June 9, 2021

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

Dear Secretary Becerra, Secretary Yellen, and Secretary Walsh:

The undersigned organizations, representing millions of patients and consumers across the country who face serious, acute, and chronic health conditions, write to address the development of regulations following passage of the No Surprises Act (NSA) as part of the Consolidated Appropriations Act, 2021 (P.L. 116-260). Our organizations represent millions of patients affected by surprise billing, with one in six Americans having received a surprise bill.¹ Consequently, we worked alongside Congress to develop the bi-partisan, bi-cameral legislation to provide protections for patients from receiving unexpected medical bills that was enacted at the end of last year. To truly ensure that patients are held harmless

from surprise billing, however, it is critical that the regulations underpinning the law have robust safeguards for patients.

As you draft regulations to implement the NSA, we ask that you take into consideration the key considerations for patients and consumers we outline below. While these comments by no means capture all the provisions and nuances impacting patients, they constitute a preliminary guide as to how to craft regulations that adequately protects patients and consumers. We therefore urge you to keep in mind two principal goals of the legislation — and Congress’ intent — when drafting regulations:

- First, the law must be implemented in a way that provides consumers with clear, comprehensive protections against surprise bills where they have not knowingly obtained out-of-network care.

- Second, the law must be implemented in a way that ensures the independent dispute resolution (IDR) process does not lead to higher costs for patients.

In addition, we strongly encourage the Departments to undertake a broad, well-funded education campaign to notify consumers of their new rights under the NSA and to put in place robust oversight and enforcement of the new law to ensure patients are protected. As we have seen, even after passage, patients continue to experience the unforeseen financial burdens of surprise bills while being treated for the coronavirus and it is critical that, going forward, consumers are made aware of their new rights. The federal law will extend comprehensive protections for the first time in the states without their own surprise billing laws and to the nearly 135 million people in self-insured plans. Investing in consumer education and oversight will help guarantee the law is implemented and enforced as Congress intended.

Ensure Clear, Comprehensive Consumer Protections Against Surprise Billing

Patients, especially those with chronic or serious conditions, are at greater risk of receiving an out-of-network bills in both emergency and non-emergency settings. We have learned that many of our patients, even those who are among the savviest health care consumers, can end up with an out-of-network bill through no fault of their own. This leaves patients who are already financially stretched with hundreds if not thousands of dollars in additional medical bills.

Fortunately, the NSA details the scenarios in which patients must be protected from surprise bills. However, there are exceptions to surprise bill prohibition when consumers knowingly and voluntarily agreed to receive care from certain out-of-network providers in certain settings. The law allows for patients to provide signed consent to receive non-emergency care out-of-network and thereby waive their surprise billing protections. However, protections cannot be waived when there is no in-network provider available, for urgent or unforeseen care, or for certain specialty providers (e.g., anesthesiologists, pathologists, radiologists and neonatologists, and others that may be identified in federal regulations).

With our patients’ lived experiences in mind, we note that it is critical that the Departments work diligently to ensure that patients and consumers, who are at the heart of this landmark legislation, are protected as fully as possible. This includes carefully examining scenarios under which an individual may receive a surprise bill, from whom, and what steps state and federal regulators will take to enforce and engrain these protections in our system of care. While our organizations appreciate that there are

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circumstances and scenarios where a patient may choose care that will result in a balance bill, we know from experience that any gaps or gray areas may be leveraged against our patients.

**Notice and Consent**

One of the most vulnerable times for a patient is right before a procedure. In addition to navigating their actual care (which might require lab tests, consults, and other steps that must be taken directly in advance of a procedure), patients must also make arrangements for follow-up care, child care, transportation, and work. This is a stressful time for even the most prepared and well-resourced patients. Notice and consent forms should account for this by ensuring that waivers of NSA protections are not delivered without special and careful explanation and acknowledgement. We strongly believe that most patients, if they truly understand the law’s protections, will not want to waive the protections of the NSA and that methods of delivery or explanation which downplay or treat these notices as perfunctory should not be permitted. The notice and consent forms should make this default clear and be written, distributed, and collected in a way that ensures that patients are knowingly and voluntarily agreeing to receive care out-of-network and incur the financial consequences. In order to implement this provision in a manner that ensures patients are knowingly and voluntarily agreeing to receive care out-of-network, where permitted, we recommend the following:

