State of California
Office of the Attorney General

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Via Federal eRulemaking Portal

The Honorable Xavier Becerra
Secretary of the U.S. Department of Health & Human Services
200 Independent Avenue, S.W.
Washington, D.C. 20201

Administrator Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
P.O. Box 8016
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RE: Comments on "Requirements Related to Surprise Billing; Part I," 86 Fed. Reg. 36,872 (Jul. 13, 2021), CMS–9909–IFC

Dear Secretary Becerra and Administrator Brooks-LaSure:

I submit the following comments in support of the U.S. Department of Health and Human Services (HHS), Department of Labor, and Department of Treasury's (collectively, the Departments) Interim Final Rule, "Requirements Related to Surprise Billing; Part I," 86 Fed. Reg. 36,872 (Jul. 13, 2021) (Interim Final Rule). The Interim Final Rule is a critical first step in implementing the No Surprises Act, a federal law that promises to protect more consumers from unexpected medical bills than ever before.

Before Congress enacted the No Surprises Act, many states (including California) had taken steps to protect our residents from the stress and financial hardship of surprise medical bills. However, even in states like mine in which balance billing protections are "comprehensive," substantial gaps remain.[1] As the Interim Final Rule recognizes, states cannot

[1] *See* Maanasa Kona, *State Balance-Billing Protections*, Commonwealth Fund (Feb. 5, 2021), https://www.commonwealthfund.org (demonstrating that prior to the No Surprises Act, more than 30 states had enacted some type of surprise billing protections, but only 17 of those states' protections are "comprehensive," meaning that they protect both emergency and non-emergency situations and have both

regulate health plans that are self-funded by employers due to the federal Employee Retirement Income Security Act (ERISA). Nor can we regulate bills by out-of-state providers, or air ambulances, a common source of costly surprise medical bills. And for the millions of Americans living in states with less comprehensive protections, residents are left with little guarantee that critical or life-saving medical care will not result in financial devastation due to surprise billing practices.

The No Surprises Act and the Interim Final Rule implementing it are essential to extending surprise medical bill protections "to more than 135 million people estimated to be covered by employer self-funded plans, as well as millions more in states without protections."[2] I commend the federal government for taking this initial step to guarantee that Americans can obtain access to emergency healthcare and hospital services without fear of bankruptcy and financial ruin. I hope that the Interim Final Rule and the regulations to follow will establish new incentives in the healthcare and health insurance markets that better protect consumers, and respectfully offer the following comments to aid in further strengthening the rule.

I. California Has Existing Laws That Protect Consumers Against Balance Billing, But Significant Gaps Remain

As the Interim Final Rule recognizes, the widespread problem of surprise medical billing "raises health care costs and exposes patients to financial risk." 86 Fed. Reg. at. 36,874. The figures cited in the Interim Final Rule are staggering. *See e.g.*, *id.* (citing studies showing that "over 39 percent of emergency department visits to in-network hospitals resulted in an out-of-network bill" and "37 percent of inpatient admissions to in-network hospitals resulted in at least one out-of-network bill," with steady increases since 2010 in both areas). Medical debt has devastating consequences, including low credit scores, loss of savings, credit card debt, inability to pay for basic necessities, and delayed education or career plans.[3] And as HHS emphasized in announcing this rule, a shocking "[t]wo-thirds of all bankruptcies filed in the United States are tied to medical expenses."[4] Studies have also consistently shown that these financial challenges

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a payment standard and dispute resolution process to determine payment amounts for out-of-network charges).

[2] Jack Hoadley et al., *Surprise Billing Protections: Help Finally Arrives for Millions of Americans*, Commonwealth Fund (Dec. 17, 2020), https://www.commonwealthfund.org.

[3] Sara R. Collins, Gabriella N. Aboulafia, and Munira Z. Gunja, *As the Pandemic Eases, What Is the State of Health Care Coverage and Affordability in the U.S.? Findings from the Commonwealth Fund Health Care Coverage and COVID-19 Survey, March-June 2021*, Commonwealth Fund (July 2021), https://www.commonwealthfund.org.

[4] Press Release, *HHS Announces Rule to Protect Consumers from Surprise Medical Bills* (Jul. 1, 2021), https://www.hhs.gov.

"are exacerbated for underserved communities," which already suffer from unequal and disparate access to healthcare. 86 Fed. Reg. at 36,875.[5]

The COVID-19 pandemic has only exacerbated this problem. According to one report, "[p]eople who suffered the most during the pandemic also suffered the most from medical bill problems."[6] At the time the COVID-19 pandemic struck, more than one-third of insured adults and half of uninsured adults in the United States already had a medical bill problem or were paying off medical debt.[7] During the pandemic, one-third of adults reported a decrease in income, with "[h]igher rates among Black and Latinx/Hispanic adults and people with low income."[8] And those individuals most affected by COVID-19 "had higher rates of medical bills and debt problems than those not affected by the pandemic."[9]

California has taken a leading role in addressing the significant hardship of balance billing and remains committed to doing so during our current public health crisis. In 2016, the state legislature tackled the problem directly through Assembly Bill 72 (AB 72), which sought to increase network participation and reduce the cost of care to unsuspecting consumers. Specifically, AB 72 "requires fully-insured plans to pay out-of-network physicians at in-network hospitals the greater of the insurer's local average contracted rate or 125 percent of the Medicare reimbursement rate."[10]

California's efforts have yielded positive results. Since the passage of AB 72, health plans report that the percentage of in-network facilities where there were even just one claim to an out-of-network doctor ranged from 0 percent to 20 percent.[11] The share of services that specialty physicians delivered out-of-network at hospitals and ambulatory surgical centers declined by 17 percent.[12] And one analysis reported "an average 16 percent increase in the

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[5] *See e.g.*, Raymond Kluender, Neale Mahoney, and Francis Wong, *Medical Debt in the US 2009-2020*, JAMA (Jul. 20, 2021) (study revealing that as of June 2020, "an estimated 17.8 percent of individuals had medical debt" and that "[m]edical debt was highest among individuals who lived in the South and in zip codes in the lowest income deciles and became more concentrated in lower-income communities in states that did not expand Medicaid").

