September 7, 2021

The Honorable Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Attention: CMS-9909-IFC
Baltimore, MD 21244-8016

The Honorable Xavier Becerra, Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

The Honorable Martin Walsh, Secretary
Department of Labor
200 Constitution Ave, NW
Washington, DC 20210

The Honorable Janet Yellen, Secretary
Department of Treasury
1500 Pennsylvania Avenue, NW
Washington, D.C. 20220

The Honorable Kiran Ahuja, Director
Office of Personnel Management
1900 E Street, NW
Washington, DC 20415

Submitted via Regulations.gov

RE: CMS-9909-IFC- Requirements Related to Surprise Billing; Part I

Dear Administrator Brooks-LaSure, Secretary Becerra, Secretary Walsh, Secretary Yellen, and Director Ahuja:

We, the undersigned organizations representing patients, consumers, and workers appreciate the opportunity to provide comments on the Interim Final Rule on “Requirements Related to Surprise Billing; Part I” (IFR) as released by the Office of Personnel Management; Internal Revenue Service; Employee Benefits Security Administration; and Centers for Medicare & Medicaid Services (the Departments). We thank the Biden Administration for their work on this IFR that builds upon the landmark passage of the No Surprises Act, and for finally protecting consumers from the harmful and unfair practice of out-of-network balance billing.

We support the broad objectives of the No Surprises Act and the IFR, which will end the egregious practice of surprise billing in many situations. Out-of-network balance billing has plagued consumers for decades and has left families on the hook for hundreds, thousands, and tens of thousands of dollars for bills they did not have reason to expect and are often unable to pay.\(^1\)\(^2\) There is also strong evidence that the abusive practice of balance billing has contributed to higher premiums and health care costs for

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everyone with commercial insurance, and it is well-documented that private equity owned provider groups and facilities have used surprise billing as a business model to keep costs high. If implemented well, this law will go a long way in providing families with the financial security they need, and will make important strides toward reining in industry abuses that lead to inflationary health care costs.

**Overall Considerations**

The July IFR is a positive step towards ending surprise medical billing, and we are grateful to the Departments for their work drafting these regulations. The IFR contains important provisions around overall scope of consumer protections, reaffirming what is set in the statute. As of January 1, 2022, consumers will be held harmless from out-of-network balance bills where they are most likely to receive them, including emergency situations, many situations when they are receiving non-emergency care in-network facilities, and in air ambulances. In these instances, consumers will only be responsible for the cost-sharing they would have paid had the provider been in-network.

This IFR also builds upon the statute’s groundwork fleshing out the Qualifying Payment Amount (QPA). The QPA is integral to how much patients owe in cost-sharing for out-of-network services and is based on the insurer’s historical median in-network rate for the relevant services. We support the Departments’ efforts around the calculation of the QPA, which is on track with recommendations from consumer stakeholders to ensure the QPA is an accurate and fair representation of the median in-network rate. Ensuring consumers’ interests are centered in the methodology to calculate the QPA and that the QPA is the primary consideration in resolving disputes between insurers and providers is critical, particularly as the Departments release subsequent rulemaking to implement the No Surprises Act.

As detailed further in this letter, to uphold the intent of the No Surprises statute, the Departments must ensure notice and consent regulations are designed to protect consumers and do not allow any loopholes for non-emergency providers to balance bill. Additionally, the complaints process must ensure an equitable and transparent experience for consumers, and consumers must have access to assistance to navigate the new protections.

The recommendations in this comment letter are critical to ensuring that consumers are meaningfully protected from out-of-network balance bills. We ask that these comments, and all supportive citations referenced herein, be incorporated into the administrative record in their entirety. Our comments focus on the following areas of the interim final rule, as outlined in the preamble:

- Section III.B.1 Scope of the New Surprise Billing Protections
  - Section III.B.1.ii Post-Stabilization Services
  - Section III.B.1.iv Health Care Facilities
  - Section III.B.1.v Items and Services within the Scope of a Visit

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• Section III.B.2. Determination of the Cost-Sharing Amount and Payment Amount to Providers and Facilities
  o Section III.B.2.ii Cost Sharing
  o Section III.B.2.iv. Specified State Law
  o Section III.B.2.vi. Methodology for Calculating the Qualifying Payment Amount
• Section III.B.3. Additional Plan and Issuer Requirements Regarding Making Initial Payments or Providing a Notice of Denial
• Section III.B.4. Surprise Billing Complaints Regarding Group Health Plans and Health Insurance Issuers; Section IV.A.4. Surprise Billing Complaints Regarding Health Care Providers, Facilities, and Providers of Air Ambulance Services
• Section IV.A.2. Notice and Consent Exception to Prohibition on Balance Billing
  o Section IV.A.2.i Standards for Notice
  o Section IV.A.2.ii. Standards for Consent
  o Section IV.A.2.iv. Exceptions to the Availability of Notice and Consent
• Section IV.A.3. Provider and Facility Disclosure Requirements Regarding Patient Protections against Balance Billing
  o Section IV.A.3.i. Content of Disclosure
  o Sections IV.A.3.ii-iii. Methods of Disclosure and Timing of Disclosure to Individuals
• Section VII.D.5. Economic Impact and Paperwork Burden: Information Collection Requirements Regarding Complaints Process for Surprise Medical Bills (45 CFR 149.150, 45 CFR 149.450)

We will also use this comment opportunity to look ahead to the administration’s future rulemaking on the No Surprises Act, particularly around the independent dispute resolution (IDR) process, which will have significant implications for health care costs and consumers.