- The notice and consent form must comply with Section 1557 of the Affordable Care Act, Titles II and III of the Americans with Disabilities Act, Title VI, Section 504 and 508 of the Rehabilitation Act and other federal language access requirements and provide information on how to file a complaint, request an appeal, and access consumer assistance (for example, from a Consumer Assistance Program or [CAPs], hospital charity assistance programs, state and federal enforcement agencies, and others). Regulations should make clear that notice and consent must be communicated effectively in a patient’s primary language, otherwise it should be deemed invalid. With regard to the requirement that notice and consent be translated and available in the 15 most common languages, regulations should require that this be based on the facility’s service area or a geographic region defined by Metropolitan Statistical Areas. Regulations should not allow the requirement to be met based on the 15 most common languages in the state, which may not correspond with the specific language needs of the facility’s likely population. Regardless of whether a notice meets this requirement, if the notice and consent cannot be communicated effectively in a patient’s primary language, it should be considered invalid.

- The content of the notice and consent form must be clear, easy to read, and understandable. It must be provided as a stand-alone document, not buried among multiple other documents a patient may have to review and sign in advance of scheduling and receiving care. The content must make it clear that signing the consent form means waiving protections against surprise billing, with a plain language explanation of the consequences of doing so (for example, “you will have to pay out-of-pocket as much as [cost estimate] if you sign this form and give your consent”). The patient should then be required to check one of two boxes for “yes” or “no,” to protect against patients simply hurrying through a form and checking all boxes. The Departments should also consider setting a minimum standard for notice and consent documentation such that it does not vary drastically between facilities, providers, or state and local jurisdictions, as well as requiring verbal assent from the patient that they are agreeing to out of network care and understand that they may receive a surprise bill.

- Consumers must have complete, accessible information in hand when asked to provide their consent to receive out-of-network care, including the Advance Explanation of Benefits (EOB)
with complete and accurate information about the costs of waiving protections. This should include an estimate of how much of their bill will be applied to their out-of-network deductible and annual out-of-pocket limit – the “allowed amount” for the service or treatment – as well as information that shows how much spending they have accrued toward their plan’s out-of-network deductible and annual out-of-pocket limit.

- The cost-estimate must be specific to the provider and procedure or service. Regulations should prohibit blanket waivers that would apply to multiple or potential providers or an episode of care that involves multiple procedures or services. States and CMS should engage in enforcement action when cost estimates differ significantly from billed charges. Ease of consumer complaints (see more below) will be crucial to this enforcement.

- Regulations must give clear guidance on the circumstances under which patients can voluntarily give consent to out-of-network care and waive their protection from surprise billing. In addition to the points above regarding full, clear information about the cost implications of waiving protections and the right to retain protections if no participating provider is available for the original scheduled date and time of the procedure, regulations should be clear that consent cannot be coerced. Texas law may provide an example on this point. Under Texas law, the patient must have “meaningful choice” to give signed consent, which is deemed impossible if, among other things, the non-participating provider requires payment of a non-refundable fee, deposit or cancellation fee.

- Regulations should address situations where patients cannot meaningfully consent or where continuity of care is important, such as following emergency care. Regulations should specify when a patient has been stabilized to the extent that they can meaningfully consent to receiving out-of-network care, as well as scenarios where even after stabilization the need for continuity of care means that a patient should continue to be protected from surprise billing under the emergency protections. Patients should not be forced to choose between receiving an out-of-network bill or transferring to a different facility in scenarios where continuity and availability of care is critical.

- To comply with the NSA’s requirement to update the notice as necessary, the Departments should use consumer testing and complaint data to identify areas where improvements are needed to ensure consent is given knowingly and without coercion.