[6] Collins et al., *supra*.

[7] *Id.*

[8] *Id.*

[9] *Id.*

[10] Loren Adler et al., *California saw reduction in out-of-network care from affected specialties after 2017 surprise billing law*, USC-Brookings Schaeffer Initiative for Health Policy (Sept. 26, 2019), https://www.brookings.edu.

[11] Department of Managed Health Care, *Assembly Bill 72 Report* (March 4, 2019), http://www.dmhc.ca.gov.

[12] Adler et al., *supra.*

number of in-network physicians across all specialties."[13] Most notably, researchers observed "a modest shift toward claims from in-network service providers across all the affected specialties timed to the law's implementation," but did not see similar changes for emergency medicine, which the law did not address.[14]

At the same time, California's law—like those of many other states—leaves significant gaps. For one, AB 72's provisions do not apply to Medicaid, Medicare or self-insured employer health plans, which are not subject to state regulations pursuant to ERISA.[15] As a result, almost six million Californians who are in self-funded insurance plans do not benefit from the protections of AB 72.[16] Similarly, AB 72 does not prohibit surprise bills from out-of-network hospitals for emergency services.[17] As a result, although the California Supreme Court decision, *Prospect Medical Group, Inc. v. Northridge Emergency Medical Group*, extended some protections against balance billing in emergency circumstances, almost seven million Californians "remain[] at risk for getting balance bill for an emergency room visit."[18] Finally, "[o]ut-of-network air ambulance bills are a particularly pernicious form of surprise medical bill, and the market distortions are even more pronounced than in other specialties."[19] Although California has enacted some protections against surprise billing for air ambulances, federal law limits the state's ability to regulate air ambulance prices, and has not set a payment standard for balance billing resulting from air ambulances.[20]

Accordingly, despite significant efforts in my state and others, federal action is needed to fully confront the problem of surprise billing. The No Surprises Act and this first Interim Final Rule implementing it are important steps in that direction. I commend the federal government's actions to protect all Americans from the long-lasting harm of surprise billing and welcome the opportunity to work together to implement the federal law.

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[13] *Id.*

[14] *Id.*

[15] *See e.g.*, Jack Hoadley et al., *States Are Taking New Steps to Protect Consumers from Balance Billing, But Federal Action Is Necessary to Fill Gaps*, Commonwealth Fund (July 31, 2019), https://doi.org/10.26099/jfne-dp10.

[16] Health Access California, *Fact Sheet: What the Federal No Surprises Act Means for Californians* (Feb. 2021), https://health-access.org.

[17] Adler et al., *Understanding the No Surprises Act*, USC-Brookings Schaeffer on Health Policy (Feb. 4, 2021), https://www.brookings.edu.

[18] Health Access California, *Fact Sheet, supra*.

[19] Brown et al., *The Unfinished Business of Air Ambulance Bills*, Health Affairs (Mar. 26, 2021), https://www.healthaffairs.org.

[20] Cal. Health and Safety Code § 1371.55.

II. The Methodology for Determining the Qualifying Payment Amount Should Allow for Greater State Flexibility

The Interim Final Rule seeks comment on the impact of consolidation on contracted rates, the impact of such contracted rates on prices and the qualifying payment amount (QPA), and on all aspects of the methodology for determining the QPA. 86 Fed. Reg. at 36,889. Allowing for state flexibility in defining the geographic regions used in the QPA methodology is critical to ensuring that the historical impacts of highly concentrated healthcare markets do not continue to inflate and skew pricing for payments made under the Act. I urge the Departments to amend the Interim Final Rule's definition of "geographic region" and to adopt the recommendation of the National Association of Insurance Commissioners (NAIC) that states be permitted to propose an alternative methodology for defining geographic regions within their jurisdictions.

A. The Qualifying Payment Amount Methodology Must Account for Historical Anticompetitive Market Influences

One of the most important features of the No Surprises Act is that it sets an upper limit on the amount an out-of-network provider can recover. It is well documented that the threat of surprise billing gives providers increased leverage to negotiate higher prices with insurers.[21] Especially for medical services where patients do not have an opportunity to seek in-network care, such as emergency or ancillary services, providers can remain out-of-network without significantly reducing their patient volume.[22] Providers can then leverage their out-of-network status to bargain for higher in-network reimbursement rates. The No Surprises Act greatly reduces this leverage by placing an upper limit on the amount an out-of-network provider can recover.

The QPA plays an important benchmarking role in setting the out-of-network limits when there is no applicable state law that otherwise sets the out-of-network rate. [23, 24] The payment that

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[21] Erin L. Duffy et al., *Policies to Address Surprise Billing Can Affect Health Insurance Premiums*, The American Journal of Managed Care (Sept. 2020), https://www.ajmc.com; Glenn Melnick and Katya Fonkych, *An Empirical Analysis of Hospital ED Pricing Power*, The American Journal of Managed Care (March 2020); Zack Cooper, et. al., *Out-of-Network Billing and Negotiated Payments for Hospital-Based Physicians*, Health Affairs (Dec. 16, 2019); Zack Cooper et al., *Surprise! Out-of-Network Billing for Emergency Care in the United States*, National Bureau of Economic Research (Jan. 2019), https://www.nber.org.

