DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Consumer Information and Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201

February 17, 2021

The Honorable Mike DeWine
Governor of Ohio
Riffe Center, 30th Floor, 77 South High Street
Columbus, OH 43215

Judith French
Commissioner
Ohio Department of Insurance
50 West Town Street
Columbus, Ohio 43215

Dear Governor DeWine and Commissioner French:

The purpose of this letter is to inform you that the Centers for Medicare & Medicaid Services (CMS) understands that Ohio has authority and intends to enforce certain provisions of the Public Health Service Act (PHS Act) as extended or added by the Consolidated Appropriations Act, 2021 (CAA) with respect to health insurance issuers, and that CMS has agreed to enter into a collaborative enforcement agreement with Ohio to enforce certain PHS Act provisions as extended or added by the CAA with respect to health care providers, facilities, and providers of air ambulance services. This letter also provides the circumstances in which the Ohio independent dispute resolution process will apply, as well as the circumstances in which the federal independent dispute resolution process will apply. This letter also explains that the federal patient-provider dispute resolution processes will apply in Ohio. Additionally, this letter reflects CMS's determination that the Ohio external review process currently has the capability to address adverse determinations related to the surprise billing protections of the No Surprises Act under section 2719 of the PHS Act, as extended by Section 110 of the No Surprises Act, consistent with 45 CFR 147.136, as amended by the Requirements Related to Surprise Billing; Part II (86 FR 55980).

The CAA was enacted on December 27, 2020.[1] Title I (No Surprises Act) and Title II (Transparency) of Division BB of the CAA amended Title XXVII of the PHS Act by establishing new protections for consumers related to surprise billing and transparency in health care. The CAA contains new requirements for health insurance issuers in the individual and group markets, health care providers and facilities, and providers of air ambulance services. It

[1] Pub. L. 116-260 (Dec. 27, 2020).

amended section 2723 of the PHS Act and added a new section 2799B-4 of the PHS Act such that these new requirements are generally enforced in the same manner as the market-wide reforms in Part A of Title XXVII.[2] Therefore, states have primary enforcement authority over these new requirements under the CAA with respect to health insurance issuers, health care providers and facilities, and providers of air ambulance services.

CMS, on behalf of the Department of Health and Human Services (HHS), has an obligation under section 2723 of the PHS Act to directly enforce the applicable provisions in Parts A and D of Title XXVII of the PHS Act that a state fails to substantially enforce. Similarly, HHS has an obligation under section 2799B-4 of the PHS Act to directly enforce the applicable requirements under Part E of Title XXVII of the PHS Act that a state fails to substantially enforce. Therefore, in June 2021, CMS asked each state to complete a written survey providing its assessment of whether the state has the authority and intends to substantially enforce the new consumer protections extended or added to the PHS Act by the CAA beginning on the applicable effective date (generally January 1, 2022). In addition, CMS asked each state whether it has an All-Payer Model Agreement or specified state law in order to determine whether the federal independent dispute resolution (IDR) process would apply in the state beginning on January 1, 2022. CMS also asked whether the state has any state resolution process for payment disputes between providers and uninsured (or self-pay) patients in order to determine whether the federal patient-provider dispute resolution will apply in Ohio. We have included a copy of this survey as an appendix to this letter. The survey includes descriptions of each applicable provision's requirements. Please note, these descriptions are not an exhaustive list of all of the new requirements and should not be used as a substitute for the statutory provisions or implementing regulations.

Enforcement

Based on the survey response and CMS communications with the Ohio Department of Insurance staff, CMS understands that the Ohio Department of Insurance will enforce sections 2719 (as applied by section 110 of the No Surprises Act), 2746 (other than section 2746(c)), 2799A-1, 2799A-2, 2799A-3, 2799A-4, 2799A-5, and 2799A-9 (other than section 2799A-9(a)(4)) of the PHS Act with respect to health insurance issuers.

The Ohio Department of Insurance stated it lacks authority to enforce sections 2799B-1, 2799B-2, 2799B-3, 2799B-8, and 2799B-9 with respect to health care providers and facilities; section 2799B-5 with respect to providers of air ambulance services; and sections 2799B-6 and 2799B-7 with respect to health care providers, facilities, and providers of air ambulance services. However, the Ohio Department of Insurance expressed interest in entering into a collaborative enforcement agreement with CMS to enforce these provisions.

