FORUM OF ESRD NETWORKS CMS / EDAC / FORUM LEADERSHIP CALL NOTES

WEDNESDAY, APRIL 29, 2020 4:00 pm ET

FORUM EXECUTIVE COMMITTEE MEMBER ATTENDES: (those highlighted are confirmed as attending)

Ralph Atkinson, MD – President

Don Molony, MD – Past-President

David Henner, DO – President-Elect & MAC Chair

Chris Brown – Secretary

Stephanie Hutchinson, MBA – Treasurer

Derek Forfang - KPAC Co-Chair

Brandy Vinson – EDAC Chair

Natasha Avery - EDAC Vice-Chair

Andrew Howard, MD, FACP – Board Member

John Wagner, MD – Board Member

Danielle Daley, Network 1

Sue Caponi, Network 2

Shannon Wright, Network 6

Helen Rose, Network 7, 15, 17

Kelly Mayo, Network 7

Vicky Cash, Network 9

Audrey Broaddus, Network 10

Diane Carlson, Network 11

Stephanie Smith, Network 12

Linda Duval, Network 13

Mary Albin, Network 14

Dee LeDuc - Forum Staff

CMS ATTENDEES: (those highlighted are confirmed as attending)

Anita Monteiro - Acting Group Director, iQIIG

Paul McGann - Chief Medical Officer for QI, iQIIG

Shalon Quinn – Acting Director, Div of Kidney Health, iQIIG

Melissa Dorsey – Acting Dep Dir, Div of Kidney Health, iQIIG

Jesse Roach, MD – Medical Officer, CMS

Ekta Brahmbhatt – QSOG, CMS

Todd Johnson – Acting Regional Program Mgr, Div of Kidney Health, iQIIG

Renee Dupee - Director, Div of Strategic Innovation, Evaluation & Communication, iQIIG

Ed Huff, CMS

Steven Preston

Lisa Rees

Johannes Hutauruk

The meeting convened at 4:00 pm ET

Ms. Quinn opened with a message of gratitude for all of the information that has been provided by the Networks and Forum, acknowledging the assistance in the distribution of information into the community. She reported that a contract Mod was just released to the Networks which may alleviate some of the concerns being expressed by the community. Ms. Rees reported that COVID-19 ICD-10 codes have now been made available in CROWNWeb and ISG continues to work on the previous request to add a tracking mechanism in CROWNWeb for patients residing in nursing homes.

Dr. Atkinson thanked Ms. Quinn and CMS leadership for these newly established weekly calls and the opportunity to provide real-time feedback about what is happening in the dialysis and transplant community. He acknowledged Ms. Archibald for receiving the Arthur S. Flemming Award.

Follow-up from April 22 Call:

- 1) <u>Transportation</u>: CMS request to quantify and identify regions where transportation of COVID-19 positive patients continues to be an issue
 - Networks that were reporting transportation issues have started collecting this information from their facilities, this started Monday, April 20
 - 4/17/2020 CMS FAQ on Medicare FFS Billing: Could CMS send a memo to provide formal clarification to questions #9 (pg.13) and #13 (pg.14)?
 - It appeared in initial guidance prior to this that ambulance services were being covered only when transporting patient to alternate site for dialysis, but FAQ seems to clarify that it also includes ESRD facility. Could CMS amend the FAQ to include the following clarifying statement? Due to infection control issues related to dialysis, dialysis patients with + COVID-19 or PUI do meet definition of medical necessity for ambulance transfer to minimize risk to other patients and allow for adequate disinfection after transport.

Discussion:

CMS continues to work on this issue and requested quantitative data to help support additional communication into the community. She referred attendees to HSS Federal Register (link below) page 166 section *AA.Origin and Destination Requirements Under the Ambulance Fee Schedule*, which includes specific language regarding the transportation of beneficiaries receiving dialysis treatment.

https://s3.amazonaws.com/public-inspection.federalregister.gov/2020-06990.pdf

AA. Origin and Destination Requirements Under the Ambulance Fee Schedule Section 1861(s)(7) of the Act establishes an ambulance service as a Medicare Part B service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. We have established regulations at § 410.40 that govern Medicare coverage of ambulance services. Under § 410.40(e)(1), Medicare Part B covers ground (land and water) and air ambulance transport services only if they are furnished to a Medicare beneficiary whose medical condition is such that other means of transportation are contraindicated. The beneficiary's condition must require both the ambulance transportation itself and the level of service provided for the billed services to be considered medically necessary. Under § 410.40(e)(1), nonemergency transportation by ambulance is appropriate if either the beneficiary is bed-confined, and it is documented that the beneficiary's condition is such that other methods of transportation are contraindicated; or, if his or her medical condition, regardless of bed confinement, is such that transportation by ambulance is medically required. That section further provides that bed confinement is not the sole criterion in determining the medical necessity of ambulance transportation but is one factor that is considered in medical necessity determinations. For a beneficiary to be considered bed-confined, § 410.40 (e)(1) states that all of the following criteria must be met: (1) the beneficiary is unable to get up from bed without assistance, (2) the beneficiary is unable to ambulate, and (3) the beneficiary is unable to sit in a chair or wheelchair.