[22] *Id.*

[23] It has been estimated that up to two-third of all claims under the No Surprises Act will not fall under any applicable state law. *See* Katie Keith, Jack Hoadley, Kevin Lucia, *Banning Surprise Bills: Biden Administration Issues First Rule On The No Surprises Act,* Health Affairs (July 6, 2021), https://www.healthaffairs.org.

[24] When a qualifying out-of-network service is rendered, the insurer must make an initial payment to the provider and identify the QPA they have calculated for the particular service. *See* 86 Fed. Reg. at

providers expect to obtain under the No Surprises Act directly affects their bargaining position and leverage when negotiating over in-network rates. As a result, it is important that the methodology for calculating the QPA not lock-in prices that have been obtained through historical market leverage in highly concentrated markets. If dominant providers expect to be able to continue to receive higher rates, then they have less incentive to try and negotiate an in-network rate moving forward.

One method the Departments can utilize to mitigate anticompetitive market influences is through the Interim Final Rule's definition of "geographic region." *See* 86 Fed. Reg. at 36,892-93. Under the Act, the QPA is determined separately for each insurer and insurer market. Thus, the data set being used to calculate the QPA is already relatively fragmented as compared to a methodology that might compare contracted rates across insurers, such as using an all-payer claims database. As a result, setting an appropriate geographic region becomes critical to ensuring that the region is defined broadly enough so the calculation of the QPA is not focused in on a region where all healthcare prices are inflated because of the presence of a dominant system with significant market leverage.

B. The Departments Should Permit States to Use an Alternate Methodology to Define "Geographic Regions"

Although the No Surprises Act offered little guidance as to how to define geographic regions, it directed the Departments to seek a recommendation from the NAIC. *See* 86 Fed. Reg. at 36,892. The NAIC responded with three different possible methodologies for defining geographic regions.[25] First, the NAIC recommended that the Departments use the geographic regions that states have already defined for individual and small group market ratings under the Affordable Care Act (ACA).[26] Second, the NAIC recommended that if a state has laws regulating surprise billing, that a state be permitted to use the geographic regions it has defined under that those laws for purposes of the No Surprises Act.[27] Third, the NAIC recommended that a state be permitted to request approval from the Secretary of HHS for an alternate methodology to be used to define "geographic region."[28]

36,957. Thus, the QPA serves a benchmarking role here insofar as the provider will be evaluating if this initial payment is satisfactory against the QPA. If the provider is not satisfied, it can trigger an independent dispute resolution process through which an arbitrator will consider rates set forth by each side. The arbitrator must consider the QPA in determining which rate to ultimately accept and must publicly report the final rate as a percentage of the QPA. *See* H.R. No. 133, 116th Cong., (2019-2020), "No Surprises Act," Sec. 103(c)(1)-(7).

[25] National Association of Insurance Commissioners, *Letter to Center for Consumer Information and Insurance Oversight (CCIIO)* (Mar. 11, 2021), https://www.naic.org.

[26] *Id.* at 1.

[27] *Id.* at 2.

[28] *Id.* at 2.

The Interim Final Rule did not adopt any of these recommendations.[29] Instead, the Interim Final Rule defines a geographic region by reference to metropolitan statistical areas (MSAs). 86 Fed. Reg. 36,953-54. This proposal is problematic for the State of California. For the reasons that follow, I respectfully suggest that the Departments revise the Interim Final Rule's definition to allow for greater state flexibility in defining geographic regions. Specifically, I recommend that the Interim Final Rule adopt the third of NAIC's recommendations—that it permit a state to request approval for an alternate methodology.

1. California's Healthcare Market Well Illustrates the Problems With Using MSAs to Calculate the QPA

The use of MSAs to define geographic regions in California is likely to yield a number of problems. For one, it will result in 27 separate regions, which is far too fragmented to allow for meaningful calculation of the QPA. It also fails to account for the problem of umbrella pricing. Umbrella pricing is a term typically used by economists to describe the effect that occurs when one hospital's higher prices allow competitors to increase their own prices. Although the QPA is calculated using the median of an insurer's contracted rates, regions that are too narrowly defined run the risk of being affected by umbrella pricing.[30] Such an effect has been observed in regions in Northern California due to the presence of the dominant system, Sutter Health.[31] Competing providers are still able to enjoy higher prices than they would elsewhere due to the presence of a dominant system that is able to extract supracompetitive pricing as they only need to seek prices that are slightly lower than the dominant system.

California serves as a primary example of why states should be permitted to seek approval for an approach to defining geographic regions that is tailored to the unique market dynamics of its state. A 2018 study by University of California Berkeley researchers found that

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[29] The Interim Final Rule specifically rejected the first NAIC proposal, finding that it "could lead to a large number of geographic regions for which a plan or issuer would have to calculate separate median contracted rates, a large number of geographic regions without sufficient information, as well as a large number of geographic regions in which the median contracted rate is influenced by outliers." 86 Fed. Reg. at 36, 892. These are concerns, however, that are present with the use of MSAs to define geographic markets in California as detailed herein.

[30] Under the language of the No Surprises Act, the QPA is calculated using an insurer's median contracted rates, rather than claims-weighted rates. In the event the Departments are urged to consider using claims-weighted rates instead, I recommend that the Departments first consider conducting a study to determine the effect that such an approach might have in terms of providing greater weight to large systems that may have higher pricing due to their dominant market position and negotiating leverage.

[31] Memorandum in Support of Plaintiffs' Joint Motion for Attorneys' Fees, Costs, and Service Award at 21, fn. 12, *People of the State of California ex rel Xavier Becerra v. Sutter Health,* (Cal. Super. Ct. S.F. City and Cnty. 2021) (No. CGC 18-565398) (description of how the Sutter Health System created a price umbrella in regions where it was dominant in Northern California).