Under a collaborative enforcement agreement, the state will perform the compliance functions of policy form review, investigations, market conduct examinations, and consumer assistance, as applicable, with respect to the noted provisions of the PHS Act as extended or added by the

[2] While the general enforcement framework is the same under sections 2723 and 2799B-4 of the PHS Act, there are differences in the federal civil money penalties that can be imposed for violations of provisions that fall under each statute. Compare, e.g., 42 U.S.C. 300gg-22(b)(2)(C) with 42 U.S.C. 300gg-134(b)(1).

CAA. Only in the event that Ohio is unable to obtain voluntary compliance will CMS consider undertaking formal enforcement action against a health care provider, facility, or provider of air ambulance services, to the extent warranted. CMS will provide a copy of the collaborative enforcement agreement directly to the Ohio Department of Insurance for signature. Without such an agreement in place, CMS will perform these regulatory functions in Ohio pursuant to section 2799B-4 of the PHS Act.

We are pleased that we will be able to accomplish our enforcement through the collaborative enforcement agreement with Ohio. We ask for your cooperation in working with CMS to effectively enforce the new PHS Act consumer protections extended or added by the CAA in Ohio. If, in the future, Ohio should act to assume direct enforcement authority of any of the noted provisions, CMS will enter into discussions with Ohio on the process for an effective transition to state enforcement under 45 CFR 150.221. We look forward to working with Ohio to ensure that your residents are afforded all of the protections in title XXVII of the PHS Act that were extended or added by the CAA.

In the September 16, 2021 Notice of Proposed Rulemaking (NPRM) entitled, *Requirements Related to Air Ambulance Services, Agent and Broker Disclosures, and Provider Enforcement* (86 FR 51730), HHS proposed to have direct enforcement authority for new CAA provisions that require issuers to submit information to HHS regarding agent and broker compensation, air ambulance services, pharmacy benefits and drug costs, and compliance with the prohibition on gag clauses on price and quality information, unless the state notifies CMS of its intent to enforce. Therefore, if the September 16, 2021 NPRM is finalized as proposed, CMS expects to directly enforce sections 2746(c), 2799A-8, 2799A-9(a)(4), and 2799A-10 of the PHS Act with respect to issuers in Ohio unless Ohio notifies CMS of its intent to enforce.

I want to take this opportunity to thank the staff in the Ohio Department of Insurance for the productive conversations related to authority and enforcement of these new consumer protections. The existing PHS Act enforcement structure is very much a partnership between states and the federal government, and we recognize and support the fundamental role states play in protecting consumers. This letter does not change Ohio's role as primary enforcer of the other market-wide reforms codified in Parts A, B, and C of Title XXVII of the PHS Act with respect to health insurance issuers that issue, sell, renew or offer health insurance coverage in the individual or group market in Ohio.[3]

Independent Dispute Resolution

Section 2799A-1 of the PHS Act governs the out-of-network rate that plans and issuers are generally required to pay nonparticipating providers and facilities for emergency services, and nonparticipating providers for non-emergency services performed at certain participating facilities. Section 2799A-2 of the PHS Act governs the out-of-network rate that plans and issuers are generally required to pay nonparticipating providers of air ambulance services for covered air ambulance services. The out-of-network rate under these sections may be determined by an All-

[3] This includes the patient protections regarding choice of health care professional from section 2719A(a), (c), and (d) of the PHS Act, recodified by the No Surprises Act as new section 2799A-7 of the PHS Act.

Payer Model Agreement under section 1115A of the Social Security Act, or if the state does not have an All-Payer Model Agreement, a "specified state law," as defined in section 2799A-1(a)(3)(I) of the PHS Act and 45 CFR 149.30. In order for an All-Payer Model Agreement or specified state law to determine the out-of-network rate, it must apply to the nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services; the plan, issuer, or coverage (including where a state law applies because the state has allowed a plan that is not otherwise subject to applicable state law an opportunity to opt in, subject to section 514 of the Employee Retirement Income Security Act); and the item or service involved.

If neither an All-Payer Model Agreement nor specified state law apply, the out-of-network rate is an amount agreed upon between the plan or issuer and the provider, facility, or provider of air ambulance services. If the plan or issuer and the provider, facility, or provider of air ambulance services do not agree upon an amount and therefore enter into the federal independent dispute resolution process, the out-of-network rate is the amount determined by a certified independent dispute resolution entity. Sections 2799A-1(c) and 2799A-2(b) of the PHS Act require the Departments of HHS, Labor, and the Treasury to establish a federal independent dispute resolution process. In order to determine whether this federal independent dispute resolution process will apply in Ohio and in what circumstances, in its written survey, CMS solicited information regarding state All-Payer Model Agreements and state laws that may be consistent with the federal definition for a "specified state law."

