ACCT FOR PATIENTS
ASSOCIATION OF CRITICAL CARE TRANSPORT

January 2, 2024

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

The Honorable Julie A. Su
Acting Secretary of Labor
U.S. Department of Labor
500 C St. NW
Washington, D.C. 20001

The Honorable Janet Yellen
Secretary
U.S. Department of the Treasury
1500 Pennsylvania Avenue, N.W.
Washington, D.C. 20220

Re: Comments from the Association of Critical Care Transport on the November 3, 2023 Proposed Rule on Federal Independent Dispute Resolution Operations, 45 CFR Part 129 [CMS-9897-P] RIN 0938-AV15.

Sent via electronic mail to www.regulations.gov.

Dear Secretaries Becerra, Su, and Yellen:

On behalf of the Association for Critical Care Transport (ACCT) for patients, we are writing regarding ongoing implementation of the No Surprises Act, including the proposed rule that was published to the Federal Register on November 3, 2023.

ACCT is a nonprofit grassroots patient advocacy organization committed to ensuring that critically ill and injured patients have access to the safest and highest quality air transport system possible. Comprised of air and ground critical care transport providers, patients, air operators, business organizations, associations, physicians, and individuals, ACCT members have a shared commitment to making the critical care transport system into one that is accountable, patient-centered and characterized by quality, safety, and value. Our mission is patients, not profits.

ACCT strongly supported enactment of the *No Surprises Act* and its inclusion of air ambulance services. We applaud the work of your and other involved departments to increase price transparency and predictability for patients and take patients out of the middle of price negotiations between providers and payers.

However, given the unique nature of air ambulance services, we strongly urge you to strengthen certain parts of this rule as applicable to air ambulances to address the cash flow crisis that has enveloped the air medical enterprise since the enactment of the NSA, not due to structural flaws with the NSA, but due primarily to abuses of the process by some group plans and health insurance issuers and the need for the rules to more specifically address the unique nature of air ambulance services.

PREFATORY BACKGROUND:

The Congress established an entirely different statutory section of the NSA for air ambulance services, recognizing that they are very different from other health care providers in federal and state oversight, and the provision of service delivery. Air ambulance services are provided in either a helicopter or fixed wing aircraft, hundreds of feet above ground, not in a fixed facility. They treat and transport 400,000 of our nation's most critically ill and injured patients. They are a critical component of the pre-hospital emergency medical services (EMS) systems in all states and localities across the nation.

Unlike the NSA Section 2799A-1 governing other health care providers, the NSA section 2799A-2 governing air ambulances does not reference state laws overseeing balance billing because the Airline Deregulation Act prohibits states from regulating the prices, routes, and services of air ambulances. While the ADA does not prohibit states from establishing rules regarding the medical care and treatment of patients aboard air ambulances, nor does it prohibit states and localities from establishing EMS protocols, it specifically forbids states from any oversight of any economic regulation of air medical service delivery. Further, all aviation aspects of the aircraft, flight, pilots, etc. are governed by the Federal Aviation Administration. Thus, both the economic and aviation components of air ambulance services are governed by the federal government.

In the absence of the Department's intervention, we are extremely concerned that air ambulance programs will falter and economically collapse in many parts of the country, jeopardizing access to life-saving care and transport for patients most in need. It is within this context that we request that the Departments utilize all relevant statutory authority as quickly as possible to head off this developing crisis, recognizing that the states are prohibited by federal law from doing so themselves for air ambulances.

KEY CONCERNS:

Lack Of Timely Claims Decisions And Payments.

Congress expected and required that payers would provide an interim payment or denial decision within 30 days. Unfortunately, in some parts of the nation, and among certain health insurance issuers, they are consistently not meeting the required 30-day deadline to provide interim payments or deny the claim. Additionally, some issuers are also not paying providers within the statutory 30-day deadline after the IDR decision has been reached. This is creating a cash flow crisis for many air ambulance providers which could result in base closures or program termination.

The financially precarious situation of one small nonprofit hospital-based air ambulance provider illustrates the severity of the problem:

- ❖ The provider has 16 individual charges fully denied by insurance companies totaling $520,000.
- ❖ The provider currently has 118 individual charges in the IDR arbitration process totaling $2.3 million in underpayments due from insurance companies.
- ❖ The provider won 9 out of 11 completed IDRs yet has only received $15,000 of the $171,000 awarded determinations. The insurance carriers are well over the 30-day window to reprocess the additional payment.
- ❖ The provider has multiple IDR requests with one IDR totaling $940,000 in underpayments that are over 30 days (now almost 300 days) from the IDR request approval.
- ❖ The provider has consistently requested the payers QPA rate/calculation but has yet to receive a QPA explanation from a payer.
- ❖ The current financial impact totals approximately $4.7 million, which accounts for almost 18% of the provider's 2022 total revenue. They have seen a 33% reduction in private insurance revenue from 2021.