44 of California's 58 counties had "highly concentrated" hospital markets.[32] Further, it is well documented that Northern California is considerably more concentrated than Southern California, resulting in higher healthcare prices.[33] The 2018 study found that inpatient prices were 70 percent higher in Northern California and that, even after adjusting for input cost differences, such as wages, procedure prices were still up to 30 percent higher in Northern California.[34] Translated in terms of procedures, the average inpatient procedure cost $223,278 in Northern California as compared to $131,568 in Southern California, and the average cardiology outpatient procedure cost $28,955 as compared to $17,653.[35]

Higher healthcare prices translate to higher premiums and out-of-pocket costs for consumers. Experts have found that health insurance premiums in Northern California are about 25 percent higher, on average, than in Southern California.[36] Covered California, the state's insurance exchange, reported a similar pattern in 2016 with an average rate increase of seven percent in Northern California compared to 1.8 percent for policyholders in Southern California.[37] As currently defined in the Interim Final Rule, this historical price variation will be reflected in calculation of the QPA due to the narrow markets that the use of MSAs creates. The impact of the current proposed use of MSAs is that dominant providers in these regions will continue to reap the benefits of its past market leverage and will have less pressure exerted on them to negotiate a reduced in-network rate.

In addition to the problem of preserving historical market power in the out-of-network rates, the use of MSAs in California will lead to inconsistent impacts on patients and healthcare costs generally due to the high number of MSAs within the state and the small number of providers in many of these MSAs. Of California's 26 MSAs, 14 contain five or fewer hospitals; 10 contain three or fewer; and five have two or fewer.[38] As currently defined under the Interim Final Rule, if an insurer does not have at least three contracted rates in a geographic region, that region is then expanded—with the first step being a region consisting of all MSAs within the state.

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[32] Petris Center, *Consolidation in California's Health Care Market 2010-2016: Impact on Prices and ACA Premiums* (March 26, 2018), https://petris.org.

[33] *Id.* at 9.

[34] *Id.* at 9.

[35] *Id.* at 40.

[36] Chad Terhune, *Major Employers Decry Sutter Health's Tactics In Dispute Over Prices*, California Healthline (April 7, 2016) https://californiahealthline.org.

[37] *Id.*

[38] Based on current MSA definitions as provided by the Office of Management and Budget (https://www.labormarketinfo.edd and https://www2.census.gov); Hospital Annual Financial Data – Selected Data & Pivot Tables – 2019 Pivot Table – Hospital Annual Selected File (May 2021 Extract) – California Health and Human Services Open Data Portal (https://data.chhs.ca.gov).

Using hospital services as just one example, by definition, there will be at least 10 MSAs in California whereby if a patient visits an out-of-network hospital seeking a covered service under the No Surprises Act, the insurer will not have at least three contracted in-network rates available to calculate the QPA. For those regions only, they will be expanded to include all MSAs within the entire state and thus may benefit from a lower QPA that is calculated as a state-wide median. By comparison, patients and insurers who visit an out-of-network hospital in what could be a very close neighboring MSA, that meets the Interim Final Rule's requirement with at least three contracted hospitals, could face a very different, and higher, price as a median for that specific MSA. Given that the QPA is used to calculate patient cost-sharing responsibilities, this impact will be directly felt by the patient who may have the misfortunate to live in, work in, or travel to the wrong MSA for healthcare.

Ultimately, the phenomenon of higher healthcare costs in highly concentrated regions is not unique to our state.[39] As explained by Professor Martin Gaynor in testimony before Congress, "the majority of hospital markets are highly concentrated, and many areas of the country are dominated by one or two large hospital systems with no close competitors."[40] As a result, California is not the only state that would be faced with concerns of locking in historical market leverage if MSAs are used to define its geographic regions.

2. The Interim Final Rule Should Permit States to Request Approval to Use Alternative Methodologies

California's experience illustrates the importance of state flexibility in calculating the QPA. I accordingly urge the Departments to consider adopting the third of NAIC's recommendations—that it permit a state to request approval for an alternate methodology to define its geographic regions.

There are a number of alternative methodologies that states could use, upon request and approval, that would provide for a more tailored approach than the MSA methodology currently set forth in the Interim Final Rule. For states like California, each of these alternatives would mitigate the problems identified above.

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[39] *See* Medicare Payment Advisory Commission, *March 2020 Report to the Congress: Medicare Payment Policy* (Mar. 13, 2020) (finding that the "preponderance of evidence suggests that hospital consolidation leads to higher prices"); Martin Gaynor, *Statement before the Committee on the Judiciary Subcommittee on Competition Policy, Antitrust, and Consumer Rights, "Antitrust Applied: Hospital Consolidation Concerns and Solutions"* (May 19, 2021) (detailing the significant body of academic research documenting the impact of healthcare consolidation on pricing); Robinson, *Hospital Market Concentration, Pricing, Profitability in Orthopedic Surgery and Interventional Cardiology*, 17 Am. J. Managed Care 241 (2011) (finding that prices for various cardiology and orthopedic procedures ranged from 19 percent to 25 percent more for hospitals in concentrated markets).

[40] Martin Gaynor, *Statement before the Committee on the Judiciary Subcommittee on Competition Policy, Antitrust, and Consumer Rights, "Antitrust Applied: Hospital Consolidation Concerns and Solutions"* (May 19, 2021).