- Federal regulators should confirm that state laws that do not allow providers to request that patients waive state surprise billing protections exceed the standards laid out in the NSA as more protective of consumers and thus are not preempted by federal notice and consent requirements. Similarly, regulations should confirm that state laws that require notice further in advance of a procedure are more protective of consumers and thus are not preempted. For example, Michigan requires 14 days’ notice and Texas requires 10 days’ notice prior to receiving non-emergency care. To do otherwise would make patients in fully insured products in those states worse off under the federal law.

Securing In-Network Care
The NSA requires non-participating providers and facilities to include in the notice given to patients a list of participating providers at the facility who are able to furnish the items and services. However, this information is of limited value to a patient scheduled to receive care in as little as 72 hours. The burden
cannot be on the patient to coordinate and schedule services with a participating provider. The burden should fall to the in-network facility and plan or insurer to ensure all providers involved in the patient’s care are on contract with the patient’s plan or insurer. Furthermore, if no participating provider is available for the original day and time of the scheduled service, the patient should not be required to reschedule in order to retain their protections from surprise billing. Rescheduling may present substantial challenges for the patient beyond mere inconvenience. Delaying care could result in worse medical outcomes (both from delayed care and the stress of a delay) and require multiple additional interactions with the health care system (and thus higher costs) if a patient must reobtain lab results or consults in advance of a procedure. Rescheduling could also have non-health financial implications by burdening patients with the need to reschedule time off from work, arrange for child care and transportation, and make other arrangements for the original scheduled date.

Scope of Protections
Regarding which other providers should be included among those prohibited from surprise billing and barred from seeking a patient’s consent, we urge federal regulators to construe this provision broadly and in a manner that is consistent with Congress’ intent in enacting the NSA—to comprehensively protect patients from surprise bills for emergency and non-emergency care.

To that end, we urge you to recognize that patients are receiving both emergency and non-emergency care in many different settings other than hospitals and hospital-based emergency departments, including urgent care centers. We ask that you take a comprehensive approach to defining the facilities and providers to which the surprise billing protections apply for both emergency and non-emergency care. Doing so is consistent with Congress’ intent to provide comprehensive protections for surprise billing. Furthermore, federal regulators should use data obtained from complaints and enforcement efforts to identify additional provider types at least annually.

In addition, many of the patients we represent require specialized care that may not be available from an in-network provider, particularly with the emergence of narrow networks. Patients’ unique medical needs may require them to seek treatment from a sub-specialist provider or specialized facility. For example, a pediatric cancer patient may require the services of a subspecialist or specialized facility (children’s hospital or cancer center). A traditional oncologist may not have the appropriate training to handle the unique needs posted by a pediatric cancer patient. In such cases, the patient’s insurer or health plan may recognize the need—or have an obligation under some state network adequacy rules—to cover services through a reimbursement arrangement with an out-of-network provider or facility. Patients who have a medical need for subspecialty care often seek coverage through the appeals process. Regulations should therefore confirm that the definition of participating provider includes single case agreements (including when care was approved through a plan’s appeals process) or similar arrangements in which an out-of-network provider or facility has a contract with an insurer or health plan to provide covered services to a specific patient. Washington’s regulations take this approach, defining participating provider to include a “single care reimbursement agreement between a provider or facility and a carrier.”

Furthermore, if the patient has obtained prior authorization from the issuer for a service or services from out-of-network provider, the facility and providers involved should be prohibited from sending a surprise bill to the patient.

Finally, consumers are protected from surprise billing by a non-participating provider if the consumer can demonstrate that they relied on inaccurate provider directory information. The burden should be on

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the plan to demonstrate the directory was accurate at the time of the patient’s search, particularly given the NSA’s new requirements for providers and plans to keep directories current and accurate.

**Consumer Information**

Regulations should require health plans and insurers to include clear information on each EOB identifying claims that are subject to the ban on surprise billing. Washington state may provide an example of an approach to this. Under Washington’s law, insurers must include a HIPAA transaction code that identifies which claims are protected from surprise billing under state law. Federal regulations can go further and require health plans and insurers to clearly indicate what portion of a bill, if any, is the responsibility of the patient to pay. Further, all notices from the health plan or insurer should include information on the complaint process, the consumer’s appeal rights, and where to get assistance with filing an appeal or complaint (for example, a state’s CAP).