Unwarranted Denials For Lack Of Medical Necessity Or Prior Authorization.

Unlike hospital services, air ambulance services aren't requested or initiated by the patient, they are requested by ground EMS or an attending physician at a referring hospital. More specifically, when ground EMS responds to a 911 call they arrive at the scene, assess the patient and determine whether the patient's emergency medical condition requires immediate air transport for clinical capability, speed of transport or both, medical necessity should be presumed, consistent with Medicare regulations.[1] When an attending physician at a hospital orders an inter-facility air transport, it is always to a higher or more specialized level of care (not including repatriation). That physician and referring hospital are subject to EMTALA and will only call for air transport if medically necessary because the hospital is not capable of caring for and in many cases cannot stabilize the patient. The referring physician under EMTALA has to determine the need for transport, the level of care during transport including a critical care team, and the mode of transport necessary for the care of the patient because the physician and hospital are subject to serious civil penalties and possible expulsion from Medicare if they violate EMTALA's requirements.

Unfortunately, we have seen a spike in claims denial post NSA due to lack of medical necessity from some insurers and in certain regions of the nation, particularly for inter-facility air transports. Below are the following types of inappropriate denials air ambulance providers have experienced, predominantly among certain health insurance issuers, and predominantly for inter-facility transports.

- ➢ *Denying the claim on day twenty-nine (29) for "lack of documentation" for an inter-facility transport from the referring and receiving hospital as to medical necessity.* This is a catch-22 for providers. Providers cannot submit a "clean claim" to demonstrate medical necessity because there is no way to physically attach the medical record to the HCFA 1500 Form. Follow-up emails with the necessary

[1] Medicare Program Integrity Manual Chapter 6 - Medicare Contractor Medical Review Guidelines for Specific Services Table of Contents (Rev. 10365, 10-02-20)

documentation get "lost" in the plans' system because they cannot be submitted together. Further, there is an impediment to the ability of air ambulance providers to even secure such documentation from transferring or receiving hospitals on a timely basis. They simply do not control the patients' medical record which is in the domain of ground EMS and the transferring and receiving hospitals. Obtaining that documentation takes time and the good will of the transferring and receiving hospitals.

- *Denying the claim for "transport beyond the closest hospital."* In general, the standard is to fly a patient to the "closest most medically appropriate facility." For example, both trauma and stroke patients are routinely flown over other hospitals if they require the highest level of care at a Level I trauma center or a comprehensive stroke center. Further, there are instances where patients are flown beyond the "closest most medically appropriate facility" because the closest hospital is on bypass, cannot accept the patient for lack of a clinically appropriate bed or lack of availability of particular clinicians (such as they are already in another surgery). Carriers often completely denying the entire claim.

- *Denying the claim based on mode of transport, "because the patient could have been transported by ground ambulance"* with no rationale for how this is determined or if a critical care ground ambulance is even available. The most vulnerable time for a patient is the out of hospital time and the physician's determination for air transport is based on their full responsibilities under EMTALA.

- *Denying the claim because "the patient should have been taken elsewhere" such as a closer hospital or because "the patient could have been transported by ground ambulance."* For scene EMS calls, the determination for whether to transport the patient by air and to which hospital, is determined by ground EMS for a scene call or a physician (or qualified medical personnel) for transport is based on established state and local EMS protocols.

- *Denying the claim for "lack of preauthorization."* Since the implementation of the NSA a number of carriers have rapidly increased denials for lack of preauthorization. Emergencies are by nature unscheduled events. In the face of an emergency, it is not reasonable or possible to obtain preauthorization from a carrier which is not timely and generally completely not possible at night.

RELEVANT STATUTORY AUTHORITIES:

We have thoroughly researched the authority of the Secretary of HHS and are confident that there is ample such authority for the Secretary to implement each and every one of our recommendations in this comment letter to the November 3, 2023 proposed rule.

First, the NSA statute under Title XXVII Part D of the Public Health Service Act (PHSA) provides a separate and distinct regulatory requirement specifically for air ambulances for the Secretaries to promulgate by regulation one IDR process for "qualified IDR air ambulance services" as provided in the NSA. Under Section 2799A-2-(b)(2)(A, the Secretaries "shall" establish by regulation one independent dispute resolution process…..under which (i) a plan, issuer or provider submits

notification to enter IDR and in accordance with the succeeding provisions of this subsection 2799A-2(b)(2) and (ii) an IDR entity determines the amount of payments.

This provides not only broad authority for the Secretaries to establish by regulation the specifics regarding the notification to enter IDR for all air ambulance services (scene and inter-facility) specifically, and the IDR process itself, including payment determination, but a specific requirement to issue such a regulation. Promulgating separate and distinct regulations for air ambulance services will better ensure that the IDR process statutory requirements are being followed as intended by the Congress. More specific recommendations are provided in our proposed solutions in the next section of this letter.