For instance, one method states could use as an alternative approach is the first of NAIC's recommendations—using the geographic regions that states have already defined for individual and small group market ratings under the ACA. This ACA-based method relied on MSAs, but allowed for greater state flexibility by permitting states the option to define alternative regions so long as they provided actuarial justifications to CMS. *See e.g.*, 45 C.F.R. Part 147. California took advantage of that option, and now has 19 rating regions for its individual and small group markets. While these regions will still reflect regional variations due to market power, these regions are well-known to plans in the state and have been developed through actuarial analysis.

Another alternative methodology that states might request approval to use is to set the geographic region as comprising the entire state. This would yield a statewide median price as the baseline price, thus dampening the effect of regions with highly concentrated markets. This methodology would provide at least two potential benefits to some states. First, because patient cost sharing is directly calculated utilizing the QPA, a patient in California would face the same underlying cost sharing responsibility regardless of the MSA within which they sought care. Second, the QPA is but one of several factors to be considered by the arbitrator in the independent dispute resolution process. *See* H.R. No. 133, 116th Cong. (2019-2020), "No Surprises Act," Sec. 103(c)(5)(C)(i)(II). Under the Act, the arbitrator considers the teaching status, case mix, and scope of services offered by the facility, the level of training, experience, and quality of the physician, and patient acuity. *Id*. Using a statewide baseline allows for adjustment of this price by non-market power factors that legitimately influence price.

Finally, states could request approval to use the second of NAIC's recommendations—if a state has laws regulating surprise billing, that a state could use the geographic regions it has defined under those laws for purposes of the No Surprises Act. Under California's regulations implementing AB 72, for instance, the methodology for calculating the out-of-network rate to be paid for non-emergency services for large group coverage utilizes the geographic regions specified for physician reimbursement for Medicare fee-for-service by HHS.[41] Other potential options that states could consider for defining their markets are commuting zones or primary care service areas.[42]

Permitting consideration of these methodologies has the additional benefit of allowing states to update and refine their adopted methodologies over time as they can obtain newer and better data to understand their healthcare markets. For instance, California is currently in the process of developing an all-payer claims database with the aim of utilizing the database to

[41] Cal. Code Regs. tit. 28, §1300.71.31, tit.10 §2238.10(a)(4)(B).

[42] Commuting zones are geographic units of analysis intended to more closely reflect the local economy where people live and work. Such regions are most often used in labor economics but also may also be appropriate to use in healthcare settings in more accurately reflecting where people seek care than MSAs when people may live and work in different MSA or non-MSA regions. Primary care service areas are geographic areas that are self-sufficient markets of primary care. These areas are designed in a manner such that most patients living in these areas use primary care services from within the area.

inform healthcare policy and reduce healthcare costs and disparities.[43] This database can be leveraged by economic, actuarial, and health policy experts to both define geographic regions that account for legitimate variations in price, while minimizing the impact that dominant systems hold.

I offer these alternatives as examples of approaches for which states could request approval. An Interim Final Rule that permits states to request approval to use an alternate methodology would allow states to adopt methods that are better tailored to their market realities. I accordingly urge the Departments to revise the Interim Final Rule to permit such requests.

III. The Interim Final Rule Should Include Urgent Care Centers and Telemedicine within Its Definition of Emergency Services

I recommend that the Interim Final Rule adopt broad definitions of urgent care centers and emergency-related telemedicine services and include them in its definition of emergency services. As the Interim Final Rule recognizes, some states, such as California, do not permit free standing emergency departments, but allow urgent care centers to provide some emergency services.[44] 86 Fed. Reg. at 36,879. AB 72 protects Californians from balance billing at in-network urgent care centers, but not at out-of-network centers. Since the No Surprises Act only covers services provided at the emergency department of a hospital or a freestanding emergency room, a Californian who seeks emergency medical services for an emergency medical condition at an out-of-network urgent care center would not be covered by the protections offered by the No Surprises Act. *See* 86 Fed. Reg. at 36,882.

A. The Interim Final Rule Should Include Urgent Care Centers, as Patients Increasingly Use Them As An Alternative to the Emergency Room

Throughout the country, patients are increasingly turning to urgent care centers as an alternative to the emergency room.[45] Urgent care clinics now handle an estimated 89,000,000

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[43] Office of Statewide Health Planning and Development, *Health Care Payments Data Program: Report to the Legislature* (March 9, 2020), https://oshpd.ca.gov.

[44] California Health and Safety Code section 1798.175 prohibits free standing emergency departments but allows facilities to advertise "urgent," "prompt" or "immediate" medical services.

[45] Urgent Care Association of America, *Urgent Care Industry White Paper: The Essential Role of the Urgent Care Center in Population Health* 4 (2019) (noting that the number of urgent care centers in the U.S. increased from 6,400 in 2014 to over 9,000 in 2019); FAIR Health, *FH Healthcare Indicators and FH Medical Price Index 2021: An Annual View of Place of Service Trends and Medical Pricing* 15 (2021) (finding utilization of urgent care centers grew 47 percent from 2018 to 2019).

patient visits annually.[46] According to the Centers for Disease Control (CDC), 26.4 percent of children and 29.2 percent of adults had visited an urgent care center or retail health clinic at least once in 2019.[47] These statistics indicate significant use of urgent care centers, especially when compared to the 130,000,000 total emergency department visits in the United States in 2018 that CDC identified.[48] CDC also reported that 19.6 percent of children and 21.3 percent of adults visited an emergency department at least once in 2018.[49]

At the same time, consumers do not necessarily distinguish between emergency rooms and urgent care centers. Indeed, many California-based urgent care providers specifically market themselves as an alternative to the emergency room. For example, a large integrated health delivery system in Northern California markets its urgent care clinics on their website "as a convenient and economical alternative to going to an emergency room."[50] Meanwhile, a chain of Southern California urgent care centers states on its website that its urgent care centers have "ER board-certified doctors and expert medical providers who can treat 80 percent of cases seen in an ER."[51] Urgent care centers have even expanded to specialty areas. Some Californian pediatric urgent care clinics advertise themselves as convenient and cost-effective alternatives to emergency rooms.[52] There is also growth in urgent care centers specializing in women's health, including OB-GYN services.[53]

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[46] Shelagh Dolan, *How the Growth of the Urgent Care Industry Business Model is Changing the Healthcare Market in 2021*, Business Insider (January 29, 2021 1:03 PM), https://www.businessinsider.com.