**Provider Directory**

We strongly support the requirement that health plans and insurers keep provider directories up-to-date and accurate, as well as the requirement that providers report information to health plans and insurers to assist in regular directory updates. Provider directories must also meet language and information access standards. We urge regulators to conduct regular audits and secret shopper studies to confirm that health plans and insurers are complying with this critical consumer protection and engage in enforcement against plans that do not meet standards.

**Patient Cost-Sharing**

In no case should a consumer’s cost-sharing be applied to any payment rate that is greater than the Qualified Payment Amount (QPA). If the actual amount paid is less than the QPA, the consumer should get the benefit of the lesser of the QPA or the amount negotiated or determined in the dispute resolution. We also ask that consumers in states where the recognized amount (i.e., the amount that is the basis for calculating the consumer’s cost-sharing) is defined under state law be guaranteed the same protection. If a state law would require consumers to pay more out-of-pocket than would apply if their cost-sharing was calculated using the QPA, the lower amount should apply.

**Consumer Complaints**

Patients typically do not know which federal or state agency has jurisdiction over their coverage. If a patient takes the step to complain – particularly while they are undergoing the stress and time required of a hospital-based procedure or emergency care – the complaint process must make it easy for them to get to the right regulator for their coverage and to get an answer. Simply telling a patient where to go next to file a complaint will discourage complaints and limit the potential of the complaint system to inform enforcement, oversight and future rulemaking.

The federal complaint system should therefore operate with a “no wrong door” policy that will receive complaints from any source, including but not limited to CAPs, and route complaints to the appropriate state or federal agency for further action. One potential example of a consumer-friendly complaint system is the one operated by the Consumer Financial Protection Board (CFPB), found here: https://www.consumerfinance.gov/complaint/process/. The CFPB complaint system is clearly accessible from the homepage and allows consumers to track and understand the status of their complaint; be notified if their complaint was routed to another government agency; lets consumers know the likely

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4 Washington Administrative Code 284-43B-040. See also One HealthPort HIPAA Transaction Usage Requirements accessed at https://www.onehealthport.com/adminsimp/hipaa-transaction-usage-requirements
timeframe for getting a response; and publishes de-identified complaints through a publicly-available database.

It will also be important to require states to share their complaint data with federal regulators, including states that have responsibility for enforcement of the provisions that apply to providers. Doing so will allow federal regulators to get a more complete picture of NSA implementation and enforcement and will be essential to informing any needed revisions to the regulations.

**Consumer Right to Appeal**
The NSA gives consumers the right to appeal to external review any adverse health plan determination relating to surprise billing. Under federal law, consumers have six months to file an internal appeal, which, if denied, can be appealed for external review. If a consumer decides to appeal an adverse health plan determination that may affect whether the claim would be subject to surprise billing protections, the provider or facility involved must be barred from billing the consumer until the appeal is resolved. In addition, consumers should be able to request an expedited appeal if there is a possibility that surprise billing protections may apply. In the absence of such a prohibition, patients may be billed for claims that a successful appeal determines should have been protected under the NSA.

**Continuity of Care**
We strongly support the requirement that health plans and insurers allow patients undergoing a course of treatment to continue to receive care at in-network cost-sharing when their provider has been terminated from the plan’s network. This protection is essential for the patients we represent. Regulations should ensure the notice provided patients is easy to read and provided in the patient’s primary language, with clear directions on how patients can indicate their intent to avail themselves of the continuity of care protections. Regulations should also confirm that the requirement that care be covered under the same terms and conditions as would have applied had the termination not occurred means that care should continue without interruption or the need to obtain further approval. Finally, regulations should make clear that these protections apply regardless of whether the provider or facility agrees to accept the contracted rate, as applies in some state laws.\(^5\)

**Dispute Resolution for Uninsured**
The NSA requires providers to give uninsured consumers a good faith estimate of the cost of their care. Failure to provide a cost estimate should automatically qualify the consumer’s bill for IDR; it would be impossible to require a consumer to demonstrate the cost “substantially exceeds” the estimate in the absence of any estimate. Further, the fee to access IDR should be set at $0. Most of the nearly 29 million uninsured have low incomes, including those at or below the poverty level in states that haven’t expanded Medicaid.\(^6\) Requiring a fee to access IDR will pose a substantial barrier for millions of people, which was not the intent of Congress.