Second, ***inter-facility transports*** are also governed by Section Title XXVII Part A of the PHSA under Section 2719A(b) dealing with patient protections and coverage of "emergency services", and over which the Secretary has regulatory and enforcement authority. Under this section, group health plans and health insurance issuers that provide or cover any benefits to services in an emergency department shall cover "emergency services" –

A. Without the need for any prior authorization determination;

B. Whether the provider is a participating provider;

C. Such services will be provided without imposing any requirement under the plan for prior authorization or any limitation on coverage for lack of a contract that is more restrictive than the requirements or limitations of participating providers.

D. Without regard to any other term or condition of such coverage (other than exclusion, or coordination of benefits, or waiting period or applicable cost-sharing).

The statutory definition of "emergency services" includes "such further medical examination and treatment as are required under Section 1867 of the Social Security Act – to stabilize the patient" which is EMTALA. And, the term "to stabilize the patient" with respect to an emergency medical condition has the meaning provided in EMTALA's Section 1867(e)(3), which specifically states that "to stabilize" means to "provide such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the *transfer* of the individual from a facility, or, with respect to an emergency medical condition as described in paragraph (1)(B), to deliver the placenta" (emphasis added).

The need for emergency, unscheduled transfer of patients, many of whom are critically unstable or with potential for rapid cardio-pulmonary or neurologic deterioration, is the core of the physician's determination to emergently transport the patient by air. This means that under Section 2719(A), plans and issuers "shall cover emergency services", including inter-facility air transport, without the need for prior authorization of services and "without regard to any other term or condition of such coverage…" The entire point of prohibiting plans and issuers from requiring prior authorization and other obstacles to obtain emergency services, including inter-facility air transport, is to ensure that coverage is not an obstacle to emergency care and treatment. The Secretary should not allow plans and issuers to deny for medical necessity of an

inter-facility air transport as these denials directly contravene the intent of the statute which is to ensure the immediate availability of emergency medical care and transport.

Third, hospitals and physicians providing "emergency services" in an emergency department are separately subject to the requirements of EMTALA, Section 1867 of the Social Security Act, which apply to all patients, not just Medicare patients, which governs the ***inter-facility transfer*** of a patient, and which the Secretary of HHS is responsible for enforcing.

Under subsection 1867 (a) hospitals must provide for a medical screening to determine whether or not an "emergency **medical condition" exists.**

Under subsection (b) If the individual has an "emergency medical condition" the hospital must provide either –

(A) within the staff and facilities available at the hospital, for such further medical examination and such treatment as may be required to stabilize the medical condition, or

(B) for transfer of the individual to another medical facility in accordance with subsection (c), otherwise known as an inter-facility transport which may be emergent in nature and require tertiary hospital level care during the transfer.

Under subsection (c), the hospital may not transfer the individual unless --

(A) it (i) obtains informed consent for the transfer, including risks thereof, from the patient or person legally acting on the patient's behalf; or (ii) a physician has signed a certification based on the information available at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the increased risks to the individual, and, in the case of labor, to the unborn child from effecting the transfer; or (iii) an appropriate qualified medical person has provided such certification if a physician is unavailable; and

(B) the transfer is an *appropriate transfer* (within the meaning of paragraph (2)) to that facility.

Under paragraph (2), *an appropriate transfer* to a medical facility is a transfer –

(A) in which the transferring hospital provides the medical treatment within its capacity to minimize risk to the patient;

(B) in which the receiving medical facility (i) has available space and qualified personnel for the treatment of the individual, and (ii) has agreed to accept transfer of the individual and to provide appropriate medical treatment;

(C) in which the transferring hospitals sends the receiving hospitals all the appropriate medical records;

(D) in which the transfer is affected through qualified personnel and transportation equipment, as required including the use of necessary and medically appropriate life support measures during the transfer; and

(E) which meets such other requirements as the Secretary may find necessary in the interest of the health and safety of individuals transferred.

Subsection (d) addresses enforcement including civil monetary penalties and civil enforcement against hospitals and physicians providing care in the emergency departments, including up to $50,000 for each violation or, if the violation is gross and flagrant, exclusion of Medicare participation.

Subsection (h) of Section 1867 specifically prohibits Medicare participating hospitals from delaying "provision of an appropriate medical screening examination required under subsection (a) or further medical examination and treatment required under subsection (b) in order to inquire about the individual's method of payment or insurance status."

Fourth, the NSA provides additional Secretarial authority to specify "such information" that must be submitted by a party initiating IDR under Section 2799a-2(b)(1)(b). We believe this authority includes the ability of the Secretaries to require that if a plan or provider does not provide an interim payment within 30 days, that would constitute bad faith.

