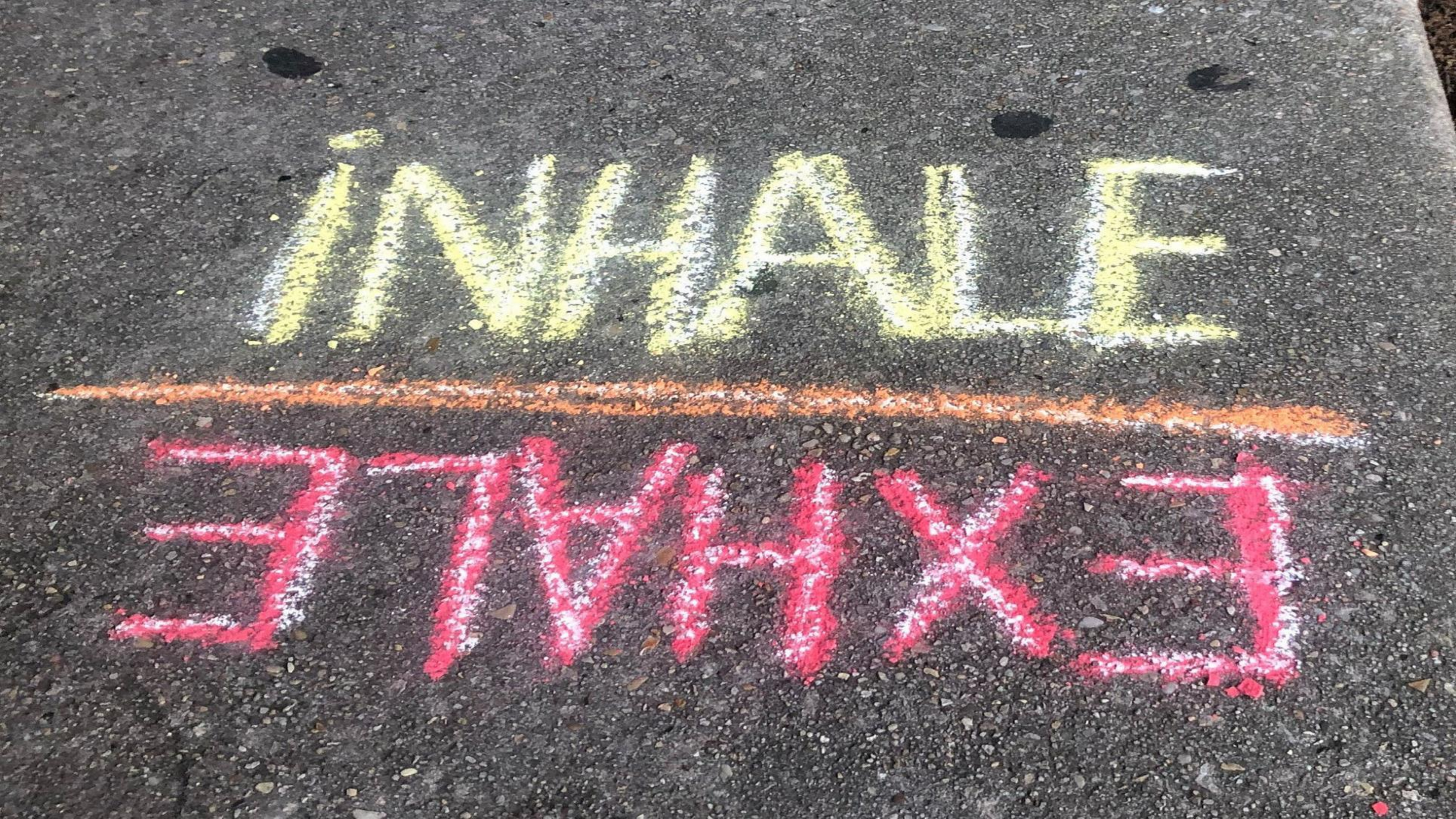
ERN
NCRA

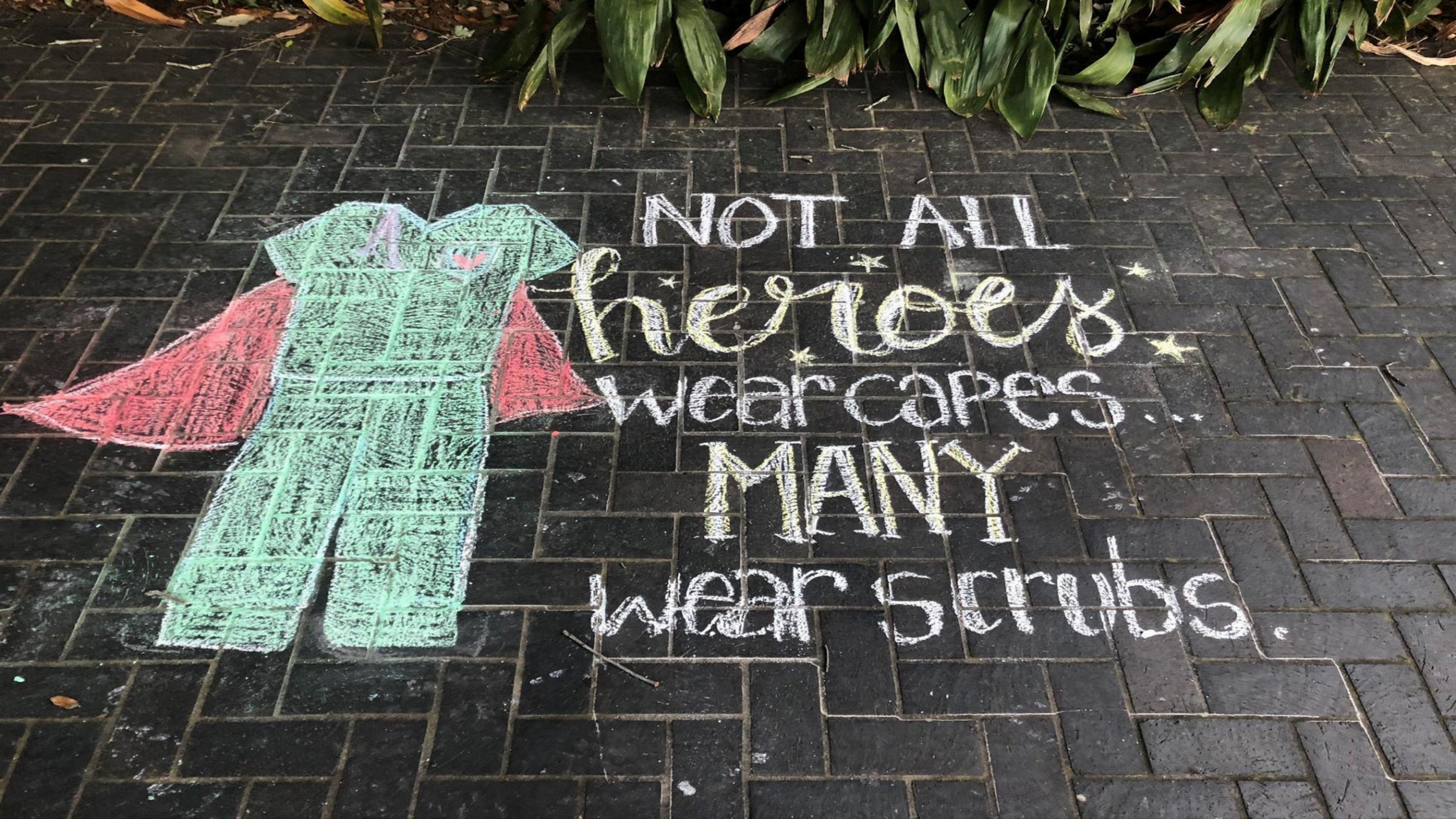
WHEN PAYORS WON'T LISTEN

THE LAW, DENIAL MANAGEMENT, AND APPEAL LETTER WRITING (AR)


YOU ARE
extraordinary


Thank
YOU
REST


INHALE
EXHALE


NOT ALL
heroes
wear capes...
MANY
wear scrubs.

CASE STUDY

COOPER'S GIANT...

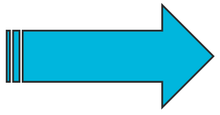
ERN TRAF

Cooper [redacted]: Summary of Medical Events

Introduction: On September 10th our baby Cooper fell ill with a rare neuro-immune disease known as Acute Flaccid Myelitis. This disease mimics polio and is very new (first case diagnosed 2012) He was misdiagnosed for the first 2 months. Here is a time-line of events.

9/10/18:

- Arrived to ER about 3:00PM. After many theories and a whole slew of tests including a CT scan, X-ray, blood work, and MRI, it was determined that our son was the victim of a rare autoimmune disorder called Acute Transverse Myelitis. His spinal cord was swelling from the brain stem to T7 and compressed his spinal cord causing him to experience paralysis and the inability to breathe effectively. It is thought that the swelling is caused by his own immune system inappropriately attacking his spinal cord after an unknown viral trigger.
- 10:00 PM He was started on steroids and transferred to the Pediatric Intensive Care Unit (PICU) for monitoring and treatment.

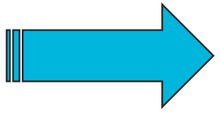


10/5/18

- Tracheostomy placed due to failure to breath on his own.