[47] Lindsey I. Black & Benjamin Zablotsky, National Center for Health Statistics, NCHS Data Brief No. 393, *Urgent Care Center and Retail Health Clinic Utilization Among Children* 1 (2020); Lindsey I. Black & Dzifa Adjaye-Gbewonyo, National Center for Health Statistics, NCHS Data Brief No. 409, *Urgent Care Center and Retail Health. Clinic Utilization Among Adults* 1 (2021).

[48] *Emergency Department Visits*, National Center for Health Statistics (last updated April 9, 2021), https://www.cdc.gov.

[49] Christopher Cairns, Jill J. Ashman & Kai Kang, National Center for Health Statistics, NCHS Data Brief No. 40*, Emergency Department Visit Rates by Selected Characteristics: United States, 2018* 1 (2021); *Table 36: Emergency Department Visits Within the Past 12 Months Among Children Age 18, By Selected Characteristics,* National Center for Health Statistics (last updated Oct. 30, 2019), https://www.cdc.gov.

[50] *Urgent Care*, Sutter Health (last visited July 13, 2021), https://www.sutterhealth.org.

[51] *About Exer Urgent Care*, Exer Urgent Care, (last visited July 13, 2021), https://exerurgentcare.com.

[52] *After Hour Pediatrics* (last visited August 4, 2021) https://afterhourpeds.net; *After Hours Pediatrics Kids Urgent Care* (last visited August 4, 2021) https://www.afterhourspediatrics.net/.

[53] Scheier, Rachel, *COVID Flags Need for California Women's Urgent Care Clinics*, Los Angeles Times (April 15, 2021) https://www.latimes.com.

In a 2021 report by FAIR Health, a nonprofit aimed at bringing transparency to healthcare costs, the most frequent reasons for urgent care visits are acute respiratory diseases and infections (23 percent of claims) and influenza and pneumonia (seven percent of claims).[54] Other common reasons for urgent care visits include injuries (six percent of claims), sprains, strains, breaks, and fractures (four percent of claims), and joint/soft tissue issues (four percent of claims).[55] Urgent care centers also offer services for moderate-acuity procedures that are not typically offered by primary care office visits. A survey of over 400 urgent care centers found that over 80 percent offered fracture care (including splinting and casting) and over 70 percent offered intravenous fluids when needed.[56] Almost 50 percent of urgent care centers surveyed had at least one staff member trained in emergency medicine.[57] Given this subset of data, it is reasonable to conclude patients are increasingly using urgent care centers to treat emergency medical conditions.

Retail clinics, which are usually found inside of drugstores, are also rapidly expanding as a low-acuity subset of urgent care centers. Over the past two decades, utilization of retail clinics has increased rapidly, with total visits growing approximately 39 percent between 2018 and 2019 alone.[58] In 2016, retail clinics handled an estimated 6,000,000 patient visits annually.[59] Although these retail clinics market themselves as appropriate for low-acuity care only, they are still sometimes used similarly to emergency departments. Research suggests that 42 percent of retail clinic visits represent substitution of other ambulatory care visits, while 58 percent represent new utilization.[60] Of the visits classified as substituted, approximately 93 percent represented substitution of office visits, and seven percent represented substitution of emergency department visits.[61] Even at a seven percent utilization rate, this would represent approximately 176,400 emergency department visits. According to the FAIR Health report cited above, the most frequent reasons for retail clinic visits are acute respiratory diseases and infections (37 percent of claims), encounters for immunization (nine percent of claims), ear infections and issues (six percent of claims), and influenza and pneumonia (six percent of claims).[62] Given this data and the rapid expansion of urgent care clinics across California and the country, it is likely that more patients will choose to go to urgent care and retail clinics to obtain emergency medical care.

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[54] FAIR Health, *supra*, at 20.

[55] *Id.*

[56] Robin M. Weinick, Staffanie J. Bristol & Catherine M. DesRoches, *Urgent Care Centers in the U.S.: Findings from a National Survey*, 79 BMC Health Servs. Rsch., no. 9, 2009, at 2, 4.

[57] *Id.* at 3.

[58] FAIR Health, *supra*, at 2.

[59] J. Scott Ashwood et al., *Retail Clinic Visits For Low-Acuity Conditions Increase Utilization and Spending*, 35 Health Affs. 449 (2016).

[60] *Id.* at 452.

[61] *Id.*

[62] FAIR Health, *supra*, at 12.

The Interim Final Rule only protects patients from surprise billing in emergency situations as it arises in hospital emergency departments and freestanding emergency departments. *See e.g.*, 86 Fed. Reg. at 36,952. Especially given the increasing use of urgent care centers and retail centers as an alternative in medical emergencies or substitutes in states that do not allow freestanding emergency departments, these alternative sites present the same risks of surprise billing that the Departments have identified with respect to hospital and freestanding emergency departments.

For instance, large insurance companies such as United Healthcare, Anthem, and Aetna contract with urgent care centers, advertise the convenience of urgent care facilities and list participating urgent care clinics on their websites.[63] Some urgent care centers disclose that they use outside laboratories to conduct certain tests.[64] Thus, much like the situation with emergency rooms, a patient may seek emergency services at an uncontracted urgent care center or at a contracted urgent care center that uses an uncontracted laboratory—which may result in a separate bill for the patient and increases the prospect of a balance bill.