Fifth, the NSA includes a Secretarial requirement to issue an interim report under section 2799a-1(c)(5)(e)(iv), as referenced in the statute under section 2799a-2(b)(5)(c)(ii)(vi), regarding whether any plans or issuers have a pattern or practice of routine denial, low payment, or down-coding of claims, or otherwise abuse the 90-day period… including recommendations on ways to discourage such a pattern or practice.

Sixth, the Secretary of HHS has enforcement authority over health insurance issuers, including imposition of civil monetary penalties, under Section 2723 of Part A of Title XXVII of the PHSA.

Seventh, the Secretary has authority under Section 2792 of the PHSA "to promulgate such regulations as may be necessary or appropriate to carry out the provisions of this title."

SPECIFIC COMMENTS TO THE NOVEMBER 3, 2023 PROPOSED RULE:

Given the cash flow crisis outlined above that is threatening a number of small and regional air ambulance providers, we have focused our comments on immediate improvements to the IDR operations for air ambulance providers in the final rule to alleviate the cash flow crisis; and additional requirements that will improve the IDR operations on a longer-term basis. Our comments follow the structure of the proposed rule and focus on where we urge the Secretaries to strengthen the rule specific to air ambulance services.

II. Overview of the Proposed Rules

B. *Use of CRCs and RARCs*.

In general, we support the Departments' proposal to utilize CARCs and RARCs. We would note that in air medicine, CARCs and RARCs are already being used to some degree, but not consistently across all payers.

While standardizing the list and use of CARCs and RARCs will be useful in determining how to respond to claims processing issues, what would be even more helpful is creating a standardized

claims processing tracking system (similar to FedEx or UPS Tracking), with standardized processing schedules/task descriptions, such that a provider of air ambulance services can readily determine when a claim has been received, where it sits at any point in time within the claims processing cycle, with standardized description/reason for any specific aspect of the claim that is being reviewed/validated and standardized description/reason for any issues causing delays in a claim moving to the next processing stage. To this end the Proposed Rule seeks comment on Page 75770 on whether disputing parties should use the Federal IDR portal for further communications between the parties if there is a dispute. We believe this is an important addition to track progress on dispute resolution.

Standardizing the CARCs and RARCs will be modestly helpful, **but will not eliminate the unnecessarily delayed claims payments, which is why we have provided additional recommendations for ensuring timely and reasonable payments.** It is imperative that the Departments hold plans and issuers accountable for maintaining their own databases and member information and updating coordination of benefits information. Delays in payment within the initial 30-day period due to their own inadequacy of maintaining databases sufficient to provide such a payment is not a reasonable excuse for such a delay. We believe it is essential to standardize communications between plans and issuers and providers and the use of CARC's and RARC's are the means to assure a timely and time stamped standard, transparent, and trackable process. We believe there need to be distinct standardized communications for air ambulances including:

- if there is a medically necessity denial, the rationale for the denial;
- how the QPA was calculated including if it has included the additional factors for air ambulances specified in the NSA and Rules;
- if there is dispute on the QPA, the database used by the issuer or carrier, or the methodology used by the provider to calculate the QPA.

C. Information To Be Shared About the QPA.

We strongly support the Departments' proposal to require the disclosure of the QPA and meaningful information about how it was derived when making the interim payment to providers of air ambulance services. Further, we support the clarification that references to "providers" includes "providers of air ambulance services" where it was previously unclear. The lack of consistent information about the QPA has certainly hindered an efficient and transparent IDR operations process. Currently, many plans and issuers are not providing any information on how they calculated a QPA, what data base and/or metrics they used, the issued QPA relationship to median in-network agreements, and whether the additional factors required under the law have been applied. Rather our experience is that plans and issuers continue to use Medicare reimbursement as a benchmark despite this being inconsistent with the law and Rules.

Currently, the QPA from plans and issuers is often a "black box." We believe the Departments' proposed changes will be helpful but still insufficient with regard to air ambulance services to curb the abuses by plans and issuers that air ambulance providers have been experiencing that we do not believe the Congress intended. We strongly urge the Departments to add the additional following requirements to ensure a fair playing field between the providers and plans/issuers that will protect the patients without harming the air ambulance providers.

First, Require Plans and Issuers to Provide an Interim Payment At An Amount Specified in the Rule. In the July 13, 2021 Interim Final Rule Requirements Related to Surprise Billing; Part I, the Departments stated:

> In the Departments' view, the statute's reference to an "initial" payment does not refer to a first installment. Rather this initial payment should be an amount that the plan or issuer reasonably intends to be payment in full based on the relevant facts and circumstances and as required under the terms of the plan or coverage, prior to the beginning of any open negotiations or initiation of the IDR process.[2]

The Departments further stated that "[t]hese interim final rules do not require plan and issuers, when making an initial payment to providers or facilities to make any specific amount of minimum initial payment." The Departments noted that some states provide such specified amounts. However, states are prohibited by the Airline Deregulation Act from regulating the prices, routes, and services of air ambulance providers, such that states cannot provide additional protections for air ambulance providers.