**Section III.B.1. Scope of the New Surprise Billing Protections**

**Section III.B.1.ii Post-Stabilization Services**

‘Post-Stabilization Services’ and ‘Reasonable Travel Distance’

The No Surprises Act protects post-stabilization services, including observation stays, until a patient is reasonably able to travel to a participating provider using non-medical transportation, and is in a condition to make judgements and provide notice and consent. Post-stabilization services including observation stays are defined as emergency services, and therefore are protected under the No Surprises Act. The IFR seeks comment on factors to consider in determining whether a patient is able to travel and provide consent. It proposes factors in the preamble, but does not yet include them in the regulation itself.

We appreciate the opportunity to comment on the definition of “reasonable travel distance,” as it is important to ensure consumers do not have to surmount unreasonable burdens in order to seek out in-network medical care. We recommend the Departments **consider the following factors, at a minimum, in determining reasonable travel distance**: travel length in miles, travel duration in minutes (including by public transportation), traffic congestion, natural barriers, and access to safe and timely modes of transportation. **We recommend the Departments:**
• Adopt maximum travel standards no greater than those used to determine network adequacy in Medicare Advantage plans. We recommend setting shorter travel time and distance standards than Medicare Advantage currently requires for inpatient services in rural areas, since transferring may create an unreasonable burden given the patient’s condition or family circumstances, and adding a distance standard for dialysis facilities. Ensure that state network adequacy laws with stronger travel time and distance standards take precedence.

• Ensure that existing definitions of reasonable travel time are adapted to take into account “pertinent factors” such as adverse natural barriers.6

• Ensure the transferring facility or provider be assigned responsibility for assisting or making travel arrangements, unless the patient elects otherwise.

Additionally, patient-specific factors, particularly disability and access to affordable, safe, and timely modes of transportation, should be considered. Notably, studies show that persons with disabilities experience longer travel times to receive medical care, despite traveling similar distances and having similar access to private vehicles.7 People with disabilities also often have elevated need for out-of-network access because in-network providers may not have physically accessible facilities or have experience treating people with that disability.

We recommend the Departments define travel as unreasonable if such travel would require a patient to cross state lines, particularly if a patient would lose protections under their state’s law by doing so.

We support the requirements that the treating provider must determine the patient’s ability to travel to a participating provider, given the individual’s medical condition; and must determine the patient’s condition to receive notice and give informed consent (or not) to out-of-network services. We also strongly support consideration of factors including the individual’s state of mind, and any conditions including substance use and cultural and contextual factors that may be impairing their ability to consent. These factors are named in the preamble, but not in the regulations. We recommend that the Departments:

• Require at least 24-hour advance notice of a post-stabilization transfer.
• Add examples to the regulation itself at 42 CFR 149.410 that reflect the factors described in the preamble.
• Develop model notices specific to patient transfers that must be signed by the provider and include information about how to file a complaint regarding a transfer or discharge with which the patient disagrees, and how to get help, including from a health consumer assistance program. Treating providers who are out-of-network will have an inherent conflict of interest in making these determinations so we are also recommending access to an expedited complaints process for patients to contest inappropriate transfers.
• Provide that consumers can request and receive a second opinion if the facility recommends transfer and the patient disagrees. The cost of the second opinion should also be treated as an emergency service, covered by the No Surprises Act.

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• Assign responsibility to the treating facility for coordinating the transfer, including assisting the patient as needed in securing transportation, ensuring a timely appointment with an in-network provider, and transferring records.
• Collect data on the number of transfers by diagnosis, provider type, and facility that will enable HHS, states, and the public to monitor whether these protections are sufficient.

Section III.B.1.iv Health Care Facilities

‘Health Care Facilities’

The statute provides protections against surprise billing for non-emergency services furnished at “participating health facilities.” The statute specifies that protections apply to hospitals, hospital outpatient facilities, and ambulatory surgical centers, and invites the agencies to define other facilities to which protections apply. The Departments specifically seek comments on urgent care centers. **We support inclusion of urgent care centers in the definition, and also recommend inclusion of other types of health facilities.**

We support the Departments’ efforts to include a number of facilities in the definition of “participating health facilities.” **However, we highly recommend that the Departments include “urgent care centers” in the definition of “health care facilities”**. The use of urgent care facilities by families seeking care has grown over the years. 8, 9, 10, 11, 12 In fact, in 2018, urgent care clinics handled almost 15% of all outpatient physician visits, and they have taken on a growing role as an alternative to emergency rooms. 13 Children also rely heavily on the use of urgent care facilities in order to receive health services. In 2019, more than 25% of children had one or more visits to an urgent care center or retail health clinic in the past 12 months. 14 America’s families are increasingly dependent on urgent care facilities to receive acute and primary care. Urgent care facilities often surprise bill their patients 15, making urgent care facilities a potential site for abusive surprise billing practices to continue. Not including urgent care centers and retail clinics in the definition of health care facilities would undermine the *No Surprises* law and Congress’s intent to protect consumers from surprise billing.