10/23/18

- Care Conference: They want us to get ready for discharge home due to Phoenix Children's Hospital rejection of Cooper for rehab due to ventilator.
- We refused to take him home and insisted that he attend rehab as intense rehab is the only know treatment for his disease



- I Consulted Dr. Greenberg who is the closest rare neuro-immune disorder specialist. He referred Cooper to The Kennedy Krieger Institute (KKI) in Baltimore Maryland.

- KKI extended admission date to 1/21/2019

12/20/18

- Discharged home
- Channel 5 news does story on Cooper's rare illness

1/15/19

- Medicaid approval

1/5/19

- Re-hospitalized for viral infection/respiratory distress

1/12/19

- Discharged home
- KKI applied for insurance coverage beginning 1/23/2019

1/23/19

- Denial letter from insurance regarding intensive rehab program for children with AFM (Only one in the country). **See attached letter
- Not medically necessary
- No referral from "Primary" treating Physician
- Does not meat MCG guidelines
- KKI says to sit tight, they will do Peer-to-peer review in a few days

1/30/19

- Peer-to-peer review: denial maintained
- At this point 5 different doctors have said they are unsure how to treat Cooper and that he needs to go to Baltimore soon to get a care plan from the doctors that are treating this disease. (Referral letters obtained)
- Channel 12 news doing story on Cooper and the inability to get medical care for him despite having insurance.