The Departments more specifically addressed the potential need for additional standards if "abuse" and "gaming" is taking place, which is exactly the situation air ambulance providers are experiencing as described previously in this comment letter. The Departments stated:

> The Departments may specify additional standards if the Departments become aware of instances of abuse and gaming where plan and issuers are delaying making an initial payment or sending a notice of denial that the provider has not submitted a clean claim. The Departments solicit comments on whether any additional standards are necessary to prevent abusive claims of payment practices.[3]

Further, the Departments solicited specific input on whether they should "set a minimum payment rate or methodology in future rulemaking, and if so, what that rate of methodology should be."[4]

In response to the July 13, 2021, Interim final rules with request for comments, ACCT, provided a comment letter on September 7, 2021 on the Surprise Billing Rule Part I, followed by another comment letter on September 9, 2021 outlining additional issues and recommendations regarding the air ambulance industry, and yet another letter responding to the Surprise Billing Rule Part II on December 6, 2021 addressing similar issues.

Since the initial implementation of the NSA and the Departments rulemaking, we have learned that relying on the plans and issuers to make an initial payment that will reasonably be payment in full in good faith is all too frequently simply not working. We believe that the "abuses" and "gaming" are so problematic as to warrant the Departments to use this NSA rulemaking to stop them from continuing. We urge the Departments to amend the November 3, 2023, proposed rule to provide additional standards that would address the most egregious problems and enable the cash to start flowing to air ambulance providers before air ambulance programs close bases or their agencies and access to life-saving air ambulance services is impeded. The ADA's federal

[2] 86 FR No 131, p. 36900.
[3] Ibid.
[4] Ibid, p. 36901.

prohibition from states setting such a rate underscores the need for the Departments to take such action at this time.

Far too many plans and issuers are failing to pay air ambulance providers anything within the 30-day statutory requirement. For those that do pay, they are often paying the Medicare rate, which is wholly inadequate, and the statute specifically forbids the IDR to utilize in establishing the out-of-network rates.[5] Or they may pay some other random rate that is nowhere near their later offer provided during the IDR process. All of this is greatly contributing to the cash flow crisis among air ambulance providers.

One of the most important steps the Departments can take to ensure that plans and issuers follow the statutory requirements of the NSA is to specify the minimum interim payment amount as:

> The lesser of:
>
> (i) the plan or issuer's QPA (with detail on its calculation); or
>
> (ii) a minimum fee based upon the Fair Health average estimated allowed amount[6] in 2020 for rotary-wing air ambulance of $18,668 for the base fee or for fixed-wing air ambulance of $24,507, and $125 mileage rate, inflated forward.

We believe that the Fair Health data is objective and a reasonable source for the Departments to utilize at least on a temporary basis. Alternatively, the Departments could utilize the methodology we provided in our prior comment letters based on GAO and HCCI data previously referenced. Once the air ambulance cost reporting data is available, the Departments will have better data upon which to establish a minimum interim payment amount, but until then, establishing this requirement to pay the lesser of the QPA or the minimum fee based on the FAIR Health data will at least get cash flowing again.

Second, Require Presumption of Medical Necessity to Curb Abusive Denials. Given the uniqueness of who is ordering air ambulance services — ground EMS and hospital physicians — medical necessity and appropriateness should be presumed and verified after payment, not before.

The Secretaries are empowered in the NSA statute to define "qualified IDR air ambulance services" as part of the regulation for "one independent dispute resolution process" for air ambulance services that the Secretaries "shall" establish. Consistent with the statutory Medicare required presumption of medical necessity for rural air ambulance transport [7], the Secretaries should establish by regulation that a "qualified IDR air ambulance service" means one that is either –

[5] HR 133-1622. (5)(D) PROHIBITION ON CONSIDERATION OF CERTAIN FACTORS.
[6] FAIR Health White Paper, Air Ambulance Services in the United States, A Study of Private and Medicare Claims, September 28, 2021.
[7] SSA 1861 (s)(7) and regulatory requirements at. *42CFR 424.10 as amended* Section 415 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

(1) an inter-facility transfer and treatment ordered by a physician (or qualified medical professional) subject to EMTALA requirements and enforcement; or

(2) a transfer and treatment from a scene call that is requested by ground EMS at the scene and is consistent with state and local EMS protocols.

Based on the statutory authorities outlined earlier in this letter, we are highly confident that the Secretary of HHS has considerable authority to require presumption of medical necessity at least ***for inter-facility transports*** under his authority under EMTALA in Section 1867 of the SSA and the Patient Protections for Emergency Services in Section 2719A of the PHSA, in addition to the specific regulatory under the NSA Section 2799A-2 over air ambulances. Further, we believe that the NSA in Section 2799A-2(b) provides regulatory authority that reasonably allows the Secretary to define "qualified IDR air ambulance services" as those which are ordered by a physician in a hospital or ordered by ground EMS in accordance with state or local protocols.

