



National Association of EMS Physicians®

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February 05, 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: CMS-9897-N

Sent via electronic mail to [www.regulations.gov](http://www.regulations.gov).

Dear Secretaries Becerra, Su, and Yellen:

We write on behalf of the membership of the National Association of Emergency Medical Services Physicians (NAEMSP), a group of over two thousand Emergency Medical Services (EMS) physicians, paramedics, and other EMS clinicians, nurses, administrators, educators, and researchers dedicated to the provision of quality emergency medical care in the pre-and out-of-hospital environment.

EMS Medicine is the clinical practice of EMS by physicians, a subspecialty recognized by the American Board of Medical Specialties. EMS Physicians provide medical oversight for EMS agencies and supervision of the EMS clinicians' care and treatment of patients. As recognized under federal law, physician medical directors may provide oversight for this care during an EMS response via their protocols and standing orders that are developed in accordance with state and local laws and individualized to suit local and operational needs. These protocols guide the care EMS personnel provide, including the interventions, procedures, medications, and recommended transport destination.

Medical Directors are responsible for ensuring the quality of care and treatment provided during transport.

From that perspective, we write to provide comments regarding the ongoing implementation of the No Surprises Act, including the proposed rule that was published in the Federal Register on November 3, 2023.

## **I. INTRODUCTION**

We provide six recommendations addressing specific challenges and improvements to the proposed rule that would directly impact the air ambulance industry and NAEMSP membership. Our recommendations for additional considerations to include in the Final Rule are outlined below:

1. Define “qualified IDR air ambulance services” as those that are ordered by a physician in a hospital or ordered by ground EMS in accordance with state or local protocols.
2. Require a presumption of medical necessity for inter-facility air ambulance transports
3. Require a presumption of medical necessity for scene air ambulance transports ordered by ground EMS
4. Clarify that limitations on the use of prior authorization for “emergency services” apply to both scene and inter-facility air ambulance transports
5. Establish a separate IDR entity certification process for air ambulance services
6. Establish a separate, dual-track complaint portal for air ambulance services

These recommendations will be described in further detail below, as well as relevant statutory authorities and other considerations that we believe will assist the Secretaries in promulgating the Final Rule.

## **II. ADDRESSING UNWARRANTED MEDICAL NECESSITY DENIALS**

Unfortunately, there has been a significant post-NSA spike in denials of claims on the basis of “lack of medical necessity”. The increase in these denials has been especially pronounced among certain insurers and in certain regions of the nation, and predominantly for inter-facility air transports. Below are several examples illustrating the types of inappropriate medical necessity denials that air ambulance providers have experienced:

- 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 to 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 and cannot accept the patient for lack of a clinically appropriate bed or lack of availability of particular clinicians (for instance, if the clinician is already in another surgery). Carriers often completely deny the entire claim.
- Denying the claim based on the mode of transport “because the patient could have been transported by ground ambulance,” with no rationale for how this is determined or if an appropriately-equipped ground ambulance is even available. The most vulnerable time for a patient is “out-of-hospital time.” The physician’s determination for air transport is based on

their full responsibilities under the Emergency Medical Treatment and Active Labor Act (EMTALA), which will be discussed in further detail later in this comment letter.

- 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, determinations regarding whether to transport the patient by air and to which hospital are determined by ground EMS under rigorous, established state and local EMS protocols.

NAEMSP believes that 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. Under the NSA statute, the Secretaries have the authority to define "qualified IDR air ambulance services." To address unwarranted medical necessity denials, the Secretary should include such a definition in the Final Rule that recognizes scene calls and inter-facility transports and provides for a presumption of medical necessity — in alignment with the statutory Medicare requirements for rural air ambulance transports. Specific recommendations, as well as relevant statutory authorities, are provided in detail below.

**Recommendation #1: We urge the Secretary of HHS to define "qualified IDR air ambulance services" as those that are ordered by a physician in a hospital or ordered by ground EMS in accordance with state or local protocols.**

Specifically, the Secretaries should establish by regulation that a "qualified IDR air ambulance service" means one that is either —

- (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.

We urge the Secretary of HHS to enforce the NSA's requirement for plans and issuers to provide an interim payment within 30 days and not issue a notice of denial for "qualified IDR ambulance services" pursuant to the above-proposed definition.

**Recommendation #2: We urge the Secretary of HHS to require that plans and issuers presume medical necessity for inter-facility air ambulance transports ordered by a physician at a hospital, subject to retrospective review during the IDR process.**

As we have indicated in this letter, the Secretary of HHS has considerable statutory authority to require the presumption of medical necessity for certain inter-facility transports<sup>1</sup> in addition to its specific regulatory authority over air ambulances.<sup>2</sup>

When the attending physician at a hospital orders an inter-facility air transport, it is always to a higher or more specialized level of care (with the exception of repatriation). In many instances, the determination

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<sup>1</sup> Section 1867 of the SSA; Section 2719A of the PHSA, "Patient Protections for Emergency Services"

<sup>2</sup> NSA Section 2799A-2; NSA Section 2799A-2(b)

that inter-facility air transport is appropriate is made under dire circumstances – when a hospital is not capable of caring for or stabilizing a particular patient or lacks the clinical resources to stabilize a patient with a certain clinical diagnosis.