2/8/19

- Filed rush appeal: ***See attached documents

InterQual® Level of Care Criteria
Acute Criteria

Review Process

Introduction

InterQual® Acute Level of Care Criteria provide support for determining the medical appropriateness of hospital admission, continued stay, and discharge. Acute Adult Criteria address the Observation, Acute, Intermediate, and Critical levels of care. Acute Pediatric Criteria include these levels of care and five additional levels of nursery care (Transitional Care, Newborn Level I, Special Care Level II, Neonatal Intensive Care Level III, and Neonatal Intensive Care Level IV).

Adult criteria are for review of patients ≥ 18 years of age. Pediatric criteria are for review of patients < 18 years of age.

Important: The Criteria reflect clinical interpretations and analyses and cannot alone either resolve medical ambiguities of particular situations or provide the sole basis for definitive decisions. The Criteria are intended solely for use as screening guidelines with respect to the medical appropriateness of healthcare services and not for final clinical or payment determinations concerning the type or level of medical care provided, or proposed to be provided, to a patient.

When evidence in the medical literature to support the efficacy and effectiveness of the intervention or service is absent, mixed, or unclear, criteria reflect the opinion of McKesson's expert clinical consultants. It is based upon current best practice and is the product of an iterative process involving multiple clinicians with diverse expertise in varied practice and geographic settings.

Reference materials

Reference materials are provided with the criteria and should be used to assist in the correct interpretation of the criteria.

- **Abbreviations and Symbols List**: Defines acronyms, abbreviations, and symbols used in the criteria.
- **Alcohol Withdrawal Assessment tool:** A worksheet to document a patient's CIWA-Ar score for alcohol withdrawal.
- **Bibliography**: References cited in the clinical content.
- **Clinical Revisions**: Provide details of changes to InterQual Clinical Criteria.
- **Drug List**: Categorizes drug names and classes mentioned within the criteria.

InterQual Disclosure Updated 10/2019

Per the Change Healthcare Disclaimer (shown on their website), InterQual® is not intended to be used for **final clinical or payment determinations concerning the type or level, or medical care provided or proposed to be provided to a patient.** It reads in pertinent part:

"The Clinical Content reflects clinical interpretations and analyses and **cannot alone** either resolve medical ambiguities of particular situations **or provide the sole basis for definitive decisions.** The Clinical Content is intended solely for use as screening guidelines with respect to the medical appropriateness of healthcare services **and not for final clinical or payment determinations concerning the type or level of medical care provided, or proposed to be provided, to a patient**."…. (Emphasis Added)

MCG Disclaimer (shown on their website)

Per the Milliman Care Guidelines Disclaimer (shown on their website):

"This Web site and the Content are for information and education purposes only. The Content should not be used to replace any written reports, statements, or notices provided by MCG. **Professionals and other persons should use the Content in the same manner as any other educational medium and should not rely on the Content to the exclusion of their own professional judgment.** MCG does not warrant the accuracy or completeness of the Content or the reliability of any statement or other information displayed or distributed through the site.

MCG Disclaimer (shown on their website)

…The care guidelines are not intended to be used **without the judgment of a qualified healthcare provider with the ability to take into account the individual circumstances of each patient's case.** In exchange for using this site, you agree not to hold MCG liable for any possible claim for damages arising from any decision you make based on information made available to you or obtained through the site." (Emphasis Added)

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TRAF

SUMMARY OF COMPLAINT – ARIZONA MEDICAL BOARD

February 19, 2019

Patricia McSorley, Executive Director
Arizona Medical Board
1740 W. Adams St. Suite 4000
Phoenix, AZ 85007

Physician:	J Tolson, M.D.
License Number:	31688
Board Certified:	Anesthesiology
Patient:	Cooper
ID:	
DOB:	
Denied Service:	Inpatient Care, Rehabilitation Level 1

Dear Ms. McSorley:

This office represents Cooper Leigh and has been asked to file a formal complaint with the **Arizona Medical Board** against Dr. Jeffrey Tolson, M.D. for his negligent medical decision resulting in Cooper's delayed treatment for Acute Flaccid Myelitis, a rare neurological immune disease that mimics polio.

In its advisory role to healthcare providers that provide medically necessary services to ERISA participants, the National Council of Reimbursement Advocacy (NCRA) and the Reimbursement Advocacy Firm (TRAF) periodically brings to your attention non-compliance issues related to—

(1) Access to medically appropriate healthcare services consistent with clinical review requirements under Arizona Statutes, Title 20, §20-1057.06, §20-2501, §20-2532 and §20-2533 or any rule adopted pursuant thereto.
(2) Breach of fiduciary duties under 29 U.S.C. 1104 & 1109 including full and fair review requirements under ERISA law.
(3) Any other health services furnished by a provider or supplier that are reimbursable under 29 CFR section 2560.503-1 or any rule adopted pursuant thereto.

We dispute Dr. Tolson's decision to deny authorization for inpatient rehabilitation services based on lack of authorization, because two of Cooper's treating physicians with expertise in this field have documented the medical necessity of this requested service and Dr. Tolson does not have the clinical expertise to make an appropriate medical decision in this matter, as shown and described below and on the attached exhibits:

- On 09/10/2018 at 3:00PM, Cooper presented to an emergency room; multiple tests were performed including a CT scan, X-ray, blood work, and an MRI. It was determined that Cooper had developed a rare autoimmune disorder called Acute

In 2003, Dr. Narayanan moved to Phoenix as a member of the Child Neurology division at Barrow Neurological Institute.