We urge the Secretaries to require that plans and issuers provide an interim payment within 30 days as required by the NSA, and not issue a notice of denial for "qualified IDR ambulance services" pursuant to our proposed definition above. As noted above, to enable plans and issuers to deny a claim for air ambulances legitimately ordered by a physician in a hospital or by ground EMS would be inconsistent with the prohibition against prior authorization and other limitations on claims for "emergency services" in Section 2719A of the PHSA. Further, to do so would be inconsistent with the intent of EMTALA, which is to prevent hospitals from withholding or delaying emergency care for financial reasons.

The NSA, EMTALA and the Patient Protections in Section 2719A all work together to ensure that patients, regardless of their ability to pay, receive emergency services in the emergency department, that patients with emergency medical conditions are treated or transported if necessary to a higher or more specialized level of care, that an inter-facility transfer is effected through qualified personnel and equipment, including the use of necessary and medically appropriate life support measures during the transfer and that their medical condition does not deteriorate during the transfer, and that ultimately, the patients are not billed beyond the applicable cost sharing amounts for all these services. It makes no sense for plans or issuers to be able to deny a claim for inter-facility air ambulance services that are governed, and in some instances required, under Section 2719A and EMTALA. It makes no sense for plans or issuers to be able to deny a claim for "lack of documentation", not "being taken elsewhere" or "should have gone by ground."

The emergency physician (or qualified medical personnel) at a transferring hospital must make several essential clinical determinations, for which he or she remains liable under EMTALA throughout a transport until the receiving hospital has accepted the patient. First, the physician must ascertain whether the patient has an emergency medical condition. Second, he or she must determine whether the hospital is capable of treating the patient and whether the patient is unstable. If the hospital is unable to treat the patient, the physician must identify the appropriate medical facility, ensure that it has capacity to receive the patient and is willing to receive the patient. If the patient is unstable, the physician must obtain informed consent or certify that the risk of transport is outweighed by the patient's need to receive a higher and more specialized level of care. The physician must determine the level of capability of the ambulance called for transport in providing the appropriate clinical level of care and timeliness of transport so as to

prevent deterioration of the patient's medical condition. Because the transferring physician is liable under EMTALA for the patient during the transport and until the receiving hospital actually assumes care the patient, all of these clinical determinations should not be second guessed by a plan or issuer for the purpose of the initial payment within 30 days and for any "qualified IDR air ambulance service." Put another way, while the amount of payment for the service will be determined through the process established in the NSA, determinations as to whether the air ambulance service was medically necessary should be presumed and subject to retrospective review.

In summary, given the prohibitions on issuers provided in Section 2719A to remove any barrier to a patient receiving emergency services for an emergency medical condition and the liability imposed by EMTALA on physicians, qualified medical personnel and hospitals with regard to a transport of a patient with an emergency medical condition, the Secretaries should add a requirement in the final rule that plans and issuers must presume medical necessity for air ambulance services ordered by a physician at a hospital or ground EMS and may not denied before and during the IDR process subject to retrospective review. We believe there is sufficient statutory authority within these three statutes to protect patient access to emergency medical services whether an inter-facility transport or a scene call.

Third, Prohibit Prior Authorization Denials for Air Ambulance Services. At a minimum, we urge the Secretary of HHS to clarify that unscheduled, time critical, inter-facility air ambulance transports are "emergency services" and that plans and issuers are subject to the requirements of Section 2719A of the PHSA, including the prohibition on requirement prior authorization. We would note unscheduled and emergent can apply to both rotor and fixed wing interhospital transports. Further, we believe that the Secretary has sufficient authority under Section 2792 of the PHSA to define air ambulance transports from the "scene" as emergency services as well and to also ensure the protections under Section 2719A. If "scene" air ambulance transports ordered by ground EMS do not constitute "emergency services" due to the need for critical care capability and timely transport, we are at a loss to understand what would be.

Fourth, Prohibit Documentation Requirements from Transferring and Receiving Hospitals Prior to Making the Interim Payment Within 30 Days and When Hospitals Fail to Provide Such Documentation to the Air Ambulance Provider. Many plans and issuers are requiring that air ambulance providers supply documentation, such as to establish medical necessity, from the transferring and receiving hospitals. This documentation is not owned or held by the air ambulance provider. Air ambulance providers must rely upon the good will of the sending and receiving hospitals to get an initial payment, or sometimes any payment. For the same reasons articulated above with regard to requiring the presumption of medical necessity, the Departments should prohibit plans and issuers from delaying payment beyond 30 days due to the failure of hospitals to provide air ambulance providers with this information. Further, at no point prior to or during the IDR process should air ambulance providers be denied payment for a claim due to the failure of a transferring or receiving hospital, or ground EMS to provide documentation verifying medical necessity.