Given how large and how quickly this industry is growing, I strongly urge the Departments to include urgent care centers in the final regulations for the No Surprises Act. Although the industry often differentiates the provision of "urgent care" from "emergency service," present urgent care centers offer emergency services to treat emergency medical conditions that are traditionally covered by regulations governing emergency rooms. Given the expansive use of urgent care centers for more traditional emergency services, the Interim Final Rule should reach any entity authorized to offer or that advertises immediate treatment of emergency medical conditions covered by the rule.

B. The Interim Final Rule Should Apply to Telemedicine

I also recommend that the Departments consider including telemedicine services within the scope of the Interim Final Rule. The pandemic has pushed telemedicine front and center in patient care. According to one study, during the pandemic, telemedicine usage increased 6,000 percent with particular growth in internal medicine and psychiatry.[65] There are now at least a dozen different telemedicine apps on the Apple Store, offering everything from basic prescription filling to urgent physical and psychiatric care. A patient with a smartphone, tablet, or computer can "see" a doctor anywhere the patient has an internet connection. Because of this convenience and relative low cost, many insurance plans offer telemedicine services and contract

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[63] *See Know Your Care Options,* United Healthcare (last visited August 4, 2021) *https://www.uhc.com*; *What To Know: Anthem's Health Care Services,* Anthem (last visited August 4, 2021); https://www.anthem.com; *DocFind,* Aetna (last visited August 4, 2021) https://www.aetna.com.

[64] For example: *Medical Services at Exer - More Than Urgent Care*, Exer (last visited August 4, 2021) https://exerurgentcare.com; *Walk-in Clinic Price List,* Minute Clinic (last visited August 4, 2021) https://www.cvs.com.

[65] *COVID-19 Drives 6,000 percent Growth in Telemedicine Use,* Definitive Healthcare (last visited August 4, 2021), https://www.definitivehc.com.

with them.[66] This, coupled with the increasing availability of home-based medical testing devices, means that a patient may have meaningful emergency services rendered by a doctor via remote connection. There is no doubt that a patient may be better served by going to a facility in person, but such virtual consultations may play a critical role in the evolution of better emergency medicine responses.

The Interim Final Rule specifically lists mental health conditions as a qualifying medical condition under the No Surprises Act. 86 Fed. Reg. at 36,962. A recent study calculated that twenty percent of all emergency departments already use telemedicine to assist in the treatment of mental health conditions—due to the lack of available mental health professionals.[67] This study reported that preliminary research reports that telepsychiatry has generally favorable outcomes.[68] Given this preliminary positive data, it is likely that telepsychiatry apps may play a significant role in the diagnosis or treatment of patients suffering from qualifying emergency mental health conditions. Telemedicine, including telepsychiatry, may play a pivotal role in emergency medicine by giving patients immediate or quick access to a medical professional who can diagnose or treat the ailment.

Emergency medicine may not be limited to the many walls of a hospital or clinic, but rather expanding into the literal palms of the hands of patients. Like conventional emergency departments and gig-economy based applications, telemedicine services eventually may contract with non-participating providers and thus subject the patient to a balance bill. As a result, the Departments should consider expressly including emergency-related telemedicine within its protections against balance billing.

Patients who seek treatment for emergency medical conditions must be protected from balance billing. Seeking treatment for an emergency medical condition is a difficult and stressful situation, and patients who receive treatment at an out-of-network urgent care should not face the additional stress and penalty of a balance bill. While state law protects Californians who seek treatment at the emergency department of a hospital or at an in-network urgent care facility such is not the case if emergent treatment is performed by an out-of-network urgent care center or telemedicine provider. Therefore, I recommend that the Departments broadly define "urgent care center" as any entity authorized to offer, or that advertises, immediate treatment of emergency medical conditions, and include them in the definition of emergency services. This broad definition recognizes that the prudent layperson may seek emergency medical services at a traditional urgent care clinic, specialty urgent care clinic, retail clinic, or via a virtual service. As discussed above, the prospect of a balance bill is present in all of these situations. This definition

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[66] For example: *24/7 Virtual Visits*, United Healthcare (last visited August 4, 2021) https://www.uhc.com.

[67] Rain E. Freeman, M.P.H. et al., *National Study of Telepsychiatry Use in U.S. Emergency Departments,* 71 Psychiatric Services 540 (2020).

[68] *Id.* at 544.

also properly excludes medical providers who do not offer immediate or emergency medical treatment.

IV. The Interim Final Rule Likely Underestimates the Number of Consumer Balance Billing Complaints the Departments Will Receive

I applaud the Interim Final Rule's efforts in creating one system to receive all balance billing complaints. 86 Fed. Reg. at 36,903. Having one federal enforcement authority accept balance billing complaints will provide consumers with a simple process to address their balance billing issues. The likelihood of consumer confusion makes it important that the process to file a complaint is seamless and easy for consumers to find and navigate. While the Interim Final Rule has an ambitious target to respond to complaints within 60 business days of receipt, the expectation of receiving 3,600 annual complaints about noncompliance by providers, facilities, air ambulances, plans and insurers seems low. 86 Fed. Reg. at 36,872.

The estimated annual balance billing involving air ambulances alone is higher than the Interim Final Rule's estimate of 3,600. A recent study found there were about 29,972 air ambulances from 2013-2017, averaging 5,994 air ambulance rides annually.[69] Seventy three percent of rotary-wing air-transportation, and 70 percent of fixed-wing air transportation results in a balance bill.[70] If a conservative estimate of 60 percent of all future air ambulances result in balance bills, there would be 3,596 annual balance bills for air ambulances. The number of air ambulance balance billing complaints alone almost equals the Interim Final Rule's estimate of all balance billing complaints.