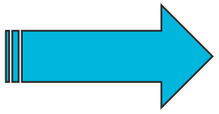
Dr. Narayanan has a special interest in the genetic basis of neurological disorders. Dr. Narayanan's research efforts focus on the neurobiology of genetic disorders (genes to pathogenesis), cell adhesion molecules and synapse formation. **(See Exhibit F — Dr. Narayanan Biography.)**

III. DR. TOLSON IS NOT QUALIFIED TO DETERMINE THE MEDICAL NECESSITY OF RARE NEUROLOGICAL AUTOIMMUNE DISORDERS.

In Dr. Tolson's denial dated January 23, 2019, he states "Request is denied for the following reasons. There is no referral from treating physician. There is no documentation by referring provider of medical necessity for second acute rehab admission. There is no documentation of functional improvement anticipated to be practical, ongoing, and sustainable. Request does not meet criteria for Inpatient Acute Rehabilitation in MCG guidelines. MCG is used for its guidelines to decide if criteria is met." **(See Exhibit B — Banner/Aetna Denial.)**

As you know, **29 CFR §2560.503-1(h)(2)** details the requirements of an employee benefit plan when conducting full and fair medical reviews, stating:

> ***The claims procedures of a group health plan will not be deemed to provide a claimant with a reasonable opportunity for a full and fair review of a claim and adverse benefit determination unless, in addition to complying with the requirements of paragraphs (h)(2)(ii) though (iv) of this section, the claims procedure —***
>
> ***(i) Provide claimants at least 180 days following the receipt of a notification of an adverse benefit determination within which to appeal the determination;***
> ***(ii) Provide for a review that does not afford deference to the initial adverse benefit determination that is conducted by an appropriate named fiduciary of the plan who is neither the individual who made the adverse benefit determination that is the subject of the appeal, nor the subordinate of such individual;***
> ***(iii) Provide that, in deciding an appeal of any adverse benefit determination that is based in whole or in part on a medical judgement, including determinations with regard to whether a particular treatment, drug, or other item is experimental, investigational, or not medically necessary or appropriate, the appropriate named fiduciary shall consult with a health care professional who has appropriate training and experience in the field of medicine involved in the medical judgement;***
> ***(iv) Provide for the identification of medical or vocational experts whose advice was obtained on behalf of the plan in connection with a claimant's adverse benefit determination, without regard to whether the advice was relied upon in making the benefit determination;***
> ***(v) Provide that the healthcare professional engaged for purposes of consultation under paragraph (h)(3)(iii) of this section shall be an individual who is neither an individual consulted in connection with the adverse benefit determination that is the subject of the appeal, nor the subordinate of any such individual.*** **(Emphasis added.)**

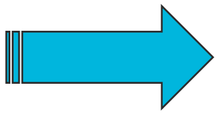


As described above, Cooper Leigh has been diagnosed with Acute Flaccid Myelitis, a rare neurological immune disease that mimics polio. Being that this disorder is incredibly rare with the first diagnosis in 2012, very few medical professionals have the appropriate clinical knowledge and expertise to determine the medical necessity of different health services and therapies aimed at treating this rare condition.

Two of the only physicians in the United States with direct experience in treating Acute Flaccid Myelitis and other rare neurological disorders have documented the medical necessity of Cooper's requested inpatient rehabilitation and referred him to The Kennedy Krieger Institute (KKI) in Baltimore, Maryland.

Thus, Dr. Tolson's medical decision to deny the medical necessity of these services raises serious concern regarding his competence and experience in treating such ailments.

As you know, Dr. Jeffrey Tolson is the Medical Director of Banner-Aetna in Arizona. Dr. Tolson is an anesthesiologist specialist and he is board certified in anesthesiology. Dr. Tolson received his medical degree from Ohio State University College of Medicine in 1991. **(See Exhibit G — Dr. Tolson, Arizona Medical Board.)** Here. Banner-Aetna has utilized an anesthesiologist to review the medical necessity of treatment for a rare neurological autoimmune disorder.



Further, per the Milliman Care Guidelines Disclaimer (shown on their website), Milliman Guidelines are not to be used solely as medical necessity criteria in place of a qualified health care professional's clinical judgment. It reads in pertinent part:

> ***"Qualified healthcare professionals may use our guidelines as a tool to support medical necessity decisions, but they should not use them as the sole basis for denying treatment or payment. Our guidelines must be applied to individual patients on a case-by-case basis and always in the context of a qualified healthcare professional's clinical judgment."*** **(Emphasis Added.)**

The sole use of UR software CANNOT replace an experienced, knowledgeable physician, nor can it replace medical necessity determinations by the attending physicians.

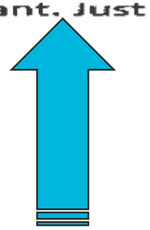
Here, Dr. Tolson's letter states *"Based on MCG guidelines and the information we have, we're denying coverage for this acute rehabilitation facility admission. The requirements for coverage are: (1) requires intensive skilled nursing services; (2) requires two or more skilled therapy types (e.g. physical, occupational, or speech therapy); (3) requires and is able to fully participate in therapy for a minimum of 15 hours per week (e.g. 3 hours per weekday); (4) needs close physician involvement; and (5) shows continued measurable improvement with progress toward functional goals for next level of care. The member doesn't meet all of these requirements."* **(See Exhibit B — Banner/Aetna Denial.)**

Considering Dr. Tolson's clinical background, it is evident that his expertise is not in rare neurological autoimmune disorders in pediatric patient, nor any remotely similar field. Dr. Tolson did not utilize MCG guidelines in conjunction with the expertise of a qualified, competent medical professional. Thus, it is clear that Dr. Tolson was not competent to evaluate the specific clinical issues at hand and his medical decision is inconsistent with those of qualified professionals.