Fifth, Utilize Calendar Days, Not Business Days. We strongly oppose the Departments proposal to shift from calendar days to business days regarding the required timeframes in the NSA. Given the extraordinary abuses and delays we have experienced already that are threatening the ability of some air ambulance agencies to survive, it is imperative that the Departments not allow for

any additional delay. The Congress did not specify business days and we believe the Congress intended calendar days.

As noted above we believe the use of CARCS and RARC's to transmit information should be the standard for all of the information. These communications should include how the plan or issuer calculated the QPA including specific information on what database, metrics, other agreements were used to calculate the QPA. Currently, as noted, without the Departments establishing and setting a standard, this is a black box creating more delays in payments and the system. The absence of enforced standards impairs open negotiation and resolution.

D. Open Negotiation and Initiation of the Federal IDR Process.

In general, we strongly support the Department's proposals to strengthen the process for communicating consistent information through the open negotiation process to facilitate and maximize the number of agreeable settlements and minimize the volume of claims going into the IDR process. Again, we believe that the likelihood of a successful open negotiation that will lead to settlement and avoid the IDR process will be furthered by requiring that the open negotiation content mimic the statutory construct for IDR consideration of the offers. Accordingly, we recommend strengthening the open negotiation content to be shared between the parties.

First, the Secretaries should require transparency to the IDR entity information about the interim payment or denial. Through the IDR initiation process, the initiating party should have to identify whether the plan or issuer has provided an interim payment or not, the amount of such payment, whether it is comparable to Medicare, and whether it is the same as the offer made by the plan or issuer. Further, the initiating party should have to identify whether any denial was made for lack of medical necessity and in contravention of the presumption of medical necessity which we have urged the Departments to require. We believe that providing this information to the IDR entity will illuminate compliance or lack thereof with the initial payment or denial within the 30-day period for the IDR entity and the Departments.

Second, add the six statutory "additional considerations" to Open Negotiation Content Production. We support the proposed rule's requirements with regard to the IDR initiating party providing a notice to the plan, issuer or air ambulance provider, and a required response, including to the Departments, and through the portal. We support the Department's contention that the more information that is provided up front, the more likely it is that the parties will come to an agreement and not have to resort to the IDR process.

The Congress made abundantly clear in the statute that besides the QPA, and the offers, the IDR entity should consider six "additional circumstances" in determining the out-of-network rate. They are as follows[8]:

> (I) The quality and outcomes measurements of the provider that furnished such services.
>
> (II) The acuity of the individual receiving such services or the complexity of furnishing such services to the individual.

[8] Section 2799A-2(b)(5)(C)(ii).

(III) The training, experience, and qualifications of the medical personnel that furnished such services.

(IV) Ambulance vehicle type, including the clinical capability level of such vehicle.

(V) Population density of the pickup location (such as urban, suburban, rural or frontier).

(VI) Demonstrations of good faith efforts (or lack of good faith efforts) made by the non-participating provider or facility or the plan or issuer to enter into network agreements, and if applicable, contracted rates between the provider and the plan or issuer, as applicable, during the previous four plan years.

Air ambulance providers, in either their notice to enter IDR or their response to it, should provide information on these "additional circumstances" before entering IDR in order to enhance the communications about the value of the service in the open negotiation process to encourage settlement and avoid IDR.

The Association of Critical Care Transport provided a detailed set of definitions in its letter of September 9, 2021, to Secretary Becerra. On a temporary basis, we again urge the Secretary to utilize these definitions to help the parties, and ultimately the IDR entity if necessary, determine an appropriate out-of-network rate. On a longer-term basis, these definitions can be updated by the Advisory Committee on Air Ambulance Quality and Patient Safety which was established by the Congress in the NSA "for the purpose of reviewing options to establish quality, patient safety, service reliability, and clinical capability standards for each clinical capability level of air ambulances."[9]

E. Federal IDR Process Following Initiation

First, Proceed with Batching of Claims for Air Ambulance Services. We support the Departments' proposal to allow batching of air ambulance claims for the base rate and mileage as a single dispute.

We note that on P 75785 the Departments seek comments on the inclusion of "all qualified IDR items and services within the same CPT code, Category I codes, or "family" to relate to the treatment of similar conditions." This highlights the structural difference between air medical and all other healthcare providers. We believe air medical claims are significantly different in substance and lumping all claims into a singular process has led to the current crisis in the processing of air medical claims and reimbursement. This is at the heart of our request and plea for the Departments to recognize this structural difference and establish separate paths with the NSA implementation for air ambulance services.