**We also urge the Departments to include a definition for urgent care centers that encompasses their offered services.** Individual state governments and health departments across the United States have

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different definitions for urgent care centers, and the lack of a consistent definition may cause confusion for consumers and providers alike. **We recommend that the Departments use the following definition:** “a medical facility that is dedicated to the delivery of unscheduled, walk-in, ambulatory care, for acute illnesses or minor traumas, outside of a hospital emergency department, free-standing clinic or physician’s office.” This can include a facility that delivers this care without the intention of developing an ongoing care relationship between the licensed provider and the patient.

**We also recommend including retail clinics in the definition of emergency care, as well as adding other types of facilities at which at least one treating provider is in-network for the patient to the list of covered facilities for non-emergency care.** The *No Surprises Act* also applies to non-emergency care. It is critical that the rule is applied to all types of health care facilities in which patients use in-network services and may be unaware that some of their associated providers are out-of-network. These include: labs; imaging facilities; dental clinics; rehabilitation/physical therapy clinics; dialysis centers; hospice facilities; birth centers; behavioral health and addiction treatment facilities; short term nursing/rehabilitation facilities; orthopedic centers; clinics. Consumers are increasingly turning to “immediate and primary care” clinics, retail clinics, and other clinics as a source of regular health care. A 2018 survey found that 90% of retail clinic users were commercially insured, making retail clinics a significant source of care amongst commercially-insured individuals.\(^{16}\) Ensuring that the *No Surprises Act* protections apply to these types of facilities will relieve consumers from the burden of trying to figure out from which facilities they can seek out medical services, without the fear of being balance billed.

**Section III.B.1.v Items and Services within the Scope of a Visit**

**Definitions of Providers and Types of Visits**

We support the Departments’ efforts to include "equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services, regardless of whether the provider furnishing such items or services is at the facility” as a part of the Departments’ definition of a “visit”.

**Section III.B.2. Determination of the Cost-Sharing Amount and Payment Amount to Providers and Facilities**

**Section III.B.2.i Cost Sharing**

We support the Departments’ determination of patient cost-sharing responsibilities under the law as being determined by the lesser of “(1) an amount determined by an applicable All-Payer Model Agreement under section 1115A of the Social Security Act; (2) if there is no such applicable All-Payer Model Agreement, an amount determined by a specified state law; or (3) if there is no such applicable All-Payer Model Agreement or specified state law, the lesser of the billed charge or the plan’s or issuer’s median contracted rate, referred to as the qualifying payment amount (QPA).” However, in the case that the out-of-network billed charge is lower than the QPA, and the provider has already collected the patient’s cost-sharing amount, **the Departments should require the out-of-network provider to send a corrected bill or refund the overpaid charges within a timely manner (e.g. 10 business days).**

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The IFR requires that plans and issuers base any coinsurance and deductible for air ambulance services provided by a nonparticipating provider on the lesser of the QPA or the billed amount. Given that the QPA is based on median contracted rates, it is important to note that very few air ambulances are actually in-network.\(^\text{17}\) Furthermore, the air ambulance market is highly concentrated, meaning that negotiated rates are even more inflated by their outsized market power.\(^\text{18}\) For these reasons, we urge the Departments to base any cost-sharing calculations on Medicare rates for this service.

Section III.B.2.iv. Interaction with State Law

The preamble suggests a number of scenarios in which a health insurer or plan who is not otherwise subject to a state law concerning balance billing might opt into the state’s law and procedures instead of into the federal system where state law permits such opt-in. While we support the concept of opting into state laws that offer equal or greater consumer protection, we urge HHS to develop strong procedures to compare the protections each state law offers with federal protections, to regularly review and update its database of state laws, and to publicly post its analysis of what state laws are and are not preempted. Additionally, any instance of opt-in must ensure that patients receive at least the federal standard of protections under the law. This information will also be critical to protecting rights of individuals covered under state-regulated plans who may need to avail themselves of stronger protections under either state or federal law, as applicable.

Section III.B.2.vi Methodology for Calculating the Qualifying Payment Amount

Definition of ‘Qualifying Payment Amount’

We strongly support the Departments’ definition of the Qualifying Payment Amount (QPA) as the median of the contracted rates recognized by the plan or issuer on January 31, 2019, for the same or similar item or service that is provided by a provider in the same or similar specialty and provided in a geographic region in which the item or service is furnished, increased for inflation. We also strongly support the Departments’ intent to minimize the usage of alternative methodologies to calculate the QPA, when possible. Both of these are clearly based on the specific direction of the No Surprises Act’s statutory language.

Definition of ‘Geographic Regions’

We strongly support the Departments’ definition of ‘geographic regions’ to be generally defined as “one region for each metropolitan statistical area (MSA) in a state and one region consisting of all other portions of the state.” We appreciate that the Departments seek to minimize instances in which a plan or issuer lack sufficient information to calculate the median of contracted rates in a particular geographic region, and also to limit the instances in which a plan or issuer has only the minimum amount of information to meet the sufficient information standard. In keeping the geographic region


broad, the Departments are also ensuring that the QPA calculation is not skewed by smaller regions with higher prices.

**Consolidation’s Impact on Prices**

The Departments seek comment as to the impact of large consolidated health care systems on contracted rates, and the impact of such contracted rates on prices and the QPA. We share the Departments’ concerns that health care consolidation could have significant impacts on contracted rates.