From: Lexie Hernandez <arh
Date: 2/20/19 7:02 AM (GM
To: Ed Norwood <ednorwoo
Subject: Re: AZ Medical Board - Complaint #41313, email 1 of 2 (PASSWORD TO FOLLOW)

Cooper has been approved for 6 weeks of rehabilitation! Now I just have to see if his spot is still available at KKI or how long this se
how you helped us if you want. Just let me know what I can do! Thank you! Thank you! Thank you!

Lexie & Cooper

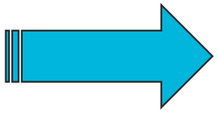


To Whom it May Concern,

In late 2018, our youngest child was diagnosed with a rare neuromuscular disease called Acute Flaccid Myelitis. He was only 8 months old at the time and spent the next few months in the Pediatric Intensive Care Unit fighting for his life. His rare diagnosis makes his treatment extremely complex. We knew his road to recovery would be long-term and tough, but we never imagined that insurance would have a say in whether he got the treatment he needed. A neuro-immune doctor who specializes in AFM emphasized the extreme importance of intensive rehabilitation as soon as possible. He was confident that Cooper had the potential to walk and breath on his own if he went through intensive rehabilitation at the Kennedy Krieger Institute in Baltimore Maryland.

This is where ERN Enterprises has been such a huge blessing to not only Cooper, but our whole family.

Before we came in contact with ERN enterprises our insurance was denying coverage of intensive rehabilitation at the only location with any experience and positive outcomes for this rare disease. They had claimed that this treatment was not medically necessary despite multiple providers and healthcare professionals recommending we get there as soon as possible. I had spent hours working on an urgent appeal as this disease has a window of opportunity for the most recovery and this window was closing. My insurance reverted my appeal to non urgent without explanation or even sending me a timely notice. We had waited 3 months for a spot to open for Cooper at the highly sought after rehabilitation center and we were about to loose it because of our insurance issues. I had filed complaints, called all the insurance customer service and advocate departments multiple times and just felt like I was spinning my wheels and getting no where. When I call ERN Enterprises, I was desperate and loosing hope. Within 1 week of Ed Norwood getting involved in Cooper's case, our insurance overturned the denial. This came just in time as the specialty rehab had not yet given away our spot and Cooper was able to get started with his treatment with only a 6 week delay. I know this was only possible due to the hard work of ERN. I'm beyond grateful for the compassionate work this company does for people in great need.



Cooper has been in intensive rehabilitation at the Kennedy Krieger Institute for 10 weeks now and has made huge functional gains thanks to the therapy and medical care he is receiving. He is off the ventilator (machine that breathes for him) and well on his way to getting his tracheostomy reversed. He has started eating by mouth and making sounds again. I had not heard my baby cry in 6 months and what a moment it was to finally hear him again. He has also started to take steps and move his arms to touch toys and pop bubbles. This care and recovery was only possible due to the compassionate efforts of Ed Norwood and his team at ERN Enterprises as they got my insurance company's attention quickly and got Cooper where he needed to be.

Some families of patients here fought for months to get their children the care they deserve. We were so blessed to only be delayed by insurance for 6 weeks. ERN's

Ed Norwood

From: Lexie Hernandez <a
Sent: Sunday, May 05, 2C
To: Ed Norwood
Subject: Re: Testimonial

Cooper is making so much progress. It's truly incredible. I watched him take his first steps a few days ago. Something I wasn't sure I would ever see. I can't even explain how incredible this place is at what they do for children with spinal cord injuries. Thank you again for getting us here.

Lexie

On Sun, May 5, 2019 at 7:16 PM Ed Norwood <ednorwood@ernenterprises.org> wrote:

So moved. So touched by your words Lexie.

Thank you.

How is Cooper doing?

Best,

Ed Norwood

Sent from my T-Mobile 4G LTE Device

-------- Original message --------
From: Lexie Hernandez <ar
Date: 5/5/19 11:21 AM (GM
To: Ed Norwood <ednorwo
Subject: Testimonial

I am so sorry that this took me so long but I wanted to be able to share how much Cooper has benefitted from the treatment that was only made possible from your efforts.

Thank you again for everything!

Lexie

WHO WE ARE

ERN/The Reimbursement Advocacy Firm (TRAF) is the representation arm of ERN/National Council of Reimbursement Advocacy (NCRA), a for profit California corporation and provider membership organization, whose mission is to provide regulatory claims representation, training and patient advocacy that restricts third–party payors from making improper denials or medically inappropriate decisions.

ERN
NCRA

WHAT WE DO

At ERN, we understand the significance of quality healthcare and its reliance on financial viability. With the support of Wickline v. State, we help providers advocate for medically appropriate healthcare and fair reimbursement (using administrative laws) because ultimately, we recognize that every case represents a human life.

HEALTHCARE IS A LAW TO BE DEFENDED.