Ohio does not have an applicable All-Payer Model Agreement that would determine the out-of-network rate. Based on CMS research and CMS communications with Ohio Department of Insurance staff, CMS understands that ORC 3902.50 – 3902.54 are specified state laws that will apply for purposes of determining the out-of-network rate with respect to emergency services and non-emergency services by nonparticipating providers at in-network facilities. The federal independent dispute resolution process under section 2799A-2(b) of the PHS Act and 45 CFR 149.520 will apply for purposes of determining the out-of-network rate with respect to services furnished to individuals in an insured group health plan, or group or individual health insurance coverage in Ohio by nonparticipating providers of air ambulance services. The Ohio Department of Insurance will enforce the outcome of the federal independent dispute resolution process for such cases in Ohio.

<u>Patient-Provider Dispute Resolution</u>

Section 2799B-7 of the PHS Act requires HHS to establish a patient-provider dispute resolution process through which uninsured (or self-pay) individuals who, under section 2799B-6 of the PHS Act, receive a good faith estimate of the cost of a scheduled service from a provider, facility, or provider of air ambulance services and are then billed charges substantially in excess of that estimate can seek a determination from a dispute resolution entity for the amount of charges to be paid. Under the regulations implementing this statute, uninsured (or self-pay) individuals have 120 calendar days from receiving the initial bill containing charges for the item or service that is substantially in excess of the expected charges in the good faith estimate to initiate the patient-provider dispute resolution process and obtain a binding payment amount determination from a selected dispute resolution entity.

Under 45 CFR 149.620(h), HHS will defer to a state's patient-provider dispute resolution process if the state has a state law that meets the following minimum requirements with respect to the item or service for which payment is in dispute:

- Payment determinations made through the state process are binding, unless the provider, facility, or provider of air ambulance services offers for the uninsured (or self-pay) individual to pay a lower payment amount than the determination amount;
- The dispute resolution process takes into consideration a good faith estimate, that meets the minimum standards established in 45 CFR 149.610, provided by the provider, facility, or provider of air ambulance services to the uninsured (or self-pay) individual;
- If the state charges a fee to uninsured (or self-pay) individuals to participate in the patient-provider dispute resolution process, the fee must be equal to or less than the federal administrative fee; and
- The state must have in place a conflict-of-interest standard that, at a minimum, meets the requirements at 45 CFR 149.620(d) and (e).

CMS will review changes to the state process on an annual basis (or at other times if CMS receives information from the state that would indicate the state process no longer meets the minimum federal requirements) to ensure the state process continues to meet or exceed the minimum federal standards.

In the event that the state process is terminated, or CMS determines that it no longer meets the minimum federal requirements described in 45 CFR 149.620(h)(2), CMS will make the federal process available to uninsured (or self-pay) individuals in that state to ensure that the state's residents have access to a patient-provider dispute resolution process that meets the minimum federal requirements.

In order to determine whether this federal patient-provider dispute resolution will apply in Ohio and in what circumstances, CMS solicited information regarding any state resolution process for payment disputes between providers, facilities, or providers of air ambulance services and uninsured (or self-pay) patients as part of CMS's written survey.

Ohio did not indicate that any applicable state resolution process for payment disputes between providers and patients currently exists. Therefore, the federal patient-provider dispute resolution process under section 2799B-7 of the PHS Act and 45 CFR 149.620 will apply for purposes of determining the amount an uninsured (or self-pay) individual must pay a provider, facility, or provider of air ambulance services for an item or service for which the billed charges are substantially in excess of the good faith estimate of the expected charges that the applicable provider, facility, or provider of air ambulance services provided the individual prior to furnishing such item or service. CMS will enter into a collaborative enforcement agreement with Ohio to enforce the outcome of the federal patient-provider dispute resolution process in Ohio.

Please notify your CMS state engagement coordinator, Angela Veney at angela.veney@cms.hhs.gov of any changes with respect to Ohio's authority or intent to enforce

any of the specified PHS Act provisions, and any changes with respect to the specified state law and state dispute resolution process.

If you have any questions or would like additional information regarding this letter, please do not hesitate to contact Angela Veney at angela.veney@cms.hhs.gov or Mary Nugent at 301-503-9718 or Mary.Nugent@cms.hhs.gov.

Thank you for your cooperation as we prepare, together, to make sure health care consumers across the country receive the full protections of the law.

Sincerely,

Ellen Montz
Director
Center for Consumer Information and Insurance Oversight