**Ensure the Dispute Resolution Process Does Not Contribute to Higher Health Care Costs for Patients**
The patients we represent cannot forgo coverage without incurring serious, potentially debilitating or deadly health consequences. While the NSA’s financial protections are critical to ensuring that those we

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represent do not receive surprise bills from providers they did not choose, these protections will be far less meaningful if the law is implemented in a way that causes insurers and group health plans to increase premiums. Since 2010, premiums and deductibles for employer-sponsored coverage have grown faster than wages.\(^7\) That means it’s getting harder each year for workers to maintain coverage and access care before meeting their deductible. The NSA must not make that problem worse and should be implemented to reduce costs for patients.

Regulations should be drafted to at least meet, if not exceed, the savings projected by the Congressional Budget Office, which estimated premiums could be reduced by one percent. To do so, we urge you to develop an IDR system and sufficient guardrails that encourages stakeholders to reach in-network agreements (so the NSA need not be triggered).

**Additional Issues**

**Preemption of State Law**

The NSA should set the floor, not the ceiling, for consumer protections. Federal regulators should make clear that the NSA does not preempt state laws that are more protective of consumers than federal law, such as the examples shared above regarding state law on notice and consent. Where state law is less protective of consumers than the NSA, the NSA should apply. Consumers in states that have enacted surprise billing protections should not have less than the full protections of the NSA. Please see Appendix A for current state surprise billing protection laws.

**Enforcement**

Guaranteeing strong, clear protections for patients will depend on robust oversight and enforcement of the NSA. The provisions that apply to insurers clearly fall to state departments of insurance to enforce, but enforcement against providers’ billing practices is not as well established in most states. We therefore recommend that you establish an enforcement position that require states to demonstrate their intent, authority and capacity to enforce the NSA against providers. To do so, regulations could develop a list of key elements that a state must have in place to demonstrate they can and will “substantially enforce” the provider provisions, including, for example, developing interagency agreements, if necessary, and demonstrating that the state agency or entity charged with enforcement has a process to take consumer complaints; is free of any conflicts of interest; has sufficient expertise and resources to enforce; has authority to obtain from providers any documents necessary to investigate a potential violation; and has authority to levy fines and penalize providers that fail to comply. In the absence of this showing, federal regulators should be responsible for enforcing the NSA in a given state.

States should also be required to report their enforcement actions to federal regulators, in order to demonstrate continued capacity to enforce the NSA provisions that apply to insurers and providers. Regulations should also require states to report on a standardized set of data points (such as data on complaints and IDR outcomes) to allow federal regulators to assess the impact of the law over time, including any effect on premiums and provider access, the frequency of violations by provider type, and any other information that would inform future rulemaking and legislation. In order to inform future policymaking, information on enforcement actions should be reported to Congress and available to the public.

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Ground Ambulances
We are concerned that the advisory committee on ground ambulances has not yet been established, despite the NSA requirement that federal regulators establish one no later than 90 days after enactment. This is an urgent issue for the patients we represent, and it is essential that surprise billing protections be extended to these providers. Patients rarely have any choice of ground ambulance service, particularly in an emergency, and can face catastrophic bills as a result. We are anxious to see the advisory committee begin its work and meet the deadline to make recommendations for actions state and federal policymakers can take to prevent surprise billing for patients who require ground ambulance services.

Conclusion
Thank you for your consideration of our comments. We stand ready to help make implementation of the NSA a success for patients and would appreciate the opportunity to discuss these recommendations with you. Emily Holubowich (Emily.Holubowch@heart.org) from the American Heart Association will follow up with your office shortly to schedule a meeting.