Further we believe, as noted above distinct standards and terminology for CARC's and RARC's be developed for air ambulances to assure transparent and time stamped tracking of communications between IDRE's, issuers and carriers and ambulance providers to assure adherence to the statute and Final Rules in regards to medical necessity denials, calculation of QPA's and databases and metrics used for calculations, inclusion or exclusion of additional factors

[9] HR 133-1676 Sec. 9823 Air Ambulance Report Requirements (1) (g)

as required by the Statute and Final Rules, and adherence to timelines consistent with the Final Rule.

Second, Establish a Separate IDR Entity Certification Process For Air Ambulance Services. We urge you to establish a separate and distinct IDR process specifically for air ambulance services. As we have underscored throughout this comment letter, air ambulance services are unique. They are treating and transporting by air critically ill and injured patients hundreds of feet above the ground. The Congress recognized such uniqueness in having a separate statutory section specifically for air ambulance services, separate authority for rulemaking, separate "additional considerations" to be utilized by IDR entities, and separate reporting requirements.

We urge the Departments to require a separate certification process for IDR entities to ensure their competence and expertise specifically with regard to air ambulance services. Pursuant to the six "additional considerations" which differ from other providers in the statute, specific expertise in air medicine is required to understand the differences between "air ambulance vehicle type and clinical capability of the vehicle", the qualifications and training of medical personnel that are unique to air medicine, what constitutes quality and measures that are appropriate to air medical transport, and the acuity and complexity of the patient's condition – all of which are unique to air medicine.

Third, Specify Good Faith Efforts and Lack Thereof. We urge the Secretaries to require that IDR entities consider a plan or issuer's lack of interim payment, or any lesser amount provided short of the plan's "offer," to constitute lack of good faith efforts to reach a contracted rate for the service provided. The Court in TMA III[10] determined that a single contracted agreement is covered by the NSA. Accordingly, lack of good faith efforts to enter into prior agreements and a settlement under the open negotiation process should be considered by the IDR entities in selecting an offer. This will discourage plans and issuers from low-balling the initial payment and making a reasonable initial payment offer, further reducing the number of claims going to IDR.

Fourth, Establish a Separate Complaint Portal for Air Ambulance Services. As part of refining the IDR process for air ambulances, the Secretaries should provide a separate and distinct complaint portal for air ambulances as well as separate and distinct enforcement mechanisms, including for investigations and the imposition of civil monetary penalties for issuer non-compliance.

Through the air ambulance-specific complaint portal, we urge you to provide two complaint tracks: (1) an urgent track for the most egregious situations that threaten provider financial viability and patient access; and (2) another for other complaints that require attention from the Departments but are less urgent. The Departments should establish a minimum threshold for complaints to the urgent track such as more than 60 days overdue in payments following resolution of the claim by negotiation or IDR from end of the 30-day NSA required timely payment.

Establishing a separate complaint portal would highlight specific issues within the air ambulance industry which differ from other aspects of the health care system, such as the case for ground EMS and attending physicians in referring hospitals that make the decision to transport a patient

[10] Texas Medical Association v. US Department of Health and Human Services, Case No. 6:22-cv-450-JDK, August 24, 2023.

by air based on their medical need. This practice would ensure payment denials within 30 days to be the rare exception and not the rule.

Fifth, Establish a Separate Tri-Departmental Oversight and Enforcement Group for Air Ambulance Services

As part of this separate process, we urge the Departments, which will now receive all the information flowing between the parties regarding the open negotiation and through the IDR process, to have a specific group monitoring and addressing air ambulance services separately from other health care services covered by the NSA.

Further, the Secretaries should aggressively investigate and enforce compliance with the 30-day deadlines at the front and back end of the IDR process for air ambulance services. The Departments should be examining specifically whether the interim payment was made, whether incessant denials or unnecessary delays took place around medical necessity, and whether final payment was made within 30 days post IDR decision.

Consistent with our recommendations above, we urge the Departments to state that in evaluating the imposition of civil monetary penalties, consideration will be given to whether the plan does not pay and does not presume medical necessity, following the Medicare model.

Finally, we urge the Departments to submit an interim report to the Congress regarding plans which have a pattern or practice of routine denial, low payment, or down-coding of claims, including recommendations on ways to discourage a pattern or practice.

CONCLUSION:

We appreciate the Departments' careful consideration in the proposed rule to improve the entire process for resolving disputes between plans/issuers and providers of air ambulance services. We urge the Departments to implement the recommendations we have provided to dramatically strengthen the final rule, and prevent the closure of multiple bases and programs that will harm access to life saving care for the most critically ill and injured patients in our health care system. We believe that all of the recommendations we have provided are within the scope of the proposed rule, and squarely within the statutory authority of the Departments, particularly the Secretary of HHS.

On behalf of the critical care transport patients, it is ACCT's mission to protect and serve, thank you for your consideration of our comments in this letter. For any questions or follow up, please contact Lisa Hawke, ACCT's legal counsel, at lisa.hawke@hklaw.com or 703-967-1389.

Sincerely,

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ACCT FOR PATIENTS