Highly consolidated health care markets are proven to result in high and increasing prices across most of the nation.\(^\text{19,20}\) Due to lack of effective government intervention to preserve competitive health care markets, hospitals and health systems have amassed a disproportionately large share of market power, resulting in consumer harm from health care prices that are determined by monopolistic market dynamics. In fact, there are few competitive health care markets left in the country. Ninety percent of metropolitan statistical areas (MSAs) have highly concentrated hospital markets and 65% of MSAs have highly concentrated specialist physician markets.\(^\text{21}\) These highly concentrated markets contribute directly to higher prices paid by consumers. An economic study found that patients who stay in hospitals that face no competition can expect to receive bills that are, on average, $1,900 greater than if they were to stay at a hospital that faces competition from four or more hospitals.\(^\text{22}\)

Hospital markets have continued to consolidate throughout the COVID-19 pandemic, posing an ongoing threat to fairly distributed market prices.\(^\text{23}\)

We strongly support the IFR’s current methodology of treating individual contracts as separate values in order to calculate the median in-network rate. We believe that this approach will work to reduce the inflation of prices that will negatively impact consumers when the QPA is calculated. We recognize that this calculation methodology may offer an opportunity for bad actors to game the system by agreeing to multiple individual contracts in order to falsely inflate the QPA calculation. To this end, the Departments should ensure that contracts and networks are monitored by state insurance regulators to weed out bad actors in this scenario.

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The Departments can take further action to combat the effects of consolidation by implementing a slightly different methodology when accounting for consolidated systems. In the case that a plan has multiple contracts with different providers housed under a single parent system, the Departments should direct plans to treat these multiple contracts within the same parent system, as a single contract when calculating the QPA. This could be calculated by the taking the mean of the contracts, and using that mean as a single value in the median calculation for QPA. This method would reduce the impact of a consolidated system’s unfair market power.

We want to also make clear that these recommendations will not address the underlying cause of high health care prices, and urge the Administration to take action to regulate and monitor hospital consolidation in the health care market.

**Section III.B.3. Additional Plan and Issuer Requirements Regarding Making Initial Payments or Providing a Notice of Denial**

*Minimum Initial Payments Pre-Arbitration*

The No Surprises Act requires plans to make an initial payment to the provider after the claim has been submitted. However, the statute does not specify what this minimum payment amount is, or a calculation to dictate this amount. The Departments are seeking comment on whether to establish a set amount for the minimum initial payment.

We believe it is critical for the Departments to establish a minimum initial payment in order to limit the number of cases that go to arbitration. As mentioned by the Departments in the IFR, certain states like Colorado and Washington, which have established minimum initial payments, have seen a lower number of cases resulting in arbitration compared to states that have loose or nonexistent initial payment requirements. 25 We recommend that the Departments establish a minimum initial payment that is aligned with the tri-agencies’ minimum initial payment set forth in the Patient Protection and Affordable Care Act (PPACA) regulations. 26 The rule set forth by HHS, DOL, and Treasury states that payments by plans to out-of-network providers or facilities should be the greatest of: (1) the median amount the plan or insurer has negotiated with in-network providers for the furnished service in the same geographic region; (2) the amount for the emergency service calculated using the same method the plan or insurer generally uses to determine payments for out-of-network services (such as, the usual, customary, and reasonable amount) for the furnished service in the same geographic region; or (3) the amount that would be paid under Medicare for the furnished service in the same geographic region. 27

In the case of arbitration, we are mindful that setting a minimum initial payment might lead to the creation of an artificial price “floor”. This “floor” could be used to put untenable upward pressure on arbitration negotiations, creating falsely inflated prices, resulting in higher health care costs eventually shouldered by consumers. Therefore, we support the minimum initial payment standard outlined above.

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26 3 See 45 C.F.R. § 147.138(b)(3).

27 Ibid.
but recommend the Departments explicitly state in future rulemaking, that the arbiter of the IDR process should be banned from considering the minimum initial payment, and not use the minimum payment limit as a “floor” or starting point, for determining final rates. Furthermore, in the case that the arbitration award is lower than the minimum initial payment, providers should be required to pay back the difference in price within a certain amount of time. Penalties should be instated if providers do not make these payments in a timely fashion, with similar requirements placed on plans during the pre-arbitration payment stage.


Complaints Process

The statute directs the agencies to establish a complaints process regarding violations of QPA requirements by plans and issuers offering group or individual coverage. We strongly support the agencies’ proposals, described in Sections III.B.4. and IV.A.4. of the preamble to the IFR to establish a process to also receive complaints regarding violations of all other consumer protections regarding balance billing. **We recommend further specificity concerning a unified and transparent complaints process regarding violations by health care plans, providers, facilities, and providers of air ambulance services of balance billing requirements.**

It is critical that the Departments establish an equitable, transparent, and meaningful complaint system to contest balance billing violations. The goal of such a system should be to protect consumers, alert federal oversight of problems, and to increase transparency in the health care system. While the Departments outline positive steps through this IFR, we are concerned that the process outlined falls short in specifying a transparent complaint tracking system that enables consumers and regulators to track the complaint through final resolution, establishing a timeline to resolution, and providing for consumer assistance through the complaint process. **Additionally, we recommend that the Departments specify that federal external appeal rights apply to denials and mispayments of surprise bills as the statute requires.** Without this provision, consumers in grandfathered plans who are not subject to the No Surprises Act and forthcoming regulations may not have appeal rights; and other consumers may find that they can only appeal matters of medical necessity and not denial of in-network coverage.28 We offer the below recommendations:

**Robust Complaint System**

As we note in our comment regarding the economic impact statement, this IFR underestimates the cost of running an effective complaints system. **We recommend that the IFR estimates be updated and that ample resources be devoted to building and running an effective, responsive complaints system that helps resolve consumer problems and informs federal oversight, including monitoring of state enforcement.**

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28 The agencies should consider a number of improvements in external appeal regulations to provide that the external review applies to all adverse benefit determinations; that the plan and issuer denial notices be provided in non-English languages. External review entities should be hired by governmental agencies, not by health plans/issuers. Denial notices must include complete information about the service subject to the adverse benefit determination, including the applicable billing and diagnosis codes, as was provided in the 2010 federal appeals regulation.
Minimizing the Burden for Consumers

We support the intent of minimizing the burden of filing a complaint and simplifying the filing process for consumers by allowing an oral or written statement to be submitted as the complaint. We also support the Departments’ assessment that only minimum necessary information is needed to open a complaint. Consumers should have a low threshold to enter this process to make it more likely they will report complaints and violations as they occur. The Consumer Financial Protection Bureau (CFPB) has a robust consumer complaints process that should serve as a model for the agencies. The Departments should also establish an online system for accepting complaints that is modeled after the CFPB consumer complaint system. The system should have the following capabilities: ease of navigation to file a complaint; logical drop-down menus for efficient use by consumers; provides space for consumers to include narrative descriptions or additional details regarding the complaint. The system should also have the capability to accept complaints by phone and by mail. Web information on the complaint process should be available in at least 15 languages and in languages spoken by 10 percent or more of a population in a given state, consistent with other CMS guidance on language access, and in all languages by phone. We recommend that HHS investigate and track each complaint to its resolution and inform consumers of the outcome.

The Departments should clarify that HHS can request additional information from the plan/issuer and the provider/facility to facilitate in the complaint investigation and review process, and that consumers are not responsible for providing information for the investigation that could be obtained from the plan or provider. For example, it would be burdensome on a consumer to make them responsible for finding and submitting the summary plan description involved in a dispute.

We strongly recommend that the rules:
- Provide a deadline for resolution of complaints, including an expedited timeline for complaints that allege that a patient is inappropriately pressured to transfer to receive in-network emergency or post-stabilization care;
- Require suspension of billing and debt collection and credit reporting while a dispute is pending;
- Link to enforcement processes that address both plan and provider responsibilities.

We are concerned that the rulemaking sets a 60-day timeline for the government to acknowledge a complaint, but fails to establish a timeline for when an investigation should begin or conclude. We suggest that the process provide, for example, two days for initial processing and posting of a complaint (and two hours or sooner depending on medical exigencies in the case of a contested post-stabilization transfer); prompt forwarding to the party subject to the complaint; two business days for the provider, plan or facility to respond (sooner in an emergency), and in the event this does not resolve the complaint a timeline to final resolution through an entity that is hearing appeals that is similar to that provided for external review of health insurance claims (e.g., 45 days with an expedited process for emergency claims including post-stabilization transfers). When HHS refers a complaint to a state regulatory authority, this same deadline must also apply, and HHS must track the response of state regulatory authorities on all complaints that it refers.

The IFR does not delineate what happens to bills during the complaint process.

**We strongly recommend that payment and debt collection, and any associated interest on a bill, be suspended while a complaint is under investigation.** We recommend that upon filing the complaint, consumers receive a "receipt" that affirms they filed the complaint and explains their rights under the "disputed" bill protections that pauses debt collection and credit reporting. Upon resolution, the time interval of the complaints process shall not toll against any payment/collection timelines.

The Departments request feedback on whether a time limit of 90 or 180 days should be imposed for consumers or their representatives to file a complaint after being made aware of the alleged violation. **We recommend the agencies do not institute a time limit for consumers or their representatives.** Consumers often receive a first bill for a service many months after the service was initially delivered, or first become aware of their liability for a medical debt belatedly when a hospital assistance program or an accident policy does not pay for their care. 30

**‘No Wrong Door’ and Investigating Complaints**

Another key piece of an effective complaints process is that consumers have adequate communication from the entity responsible for complaints in a timely matter. **Guidance on assisting consumers must include a “no wrong door” policy to enable consumers to get the help they need regardless of the status or licensure of the provider or plan involved in the payment dispute.** Even when complaints are referred elsewhere for enforcement, for example, to the state with primary enforcement responsibility, we recommend that the IFR require the originating agency to respond to the complaint and report back to HHS on the resolution. Further, complaint systems regarding health plans and regarding providers and facilities must be integrated. Consumers will not always know whether their problem is with their health plan or with their provider, and the records regarding a given complaint should be centralized and tracked.

It is very important for the agencies to follow up on every complaint. As CFPB does, the Departments should notify the party against whom the complaint was filed and require that party to respond to the Departments. Additionally, the complaint should be forwarded to the state enforcing agency and/or medical board, so state regulators can properly track and respond where they have jurisdiction.

**Aggregated Complaints Database**

We support the Departments’ efforts to notify the complainant of the outcome of any investigation or enforcement actions, including an explanation of findings, resolution, or any corrective action taken. **Importantly, we urge the Departments to go further by tracking all complaints in a database, and note when a provider, facility, plan, or issuer do not acknowledge the complaint or when a state enforcement agency does not respond to the referral.** Consumer complaints should be aggregated in a database and publicly reported by the agencies so that repeat offenders of egregious balance billing are easily identifiable.