WE EXIST TO FACE GIANTS. TO "ADVOCATE FOR MEDICALLY APPROPRIATE HEALTHCARE PURSUANT TO WICKLINE VS. STATE"

FOUR WAYS TO BE A CHAMPION FOR MEDICALLY APPROPRIATE HEALTHCARE

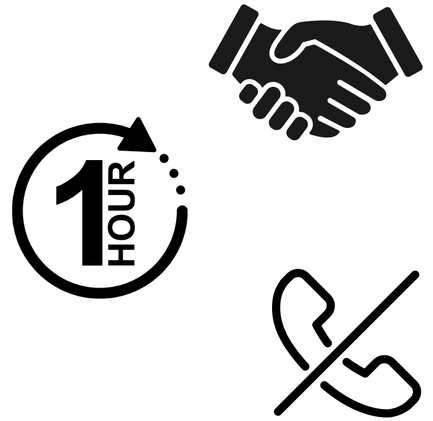

ERN
NCRA
CAN I DO THIS?

ERN
NCRA

THE PURPOSE OF THE LAW IS TO BRING ME TO A PLACE OF RECOVERY.

POLICY CHALLENGES
CMS

MA ORGANIZATIONS ARE FINANCIALLY RESPONSIBLE FOR POSTSTABILIZATION CARE SERVICES WHEN...



- They have been approved
- You render services within 1 hour of your request
- They did not respond your request after one hour, they cannot be contacted and the plan physician cannot reach an agreement about the enrollee's care

MA ORGANIZATIONS ARE FINANCIALLY RESPONSIBLE FOR POSTSTABILIZATION CARE SERVICES WHEN...

- A plan physician assumes responsibility for the enrollee's care at the treating facility OR through transfer
- An MA organization representative and the treating physician reach an agreement about the enrollee's care
- OR the enrollee is discharged

POLICY CHALLENGE:
CENTER FOR MEDICARE AND MEDICAID SERVICES

DID YOU KNOW?

MA plans are failing to preapprove care within the statutorily required one (1) hour and then denying claims for medical necessity—**even if ordered by a plan provider**.

Authority: 42 CFR §422.113 (See 42 CFR 438.114(e) for Medicaid)

FEDERAL REGISTER VOLUME 63, NUM 123:

“We do not agree that the M+C organization should have **the absolute right to control the care that is given to the member when it does eventually respond and the one hour time period has elapsed**. Safe transfer of responsibility should occur with the needs and the condition of the patient as the primary concern, so that the quality of care the patient receives is not compromised.”

POLICY CHALLENGE:
CENTER FOR MEDICARE AND MEDICAID SERVICES

WHAT CAN YOU DO?

- Once the beneficiary is admitted and the 1-hour time for the MA to respond has lapsed, the continuity of the patient's care is the utmost concern, and the MA plan is discouraged from disrupting care that could have an adverse impact to the beneficiary.

- Vigorously defend retrospective denials and requests for medical records, after patient discharge, in light of 422.113 (c)(3), which states: The MA organization's financial responsibility for post-stabilization care services it has not **pre-approved ends when - (iv) The enrollee is discharged.**

- Flag all MA plans conducting retrospective medical reviews and denying for medical necessity, and run a report showing (by Plan), # of beneficiary claims denied improperly, and # of uncompensated dollars effected.

- Notify your RAC leader and Ed Norwood to determine next steps for escalation to the appropriate plan and/or regulatory agency.

when:

- The MAO does not respond to a request for pre-approval within one hour;
- The MAO cannot be contacted; or
- The MAO representative and the treating physician cannot reach an agreement concerning the enrollee's care, and a plan physician is not available for consultation.

(In this situation, the MAO must give the treating physician the opportunity to consult with a plan physician. The treating physician may continue with care of the patient until a plan physician is reached or one of the criteria below is met.)

20.5.3 – End of Post-Stabilization

The MAO's financial responsibility for post-stabilization care services it has not pre-approved ends when:

- A plan physician with privileges at the treating hospital assumes responsibility for the enrollee's care;
- A plan physician assumes responsibility for the enrollee's care through transfer;
- An MAO representative and the treating physician reach an agreement concerning the enrollee's care; or
- The enrollee is discharged.

When a treating physician is contracted with the plan, CMS views him or her as a the plan for purposes of our rules and guidance. The rules above are intended for enrollee protection and guidance to plans for working with out-of-network providers. When we address "financial responsibility," we are referring to a plan's obligation to pay for (cover) the enrollee's services. That includes out-of-network providers, because those providers can bill enrollees if the plan denies their coverage/billing.

ABN(?)

Except under very limited circumstances, enrollees cannot be liable for in-network services, and therefore would not otherwise have an appealable interest – see 42 C.F.R. 422.562(c)(2). A network provider may not "stand in the shoes" of an enrollee by signing a waiver of liability (WOL) under the subpart M appeals process, but rather must follow the terms of his or her provider/plan contract.

individual physician
Contracted w/ SCAN (MA)

- *Temporarily reduce plan-approved out-of-network cost-sharing to in-network cost-sharing amounts; and*

- *Waive the 30-day notification requirement to enrollees as long as all the changes (such as reduction of cost-sharing and waiving authorization) benefit the enrollee.*

Typically, the source that declared the disaster will clarify when the disaster or emergency is over. If, however, the disaster or emergency timeframe has not been closed 30 days from the initial declaration, and if CMS has not indicated an end date to the disaster or emergency, plans should resume normal operations 30 days from the initial declaration. MAOs not able to resume normal operations after 30 days should notify CMS.

MAOs must disclose their policies about providing benefits during disasters on their plan websites.

If the President has declared a major disaster or the Secretary has declared a public health emergency, MAOs must follow the guidance in chapter 5 of the Prescription Drug Benefit Manual, regarding refills of Part D medications. The Prescription Drug Benefit Manual may be found at: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/Pub100_18.pdf.

