFR complaint process, a complaint is defined as a written or oral communication claiming a potential violation by a plan, or by a provider, facility, or provider of air ambulance services. The complaint must include a statement with information about the potential violation sufficient to identify the parties involved and the action or inaction that is the subject of the complaint. It may include information about timing and the state where the violation occurred. The tri-agencies have declined to establish a timeline for filing a complaint in the IFR. **CHA is conceptually supportive of a streamlined complaint process.**

However, we are concerned about the lack of a time frame for filing a complaint. It will be necessary, during the investigation of a complaint, for facilities or providers to submit information to the tri-agencies as part of the discovery process. Without a time limitation on when a complaint can be filed, facilities and providers will be forced to either retain documents indefinitely (which is impractical due to the expense of document maintenance and storage) or risk being unable to respond to a request for documents by the tri-agencies in response to a complaint. The IFR requires non-participating emergency facilities, participating health care facilities, and non-participating providers to retain written notice and consent documents for at least seven years after the date that the item or service was furnished. CHA further notes that it is likely there will be a processing delay between when a complaint is filed and when the enforcing entity requests related documents from a facility, provider, or health plan.

Therefore, CHA strongly recommends the tri-agencies set a five-year time frame for filing a complaint. First, we believe five years is more than sufficient time to allow for filing a complaint. Second, we believe that setting a time period for filing a complaint that is shorter than the document retention period provides the necessary time for the enforcing entity to research the complaint, request documents, and the facility, provider, or plan to retrieve the necessary documents and respond to the request.

Balancing Access to Specialists

HHS seeks comment on striking the appropriate balance between allowing a specialist to refuse to treat an individual unless the specialist can balance bill the individual, while ensuring that the individual is not pressured into waiving the balance billing protections. CHA appreciates HHS' concern about balancing access to specialists while ensuring the patient is not pressured into waiving balance billing protections. **CHA believes that Congress, in drafting the No Surprises Act, has provided robust patient protections that more than adequately ensure that patients are not "pressured" into waiving their protections.** For post-stabilization services, the statute requires that the conditions of EMTALA are satisfied, and the patient is capable of traveling via non-medical transportation to another facility or

provider. The IFR has already gone beyond the statutory language by adding an undefined "reasonable distance requirement" and requiring the attending physician to take into account factors such as a patient's ability to afford non-medical transportation when determining if the patient is capable of providing consent for post-stabilization services. For services provided at an in-network hospital by an out-of-network provider, the statute prohibits the notice and consent process from being used to balance bill the patient for certain ancillary services. Congress' intent in its passage of the No Surprises Act was to protect patients from situations where they did not have a choice of provider. We believe the statute, as written, achieves this goal. Contrary to Congress' clear intent, any attempt by the tri-agencies to further expand the requirements on out-of-network specialists will go beyond protecting patients from balance billing and alter the balance of contract negotiations between health plans and affected specialists in favor of health plans.

Given the comprehensive requirements placed on providers and facilities intended to protect patients from unknowingly (or unwillingly) being balance billed, we do not believe HHS should expand the types of specialists or scenarios where specialists are subject to the requirements of the No Surprises Act related to balance billing. CHA notes that the model Notice and Consent form (CMS-10780) prompts the patient in multiple places to contact their health plan to find an in-network provider. If there is no in-network provider within a reasonable distance of the patient, CHA questions the adequacy of the health plan's network. Given this, if HHS further expands the scenarios or types of specialists where the No Surprises Act's balance billing requirements apply, it will significantly reduce the willingness of specialists who primarily practice in office-based settings from seeing patients in hospital settings. And as an unintended consequence, it will further exacerbate access to care issues — particularly in rural markets and for underserved populations who typically receive care from safety net facilities.

Further, there are select situations where out-of-network providers identified as "ancillary" providers in the No Surprises Act should be able to use the notice and consent process for balance billing purposes. **CHA recommends that, when the primary professional is out of network (e.g., a surgeon), the ancillary providers associated with that primary professional should also be allowed to access the notice and consent process if there is sufficient time to provide notice and obtain consent from the patient.** Any ancillary provider who is not known at the time of scheduling and who was not included in the notice and consent forms would not be permitted to balance bill.

CHA also notes that certain types of providers defined as ancillary in the No Surprises Act frequently deliver the primary service and are chosen by the patient. For example, anesthesiologists perform certain pain management injection procedures. In this situation, they are the primary provider, not an ancillary provider. **Therefore, we ask the tri-agencies to clarify that the ban on balance billing within the specialties outlined in the law only applies when the specialties are ancillary to a primary service and the primary service provider is in-network.**

No Surprises Act Enforcement Discretion

The IFR notes that the tri-agencies considered delaying implementation of the No Surprises Act. The rule reviews the significant issues that must be addressed by multiple stakeholders to justify promulgating implementation rules using an IFR (instead of the normal process of issuing proposed and final rules). The issues identified include:

- There is a short period of time between enactment of the law (December 27, 2020) and the application of its requirements on affected parties (plan years beginning on or after January 1, 2022).
- The law and regulations require plans and issuers to make significant changes in the manner that they pay for items and services subject to cost-sharing and balance billing protections, including claims processing changes.
- Plans and issuers must account for these changes in setting premium or contribution rates; interim final rules permit them to take into account finalized regulations in determining rates and plan offerings.
- Health care facilities and providers, as well as air ambulance providers, must implement the requirements relating to authorized balanced billing for items and services, including notice and consent procedures and requirements for public disclosure of policies.
- States require time to assess the enforcement requirements established under the Act; those states that opt to enforce the requirements may have to update their statutes or regulations.

CHA agrees that all the issues cited above are significant, and we appreciate the tri-agencies crisp articulation of them. Beyond the issues discussed in the IFR, the regulations providing additional, necessary details related to the good faith estimate, advanced EOB, and IDR process remain outstanding[24]. These regulations are anticipated to be released at the earliest — during the third quarter of 2021. **Given the short time frame and paucity of crucial information necessary to operationalize the requirements of the No Surprises Act, CHA does not believe it is possible for plans, providers, facilities, and states to make the necessary changes to their information systems and operational processes to fully comply with the requirements of the No Surprises Act by January 1, 2022.**

We appreciate the tri-agencies' efforts to quickly implement these regulations to protect patients. However, we are concerned that a rushed implementation based on incomplete and misunderstood regulations is contrary to the interests of affected patients and all consumers. For patients directly impacted by the law, a rushed and haphazard implementation will create confusion related to the information that is provided to them and when the protections apply. Further, health plans will pass the costs associated with a rushed implementation (both extraordinary efforts to develop compliant systems and any necessary rework as additional clarity is provided about the implementing regulations) in the form of increased premiums to consumers. **CHA asks the tri-agencies to protect patients from confusion and consumers from higher premiums as a result of the No Surprises Act by providing broad enforcement discretion for all of the No Surprises Act's requirements. Given the need to build complex IT infrastructure to exchange data between health plans, facilities, and providers, we ask that enforcement discretion extend from the law's effective date — January 1, 2022 — until 12 months after all the final rules necessary to implement the Act have been promulgated.**

CHA appreciates the opportunity to offer comments to the tri-agencies on issues related to the No Surprises Act. We look forward to partnering with the tri-agencies and health plans to develop and

[24] CHA's recommendations regarding the IDR process and transparency provisions of the No Surprises Act are available on the CHA website.

implement a regulatory framework that achieves the goals of the No Surprises Act. If you have any questions about the comments, please contact me at (202) 270-2143 or cmulvany@calhospital.org.

Sincerely,
/s/
Chad Mulvany
Vice President, Federal Policy