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Role of Consumer Assistance Programs

Consumers must have access to assistance to navigate the complaints process and their protections. Consumer assistance programs (CAPs) were federally established under Section 1002 of the Affordable Care Act (Section 2793 of the Public Health Service Act) as independent offices that coordinate with regulators to respond to consumer inquiries and complaints, assist consumers with filing appeals, track problems, and educate consumers about their rights and responsibilities.

We urge the Departments to give CAPs a formal role in the complaints process, and to fund and empower them to do so. The formal role of CAPs should include:

- Providing outreach to consumers about their rights under the law;
- Assisting consumers in filing complaints and appeals about surprise bills;
- Assisting consumers to compare good faith estimates of out-of-network charges to their likely in-network costs for those services;
- Assisting consumers to contest the notice and consent process when, for example, there is evidence that emergency and post-stabilization protections should continue;
- Assisting consumers in pursuing arrangements for their plans to pay for out-of-network services if in-network care is not reasonably available;
- Reporting to states, federal agencies and the public about problems that consumers encounter, helping to identify patterns by bad actors. Rules should require agencies and plans to accept complaints filed by CAPs on behalf of consumers, and to communicate back to CAPs regarding the status of those complaints. CAPs should be listed as a resource on all consent forms.

Congress has not appropriated federal funding for CAPs in recent years resulting in programs that have not received grant funding since 2014. In several states where CAPs have continued with state funding, they have achieved tremendous successes, saving consumers significant amounts of money; helping consumers obtain needed medications, psychiatric services, and other medical care; and contesting wrongful charges for COVID-19 care and for balance billing. However, the majority of states currently have no CAP to assist consumers in asserting their rights under federal and state law, and no CAPs are adequately funded to assist the large number of consumers who stand to benefit from the new federal surprise billing protections. Separately we are urging Congress to adequately fund CAPs in 2022 and ensure that there is stable funding going forward. In the short term, we urge the Administration to dedicate a portion of implementation funding appropriated by No Surprises Act to CAPs for specific purpose of building capacity to help consumers with surprise billing problems and reporting to HHS on consumer experiences and outcomes.

Section IV.A.2. Notice and Consent Exception to Prohibition on Balance Billing

This section establishes the requirements for providers seeking exemption from the balance billing protections. It is imperative that these exceptions be applied narrowly and do not create a loophole that improperly waives patient protections.

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31 C Fish-Parcham and E. Benjamin, “Congress Should Appropriate Funds for Consumer Assistance Programs in Every State,” Families USA and Community Service Society of New York, July 2021.

It is critical that the notices to patients are presented in a manner that is non-coercive, clear, and accessible so that patients can make informed decisions about their preferred provider. Several of the undersigned organizations commented on the model notice and consent form that the Departments published with the July 13 IFR. We urge the Departments to review and consider adopting those recommendations.33

Section IV.A.2.i Standards for Notice

Provider Signature on Notice

We strongly recommend that the provider or facility be required to sign and acknowledge the notice and consent form. The provider or facility's signature would certify that the cost estimates provided were made in good faith. In addition, in the event the good faith estimate turns out to be wildly different from the actual charges, the patient should have access to the IDR process to review the reasonableness of charges. The provider should be required to submit the signed waiver to the health plan along with the provider's bill. In cases where the provider is not billing, e.g., a closed-network health plan, rules should provide a deadline that will enable insurers to match forms to claims.

We support the Departments’ efforts to reduce unnecessary duplication, however including all applicable treatments on one notice and consent form would confuse consumers. Consumers will be less likely to agree to single providers or services if the disclosure notice includes all services for which they could be balanced billed while eschewing care from other to the consumer’s discretion. We strongly recommend that each provider be required to submit a separate notice to consumers to avoid any confusion.

Timing of Notice

The statute puts forth that consent to out-of-network care can only be given 72 hours in advance of the scheduled appointment. In the rulemaking, the Departments also established that in instances where the appointment occurs less than 72 hours after scheduling, notice and consent can be given on the same day as the appointment was made and must be given at least 3 hours in advance of the appointment itself. While the Departments intend for the 3-hour restriction to help ensure that consent is truly voluntary and help avoid a patient feeling pressure to sign away their rights, we see this 3-hour rule as ripe for abuse. We urge the Departments to clarify that providers can only seek consent if the patient contacted the provider and sought treatment before being admitted to the facility. There could perhaps be a narrow and distinct exceptions process for patients to seek out of network care after being admitted. For example, if post-admission, a patient wants a second opinion from a particular out-of-network provider, the patient could initiate this process; a distinct consent form should be developed for this, indicating that the patient is seeking the care and explaining when rights to in-network rates (such as through a single case agreement) might apply.

No Surprises Act protections should apply if a patient does not consent, if there are no in-network providers within the facility for emergency care, if there are no in-network providers for a non-

emergency service within reasonable travel distance, and if a complaint regarding a post-stabilization transfer is pending.

Section IV.A.2.ii. Standards for Consent

Post Stabilization Services

We support the statute’s and the Departments’ inclusion of observation stays as part of the emergency visit.