160 — *Beneficiary Protections Related to Plan-Directed Care*

(Rev. 121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

Organization Determinations: An enrollee, or a provider acting on behalf of the enrollee, always has the right to request a pre-service organization determination if there is a question as to whether an item or service will be covered by the plan. If the plan denies an enrollee's (or his/her treating provider's) request for coverage as part of the organization determination process, the plan must provide the enrollee (and provider, as appropriate) with the standardized denial notice (Notice of Denial of Medical Coverage (or Payment)/CMS-10003). For the requirements related to organization determinations and issuance of the standardized denial notice (CMS-10003), see chapter 13 of the MMCM located at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c13.pdf.

Limitations on Enrollee Liability: CMS considers a contracted provider an agent of the MAO offering the plan. As stated in the preamble to the January 28, 2005 final rule (CMS-4069-F):

"MA organizations have a responsibility to ensure that contracting physicians and providers know whether specific items and services are covered in the MA plan in which their patients are enrolled. If a network physician furnishes a service or directs an MA beneficiary to another provider to receive a plan-covered service without following the plan's internal procedures (such as obtaining the appropriate plan pre-authorization),

Notes to Table II:

1. See *chapter* 5 of the Prescription Drug Benefit manual located at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html for the definition of required drug coverage.

2. *Program for the All-Inclusive Care of the Elderly* (PACE) organizations offering PACE Programs, as defined in *section* 1894 of the Act generally have elected to provide Part D coverage in order to receive payment for the prescription drug coverage that they are statutorily required to provide.

10.16 – Medical Necessity

(Rev. 121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

Every MA plan:

- Must have policies and procedures, that is, coverage rules, practice guidelines, payment policies, and utilization management, that allow for individual medical necessity determinations (42 CFR §422.112(a)(6)(ii));

- Must employ a medical director who is responsible for ensuring the clinical accuracy of all organization determinations and reconsiderations involving medical necessity. The medical director must be a physician with a current and unrestricted license to practice medicine in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia (42 CFR §422.562(a)(4));

- If the *MAO* expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the organization determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, before the *MAO* issues the organization determination decision. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia (42 CFR §422.566(d), MMCM *chapter* 13, 40.1.1);

- Must make determinations based on: (1) the medical necessity of plan-covered services - including emergency, urgent care and post-stabilization - based on internal policies (including coverage criteria no more restrictive than original Medicare's national and local coverage policies) reviewed and approved by the medical director; (2) where appropriate, involvement of the organization's medical director per 42 CFR §422.562(a)(4); and (3) the enrollee's medical history (e.g., diagnoses, conditions, functional status), physician recommendations, and clinical notes. Furthermore, if the

plan approved the furnishing of a service through an advance determination of coverage, it may not deny coverage later on the basis of a lack of medical necessity (Program Integrity Manual, *chapter* 6, Section 6.1.3(A)); and

- Must accept and process appeals consistent with the rules set forth at 42 CFR Part 422, Subpart M, and *chapter* 13 of the *MMCM*.

20 – Ambulance, Emergency, Urgently Needed and Post-Stabilization Services

(Rev. 120, Issued: 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

20.1 – Ambulance Services

(Rev. 121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

MAOs are financially responsible for ambulance services, including ambulance services dispatched through 911 or its local equivalent, when either an emergency situation exists as defined in *section* 20.2 below or other means of transportation would endanger the beneficiary's health. The enrollee is financially responsible for plan-allowed cost-sharing. Medicare rules on coverage for ambulance services are set forth at 42 CFR 410.40. For original Medicare coverage rules for ambulance services, refer to chapter 10 of the Medicare Benefit Policy Manual, publication 100-02, located at http://www.cms.hhs.gov/manuals/Downloads/bp102c10.pdf.

20.2 – Definitions of Emergency and Urgently Needed Services

(Rev. 120, Issued: 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

An emergency medical condition is a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in:

- Serious jeopardy to the health of the individual or, in the case of a pregnant woman, the health of the woman or her unborn child;
- Serious impairment to bodily functions; or
- Serious dysfunction of any bodily organ or part.

Emergency medical condition status is not affected if a later medical review found no actual emergency present.

Emergency services are covered inpatient and outpatient services that are:

- Furnished by a provider qualified to furnish emergency services; and

- Internal CMS communication between Kimberly August, Tamara Harvey, and Aimee Reich regarding the applicability of the Medicare Managed Care Manual for contracted versus non-contracted providers.

In addition to the substantial delay in responding to this FOIA request consistent with **45 CFR Part 5 (Freedom of Information Regulations)**, CMS did not provide any documentation that satisfies the above requests. Further, pertaining to items I-IV, CMS did not indicate which documents relate to the above requests, nor did they state to those unanswered, "No records responsive to this request." (See Exhibit A – FOIA Response Letter.)

As you know, federal law requires FOIA requests to be fulfilled within 20 business days. As it appears that none of the provided documents address the requested information, this FOIA request has not been concluded and is now **120 business days past due.**

II. THE REGULATIONS PRESCRIBED UNDER 42 CFR PART 422 APPLY TO BOTH CONTRACTED AND NON-CONTRACTED PROVIDERS.

Included in CMS' response to our July 9, 2018 FOIA request is an internal CMS email which attempts to misconstrue a contracted provider's rights prescribed under **42 CFR Part 422, Subpart C, Sections 100 - 134**. As stated in this email, CMS maintains the position that "these rules and appeal rights are for enrollees and out-of-network providers – not ***contracted*** providers."