For inter-facility transports, the attending physician (or other qualified medical personnel) at a transferring hospital must make several essential clinical and non-clinical determinations. These determinations are outlined below:

- 1) The physician must ascertain whether the patient has an emergency medical condition.
- 2) The physician must determine whether the hospital is capable of treating the patient and whether the patient is unstable.
- 3) If the hospital is unable to treat the patient, the physician must identify the appropriate medical facility, ensure that it has the capacity to receive the patient, and is willing to receive the patient.
- 4) 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.
- 5) 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.

These determinations are not only required as a part of a physician's ethical and professional responsibilities but also as a legal obligation with respect to the strong patient protection requirements established by EMTALA. All EMTALA violations – which can result in significant repercussions, including large civil monetary penalties and exclusion from Medicare and other federal reimbursement programs – are considered extremely serious. Both the referring physician (or other qualified medical professional) and hospital remain liable under EMTALA for a patient's condition throughout transport until the receiving hospital has accepted the patient. Considering the consequences of EMTALA violations, a referring physician and hospital will only call for inter-facility air transport if that transport is medically necessary.

NAEMSP believes the clinical determinations made by a referring physician (or another qualified medical professional) should not be second-guessed by a plan or issuer 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 an inter-facility air ambulance service was medically necessary should be presumed, subject to retrospective review.

**Recommendation #3: We urge the Secretary to require that plans and issuers presume medical necessity for scene air ambulance transports ordered by ground EMS, subject to retrospective review during the IDR process.**

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. We believe that medical necessity should be presumed, consistent with Medicare regulations.

### **III. INAPPROPRIATE USE OF PRIOR AUTHORIZATION**

Since the implementation of the NSA, a number of carriers have reported an increase in inappropriate prior authorization denials. 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. Further, the need for emergency, unscheduled transfer of patients, many of whom are critically unstable or with the potential for rapid cardio-pulmonary or neurologic deterioration, is the core of a physician's determination to emergently transport a patient by air.

NAEMSP believes that 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. Additionally, 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. We also believe that the Secretary of HHS has sufficient authority.<sup>3</sup> to define air ambulance transports from the "scene" as emergency services and to ensure that plans and issuers are subject to the requirements of Section 2719A of the PHSA, including the prohibition on prior authorization.

**Recommendation #4: We urge the Secretary of HHS to clarify that unscheduled, time-critical, inter-facility air ambulance transports are "emergency services," to clarify that air ambulance transports ordered by ground EMS from the scene are "emergency services," and ensure that plans and issuers adhere to federal law's patient protections – including the prohibition on prior authorization.**

Section 2719(A) of the Public Health Service Act provides certain patient protections and coverage requirements for health insurance plans and issuers that provide coverage of "emergency services" as a benefit.<sup>4</sup> The Secretary of HHS has regulatory and enforcement authority over this federal law, which governs medical transport. 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"

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- 1) Without the need for any prior authorization determinations;
- 2) Whether the provider is a participating provider;
- 3) 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.
- 4) 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

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<sup>3</sup> Section 2792 of the PHSA

<sup>4</sup> Section Title XXVII Part A of the PHSA under Section 2719A(b)

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”.

The need for emergency, unscheduled transfer of patients, many of whom are critically unstable or with the potential for rapid cardio-pulmonary or neurologic deterioration, is the core of a 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.

The entire point of prohibiting plans and issuers from requiring prior authorization and other obstacles to obtaining emergency services, including interfacility air transport – is to ensure that coverage is not an obstacle to emergency care and treatment. Prior authorization denials directly contravene the intent of the statute, which is to ensure the immediate availability of emergency medical care, which may require transport to a higher level of care.

#### **IV. ACCOUNTING FOR THE UNIQUENESS OF AIR AMBULANCE SERVICES IN THE FEDERAL IDR PROCESS**

The NSA statute 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."<sup>5</sup> 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 a notification to enter IDR “and in accordance with the succeeding provisions of this subsection” (ii) an IDR entity determines the amount of payments.

This not only provides the Secretaries with broad authority to establish by regulation the specifics regarding notification to enter IDR for all air ambulance services (scene and inter-facility) and the IDR process itself, including payment determination – it also establishes a specific requirement to issue such regulations. Promulgating separate and distinct regulations for air ambulance services will better ensure that the IDR process statutory requirements are being followed as intended by Congress.

**Recommendation #5: We urge the Departments to establish a separate and distinct IDR entity certification process for air ambulances to ensure IDR entities' 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.

**Recommendation #6: We urge the Secretaries to provide for a separate and distinct, dual-track 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.**

We urge the Secretaries to provide two complaint tracks through the air ambulance-specific complaint portal:

- (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.

Establishing a separate complaint portal would highlight specific issues within the air ambulance industry that 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 that air ambulance transport is medically necessary.

#### **V. CONCLUSION**

NAEMSP greatly appreciates this opportunity to offer comments on this important topic. If you have any questions about the contact information for this letter, please feel free to reach out to me directly or contact our counsel, Lisa Hawke, at [Lisa.Hawke@hklaw.com](mailto:Lisa.Hawke@hklaw.com).

Sincerely,

José Cabañas, MD, MPH, FAEMS

President