For reference, California's Independent Dispute Resolution (IDR) at the Department of Managed Health Care (DMHC) received 100 complaints since 2017. While this number might seem low, each IDR complaint is bundled, meaning one single IDR complaint can have up to 50 individual complaints. Additionally, DMHC's IDR process does not address complaints about balance billing issues. Rather, DMHC's IDR process allows health plans and noncontracting individual health professionals to resolve disputes whether payment of the specified rate was appropriate.[71]

The Interim Final Rule's estimate of consumer balance billing complaints is important because HHS has discretion to "refer [a balance billing] complaint to another appropriate Federal or State Resolution process."[72] In submitting this comment, I seek to ensure that the estimation of consumer complaints and devoted resources aligns with the amount of balance billing reported

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[69] *Id*.

[70] Chabra et al, *Most Patients Undergoing Ground And Air Ambulance Transportation Receive Sizable Out-Of-Network Bills*, Health Affairs (May 2020) https://www.healthaffairs.org.

[71] Cal. Health & Safety Code § 1371.9.

[72] 45 CFR § 149.150(b)(3)(i).

and avoid a situation wherein HHS may become overwhelmed with complaints and refer a higher than anticipated amount of complaints to the states for processing.

V. Providers Should Include and Accept Payment in Full Based on a Good Faith Estimate

One additional area in which the Interim Final Rule can be strengthened is by prohibiting providers from collecting more than their good faith estimates for any given treatment. Out-of-network providers who receive a signed informed consent to balance bill a patient should be required to provide a good faith estimate of the cost.[73] "It should be considered a doctor's [and provider's] obligation to provide [a patient] with financial information."[74] Accordingly, providers and facilities should also be bound by the estimate provided to patients.

This is the approach taken in California's 2016 law, AB 72. The law requires a written estimate of the consumer's total out-of-pocket cost of care at the time the consent is provided. The provider then cannot collect more than the estimated amount without authorization, unless unforeseeable circumstances arise.[75] The Interim Final Rule provides that if an out-of-network provider who plans to balance bill does not include a good faith estimate of costs, the notice and consent criteria will not be met for those providers. 86 Fed. Reg. at. 36,937. But the burden for nonparticipating providers to provide and be held accountable to a good faith estimate should be weighed against the burden of patients receiving and being held responsible for a bill substantially higher than expected when providing and consenting to receive a balance bill. Indeed, by one estimate, only 39 percent of Americans can afford to pay for an unexpected $1,000 expense.[76]

Considering these factors, I recommend that the Interim Final Rule adopt a standard much like California's: unless an unforeseen medical procedure becomes necessary, the Interim Final Rule should prohibit providers from collecting more than their good faith estimate. The rule should also require providers to consider a consumer's payment of the good faith estimate to be payment in full.

VI. Federal and State Governments Should Work Together to Address the Problem of Surprise Billing for Ground Ambulance Services

The Interim Final Rule is a necessary first step to address balance billing at a federal level. However, one area that remains unaddressed is ground ambulance balance billing. There

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[73] *Id*.

[74] Rosenthal, Elisabeth, *An American Sickness: How Healthcare Became Big Business and How You Can Take It Back*, p. 359 (2017).

[75] Cal. Health & Safety § 1371.9(c)(3); Cal. Insur. § 10112.8(c)(3).

[76] Konish, Lorie, *Just 39 percent of Americans could pay for a $1,000 emergency expense* (Jan 11, 2021), https://www.cnbc.com/.

are currently minimal statewide or federal laws to protect patients from ground ambulance balance bills. Medicare's prohibitions on balance billing and state's balance billing protections do not generally extend to ground ambulance charges.[77]

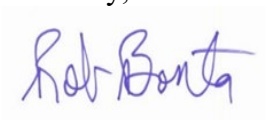
The magnitude of ground ambulance balance billing is high. More than twenty million ambulance rides occur annually in the United States.[78] The prevalence of potential surprise bills in ground ambulance is 79 percent for emergency rides, and 52 percent for nonemergency rides.[79] "The sum of all ground ambulance potential surprise bills in the period 2013-17 was $646 million, or $129 million per year."[80] One study found 71 percent of ground ambulance rides were billed out-of-network.[81] Ground ambulance encounters with potential surprise bills were over fifty-five times more common than air ambulance encounters with potential surprise bills (1,048,619 versus 18,810).[82]

Unfortunately, the No Surprises Act did not include any provisions to protect against balance billing for ground ambulance services. I hope that the Departments will look for opportunities to work together with state and local governments to address this significant remaining gap.[83]

VII. Conclusion

I strongly support the Departments' thorough efforts to advance protections at a federal level to protect consumers from balance billing. I appreciate your consideration of these comments and look forward to a continued partnership. Please do not hesitate to contact my office if you have any follow up questions or concerns.

Sincerely,



ROB BONTA
Attorney General

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[77] Chabra et al., *supra*.

[78] Rui et al., *National Hospital Ambulatory Medical Care Survey: 2016 emergency department summary tables*, National Center for Health Statistics (Mar. 17, 2020), https://www.cdc.gov.

[79] Chabra et al., *supra*.

[80] *Id*.

[81] Bandara D, Mayorga ME, McLay LA. *Priority dispatching strategies for EMS systems*, J. Oper. Res. Soc. 572-87 (2014).

[82] Chabra et al., *supra*.

[83] Health Access California, *Fact Sheet, supra*.