While Subpart M Appeal rights (422 CFR §560-626) may not apply to contracted providers, the legislative intent of **42 CFR Part 422, Subpart C - Benefits and Beneficiary Protections (§§ 422.100 - 422.134)** (which includes §422.113) does, as this Subpart includes specific details governing the role of contracted providers within a MAO. For instance, **42 CFR §422.112(a)(1)(i)** states that Medicare Advantage Organizations must "*maintain and monitor a network of appropriate providers that is* ***supported by written agreements*** *and is sufficient to provide adequate access to covered services to meet the needs of the population served.*" Further, **42 CFR §422.112(a)(9)** states the MAOs must also "*provide coverage for ambulance services, emergency and urgently needed services, and* ***post-stabilization care services in accordance with §422.113***."

As the above cited regulations expressly define the relationship between MAOs and contracted providers, including the provision of statutory payment obligations pursuant to **42 CFR §422.133**, it is improbable that this section of law is only intended to apply to non-contracted providers.

In addition, SCAN's application of Traditional Medicare regulations to support payment of claims for Medicare Advantage claims is inappropriate. Please note, with Traditional Medicare an authorization is not required and if there is any retrospective review, the provider protects themselves by informing the patient prior to services that Medicare may not cover a service and not pay for that service and have the patient sign an Advanced Beneficiary Notice of Non-coverage ("ABN") protecting the hospital if Medicare should deem an inpatient admission or post-stabilization services not medically necessary.

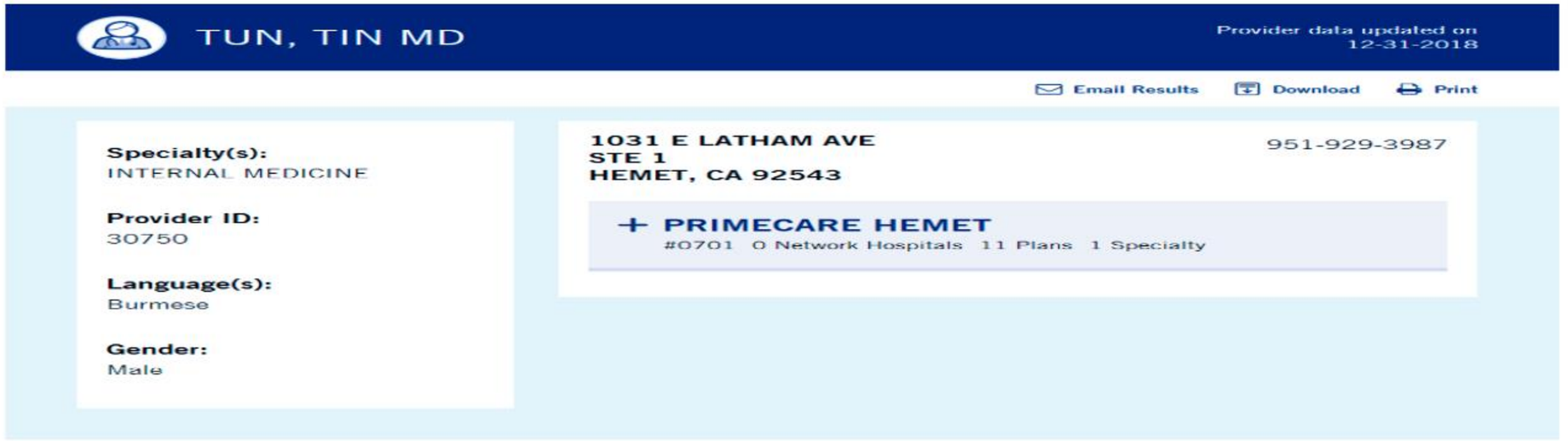
The CMS publication titled "*Improper Use of Advance Notices of Non-coverage*" dated May 5, 2014 provides further evidence that the statutory timeframes to approve or deny post-stabilization services apply to both contracted and non-contracted providers.

In its guidance, CMS states that an Advance Beneficiary Notice of Non-coverage (ABN) is not to be used by MAOs because "a Medicare Advantage enrollee has always had the right under the statute and regulations to an advance determination of whether services are covered prior to receiving such services." (See Exhibit B – Improper Use of ABNs.) From this verbiage and in the context of post-stabilization services, a logical inference would be that the right to an advance determination (e.g. pre-approval) of covered services is prescribed and protected by **42 CFR 422.113(c)(2)**. If these regulations did not apply to contracted MA providers, there would be no way of obtaining an advance determination of covered services prior to rendering care, and thus eliminating a provider's ability to notify MA beneficiaries receiving post-stabilization services of potential financial liability.

III. PER CMS POLICY, CONTRACTED PROVIDERS ARE CONSIDERED AGENTS OF THE PLAN.

Per CMS commentary included in its response to our July 9, 2018 FOIA request, "When a treating physician is contracted with the plan, CMS views him or her ***as the plan*** for purposes of our rules and guidance." (See Exhibit C – FOIA Response, pg. 2) Thus, as CMS considers a contracted provider to be a plan provider, the contracted provider's determination constitutes a "favorable organization decision."

This premise is supported through various CMS publications and opinions. For example, the CMS CDAG/ODAG guidance published September 4, 2013 (See Exhibit D – CDAG/ODAG Updates.) states that "The provision of an item or service by a ***contract provider constitutes a favorable organization determination***."



Who are the treating physicians or provider - are they contracted with the MAO?

ERN
NCRA

CASE STUDY

CONTRACTED PROVIDERS AGENTS OF THE PLAN