We recommend the Departments acknowledge the potential conflict of interest for the treating provider to assess a patient’s ability to provide informed consent. Out-of-network providers would have an incentive to find a patient’s medical condition to be suitable to provide consent. Patients, and their advocates and representatives, should therefore have access to an expedited complaints process and a second opinion if they believe a transfer is inappropriate. We strongly support the Departments’ assertion that “the individual should be involved in the decision-making process, if possible” and recommend that the provider be required to provide documentation regarding the patient’s medical condition, fitness to transfer, and the extent to which the individual had a say in the decision.

In order to ensure that the consumer experience with the consent form provides optimal protection, we recommend that health care facilities be obligated to assist the patient with contacting the plan to find in-network alternatives in the event that the patient needs to transfer. We strongly suggest removing the burden for consumers to initiate contact with their plans.

We support standards that classify patients experiencing severe pain, intoxication, incapacitation, and dementia as incapable of giving informed consent. We also recommend considering patients who are still experiencing effects of all forms of substance use incapable of giving informed consent. In addition, the standard should classify patients with medical conditions that affect a patient’s ability to make judgements or communicate as ineligible to give informed consent.

Finally, we support including the coordination of care transitions under the definition of emergency services. We recommend that patients receive a minimum of 24 hours advance notice of a transfer so that adequate arrangements can be made. Additionally, the Departments should specify that treating providers must furnish records of the immediate treatment to the patient and be available to discuss the patient with the new provider, if requested. Providers should also be required to transfer any applicable records about the patient’s medical history, for example their medication regiment and coexisting conditions.

Section IV.A.2.iv. Exceptions to the Availability of Notice and Consent

Meaningful Choice of Provider and Specialties Exempt from Notice and Consent

The No Surprises Act identifies certain ancillary services that are exempt from the notice and consent provisions and where patients cannot waive their balance billing protections. We recommend adding an exception to the notice and consent process to guarantee that people who do not have a meaningful choice of provider will not be subject to out-of-network charges. The Departments can look at Texas language under 28 TAC § 21.4903 as an example of this sort of “meaningful choice” protection.
Additionally, notice and consent should only be allowed for out-of-network providers with whom patients schedule care prior to admission at a facility.

We strongly recommend that the Departments include exempt providers furnishing inpatient mental health services, cardiology services, and rehabilitative services from notice and consent if a patient has not purposefully scheduled with them in advance of admission or unless the patients themselves initiated a request for a second opinion from an out-of-network specialist. Research from the Kaiser Family Foundation shows that admissions for psychological or substance abuse care have higher likelihood to include an out-of-network claim than admissions for physical conditions. We also recommend that the Departments not exclude any advanced diagnostic labs from No Surprises Act protections given that radiology accounts for 22.6% of out-of-network charges.

Section IV.A.3. Provider and Facility Disclosure Requirements Regarding Patient Protections against Balance Billing

Section IV.A.3.i. Content of Disclosure

Model Disclosure Notice

This section gives directives on the content of the required disclosures for patients. It is crucial that these disclosures give consumers a clear picture of their protections and rights under the law. Several of the undersigned organizations commented on the model disclosure notice that the Departments published with the July 1 IFR. We urge the Departments to review and consider adopting those recommendations.

We recommend that the notice must include information on the complaints process and for CAPs so that consumers have a clear picture of where to go for help understanding their rights or for contesting a balance bill.

Sections IV.A.3.ii-iii. Methods of Disclosure and Timing of Disclosure to Individuals

We recommend requiring the disclosure notice to be shared with patients at the time of scheduling, on their Explanation of Benefits (EOB), and with every patient bill for out-of-network emergency services and for out-of-network in-facility services. In addition to providers and insurers, we urge the Departments to require medical bill collectors to distribute the full model disclosure notice.

For all emergency services and in-facility services, both provider bills and health plan EOBs should include brief, specific information tied to the actual billed or claimed amount, e.g., “This is a bill for emergency services. The most that you can be required to pay is xx. If you have concerns about the

36 Ibid.
amount of this bill or how this claim is handled, you can contact the Surprise Medical Bill complaints program at ... or your state consumer assistance program at ...” Similarly, for other care in an applicable facility, the EOB should clearly explain the specific amount an out-of-network provider is allowed to bill a consumer who has not provided advance consent for out-of-network care.

Full information about all consumer protections and model notices under the No Surprises Act, along with links to the complaint process and relevant enforcement agencies, should be posted on the plan’s website.

VII.D.5 Economic Impact and Paperwork Burden: Information Collection Requirements Regarding Complaints Process for Surprise Medical Bills (45 CFR 149.150, 45 CFR 149.450)

HHS’s Estimation of Volume of Complaints and Time Allotted for Processing

We are concerned about HHS’s estimates of both the volume of expected complaints and the resources and time they expect to devote to each complaint. The Departments indicate they expect there will only be around 3600 complaints submitted annually against providers, facilities, providers of air ambulance services, plans, and issuers. This is a significant underestimation.

Recent studies show that there are likely millions of balance billing situations every year. Nearly one in five Emergency Department visits result in out-of-network charges, and more than one in five claims for lab services provided at in-network hospitals were billed as out-of-network. Based on those rates, one could estimate that there are roughly tens of millions instances of balance billing per year. Even if the vast majority of plans and providers followed the law perfectly in the first year of enactment, 3600 complaints on a base of ten million possible balance bills would be a radically low rate. For contrast, in 2020, the CFPB received half a million complaints about banks and credit card companies. The rule estimates the incidence of surprise bills to be about 10 million annually. Even if 90% of all surprise bills are handled appropriately in the first year, that would leave more than 1 million mis-handled claims for which consumers would need assistance.