Sincerely,

American Cancer Society Cancer Action Network
American Diabetes Association
American Heart Association
American Kidney Fund
American Liver Foundation
American Lung Association
Arthritis Foundation
Cancer Support Community
CancerCare
Cystic Fibrosis Foundation
Epilepsy Foundation
Hemophilia Federation of America
Mended Little Hearts
Muscular Dystrophy Association
National Alliance on Mental Illness
National Hemophilia Foundation
National Patient Advocate Foundation
Pulmonary Hypertension Association
Susan G. Komen
The AIDS Institute
The Leukemia & Lymphoma Society
WomenHeart: The National Coalition for Women with Heart Disease
APPENDIX A

Below is a list of states that have the most comprehensive surprise billing legislation currently enacted. Although other states have passed some legislation, those laws reflect a more limited approach to patient protections.⁸

<table>
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<tr>
<th>State</th>
<th>Setting</th>
<th>Type of Protection</th>
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<tbody>
<tr>
<td>California</td>
<td>Emergency department and nonemergency care within an in-network hospitals</td>
<td>Hold harmless protection - the consumer is not held liable financially for any portion of the bill beyond in-network cost-sharing; prohibits providers from sending any surprise bill to the patient for any amount beyond in-network level cost-sharing</td>
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<td>Colorado</td>
<td>Emergency department and nonemergency care within an in-network hospitals</td>
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<td>Georgia</td>
<td>Emergency department and nonemergency care within an in-network hospitals</td>
<td>Hold harmless protection - the consumer is not held liable financially for any portion of the bill beyond in-network cost-sharing; prohibits providers from sending any surprise bill to the patient for any amount beyond in-network level cost-sharing (the payment standard does not apply to out-of-network facilities and insurers are required to make some payment but there is no specific formula)</td>
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<td>Emergency department and nonemergency care within an in-network hospitals; with respect to emergency and nonemergency services provided by out-of-network providers at in-network facilities, protections are limited to a set of designated specialties</td>
<td>Hold harmless protection - the consumer is not held liable financially for any portion of the bill beyond in-network cost-sharing (only applicable to facility based-providers); prohibits providers from sending any surprise bill to the patient for any amount beyond in-network level cost-sharing (attaches when the consumer assigns the benefit to the provider, but the hold harmless protection applies even without assignment)</td>
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<td>Maine</td>
<td>Emergency department and nonemergency care within an in-network hospitals</td>
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<td>Maryland</td>
<td>Emergency department and nonemergency care within an in-network hospitals</td>
<td>Hold harmless protection - the consumer is not held liable financially for any portion of the bill beyond in-network cost-sharing (in PPOs, only applies to on-call physicians and hospital based physician); prohibits providers from sending any surprise bill to the patient for any amount beyond in-network level cost-sharing (attached when the consumer assigns the benefit to the provider)</td>
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<td>Michigan</td>
<td>Emergency department and nonemergency care within an in-network hospitals</td>
<td>Prohibits providers from sending any surprise bill to the patient for any amount beyond in-network level cost-sharing</td>
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<td>New Hampshire</td>
<td>Emergency services provided by a nonparticipating provider in a network hospital and nonemergency care within an in-network hospitals; with respect to emergency and nonemergency services provided by out-of-network providers at in-network facilities, protections are limited to a set of designated specialties</td>
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<td>Oregon</td>
<td>Emergency services provided by a nonparticipating provider in a network hospital and nonemergency care within an in-network hospitals</td>
<td>Prohibits providers from sending any surprise bill to the patient for any amount beyond in-network level cost-sharing</td>
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<td>Texas</td>
<td>Emergency department and nonemergency care within an in-network hospitals</td>
<td>Hold harmless protection - the consumer is not held liable financially for any portion of the bill beyond in-network cost-sharing (only in HMOs and EPOs, not PPOs); prohibits providers from sending any surprise bill to the patient for any amount beyond in-network level cost-sharing</td>
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<td>Virginia</td>
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