We are also concerned that the Departments only expect to devote about 30 minutes of staff time, on average, per complaint. We urge the Departments to provide further explanation and justification for the 30 minutes estimate. For example, it could take days just to figure out whether any given case falls under federal or state law protections.

Likely due to the low estimates of both volume of complaints and time spent on each complaint, the agencies only allocate a budget of $10 million annually for processing complaints. This would potentially severely underfund this process. By contrast, the healthcare.gov call center costs around $500 million annually, and during a peak enrollment window in 2020 saw over 4 million calls in a seven-week

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We urge the Departments to reconsider their complaints budget based on more accurate estimates of time and resources described above.

**Future Rulemaking: Independent Dispute Resolution**

A critical piece of the *No Surprises Act* that was not addressed in this IFR is the independent dispute resolution (IDR) or arbitration process that will be used by providers and insurers to settle disputes that arise regarding how much the insurer must pay an out-of-network provider. We look forward to formally commenting on those regulations when they are published. In the meantime, we urge the Departments to draft rulemaking that upholds the congressional intent of the *No Surprises Act* and protects consumers from inflated health care costs.

Arbitration is shown to lead to consistently higher provider payments and health care costs in states where it is a part of the balance billing process. It additionally provides an incentive for providers to stay out of network, as demonstrated in New Jersey and Texas. For these reasons, the arbitration system should be a “last resort” for payment disputes in order to keep overall costs down and prevent overuse and/or abuse of arbitration.

Regulations should establish clear guidelines for arbitrators to ensure a predicted and consistent result from payment disputes, including ensuring that the (QPA) is the primary factor in deciding cases. In addition to the QPA, the statute lists a variety of other factors (e.g., provider experience, case complexity, and prior contracted rates) that the arbitrator can consider in making decisions. The proper balance of these considerations, as explained below, will be critical for arbitration outcomes, and the agencies should ensure that decisions are not consistently above in-network rates which would have an inflationary impact.

Provider expertise and case acuity should only be considered when the designated QPA does not already take these factors into account. Provider experience and training is not a relevant factor in making determinations about health care prices or payment rates nor should it be used as a justification for increasing provider reimbursement above the median of already inflated commercial rates.

Importantly, given that 90% of metropolitan statistical areas (MSA) have highly concentrated hospital markets, 65% with highly concentrated specialist physician markets, and 57% with highly concentrated insurer markets, there are few truly competitive health care markets left in the U.S. health care system. In markets with moderate to high levels of concentration, the arbitrator should consider the fact that prior contracted rates or median in-network rates are the result of insurers and providers

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battling for relative market power and the ability to set prices. Substantial evidence links increased consolidation to high and rising health care prices, particularly in the commercial market.\textsuperscript{44,45,46}

Additionally, with regard to IDR entities, it is likely that the Departments will contract with Independent Review Organizations (IROs) to provide IDR services as IROs bring expertise both on clinical matters and in matters involving insurance/health plan coverage and payment issues.

Unfortunately, under federal appeals regulations, all employer plans and issuers in many states are permitted (even required) to contract directly with IROs to provide external review of denied claims. It is imperative that this provision under federal appeals regulations be changed if IROs are to be engaged in the IDR process in order to satisfy the conflict of interest requirements under the \textit{No Surprises Act}.

Congress enacted the \textit{No Surprises Act} to address the urgent health care affordability challenge facing patients with the goal of lowering consumer costs both through the balance billing protections themselves and through downward pressure on health care costs.\textsuperscript{47} \textbf{Congressional intent can only be honored by drafting regulations that minimize the inflationary impact of arbitration and make the QPA, on which patient cost-sharing is based, the primary factor in resolving payment disputes.}

\textbf{Conclusion}

On behalf of our organizations representing consumers, patients, and workers, we appreciate the opportunity to provide the above recommendations and feedback. We offer our support in providing feedback and technical assistance as you are developing subsequent rulemaking in the coming weeks and months. Please contact Jane Sheehan, Director of Federal Relations at Families USA, at JSheehan@familiesusa.org for further information.

Sincerely,

Families USA Action
ACA Consumer Advocacy
Arthritis Foundation
Center for Independence of the Disabled, NY
Community Catalyst
Consumers for Affordable Health Care
CWA Local 1081
Every Texan (formerly Center for Public Policy Priorities)
Georgians for a Healthy Future

\textsuperscript{44} Martin Gaynor, “What to Do About Health-Care Markets? Policies to Make Health-Care Markets Work,” The Hamilton Project, March 2020, Available at: \url{https://www.brookings.edu/wp-content/uploads/2020/03/Gaynor_PP_FINAL.pdf}
Health Access California
Health Care Voices
Medicare Rights Center
Missouri Health Care for All
MomsRising
National Alliance on Mental Illness
National Consumer Law Center
National Consumers League
Nebraska Appleseed
New Jersey Appleseed Public Interest Law Center
New Jersey Citizen Action
New Jersey Health Care Quality Institute
Northwest Health Law Advocates
Office of the Health Care Advocate, Vermont Legal Aid
State Office of the Healthcare Advocate, Connecticut
Tennessee Health Care Campaign
Universal Health Care Action Network of Ohio
Utah Health Policy Project
Washington Healthcare Access Alliance