The origin and destination requirements for coverage of ambulance services are addressed in our regulations at § 410.40(f). As provided in that section, Medicare covers the following ambulance transportation:

• From any point of origin to the nearest hospital, critical access hospital (CAH), or skilled nursing facility (SNF) that is capable of furnishing the required level and type of care for the beneficiary's illness or injury. The hospital or CAH must have available the type of physician or physician specialist needed to treat the beneficiary's condition;

- From a hospital, CAH, or SNF to the beneficiary's home;
- From a SNF to the nearest supplier of medically necessary services not available at the SNF where the beneficiary is a resident, including the return trip; and
- For a beneficiary who is receiving renal dialysis for treatment of ESRD, from the beneficiary's home to the nearest facility that furnishes renal dialysis, including the return trip.

We continue to believe that our current regulatory requirements governing coverage of ambulance services are appropriate under normal circumstances. However, in the context of the PHE for the COVID-19 pandemic, we recognize that providers and suppliers furnishing ground ambulance services and other health care professionals are faced with new challenges regarding potential exposure risks, for Medicare beneficiaries and for members of the community at large. Therefore, on an interim basis, we will expand the list of destinations at § 410.40(f) for which Medicare covers ambulance transportation to include all destinations, from any point of origin, that are equipped to treat the condition of the patient consistent with Emergency Medical Services (EMS) protocols established by state and/or local laws where the services will be furnished. The EMS protocols are recognized operating procedures that all emergency service professionals such as emergency medical technicians (EMTs) and paramedics must follow for patient assessment, treatment, transportation and delivery to definitive care. These protocols are designed by national, state and/or local medical authorities and institutions. Based on these protocols, a patient suspected of having COVID-19 that requires a medically necessary transport may be transported to a testing facility to get tested for COVID-19 instead of a hospital in an effort to prevent possible exposure to other patients and medical staff.

These destinations may include, but are not limited to: any location that is an alternative site determined to be part of a hospital, CAH or SNF, community mental health centers, FQHCs, RHCs, physicians' offices, urgent care facilities, ambulatory surgery centers (ASCs), any location furnishing dialysis services outside of an ESRD facility when an ESRD facility is not available, and the beneficiary's home. This expanded list of destinations will apply to medically necessary emergency and non-emergency ground ambulance transports of beneficiaries during the PHE for the COVID-19 pandemic. Consistent with section 1861(s)(7) of the Act, there must be a medically necessary ground ambulance transport of a patient in order for an ambulance service to be covered.

2) **Shortage of CRRT Fluids & Machines**:

- CMS had plans to meet with ASPR and FEMA, are there any updates to share?
- Dr. Wagner will provide an update from NYC

Discussion:

Dr. Roach reported CMS continues to work through this issue, corresponding with ASPR, FEMA and the FDA. Attendees considered recent community discussions regarding the manufacturing of ultra-pure dialysate by facilities. Dr. Henner shared that he was recently contacted by Danilo Concepcion, Operations Manager of Renal Services in St. Joseph Hospital in Orange, CA, who offered to provide information/education about this process. Dr. Roach reported that CMS is working with the FDA to develop guidance on the proper procedures for doing this, recognizing the definition of ultra-pure and the use of such fluids must be clearly defined. He noted that the FDA does not want to interfere in the practice of medicine unless it is unsafe and allowing facilities to do this is acceptable. Dr. Roach offered his contact email if facilities would like more information and/or to speak with the FDA before pursuing this option. Jesse.roach@ccms.hhs.gov

Dr. Wagner shared that he has had the pleasure of working with many colleagues around the NYC metro area who are treating COVID+ patients; a team of these colleagues recently published an article in CJASN regarding their experiences treating AKI patients including the acute dialysis nursing shortage. He shared that just in this past

week, his facility had 23 acute PD patients on therapy and 30 catheters placed in the last few weeks. This being a program that had zero patients prior to the pandemic. They just received an additional supply of CRRT fluid from Baxter this week, so the historical allocation supply they had been limited by, has been partly eliminated. However, if a facility didn't order hemofilters in the months prior to the pandemic, there is no access to hemofilters. The need for trained dialysis nurses has also been somewhat relieved with the help of ANNA's online tool to identify and deploy trained dialysis nurses where most needed. To this point, equipment shortages has not been as much of a constraint because facilities didn't have the nursing staff to run the machines, however, once the nursing staff is available more equipment will be desirable. Facilities are ordering machines but due to manufacturing delays these may not arrive until June, past the time of the most need. Considering these factors, it will be crucial to establish an allocation system and a communication system to efficiently distribute machines, fluid and nursing/tech staff where needed when needed.

Dr. Roach will take this information back to ASPR and FEMA as they continue work in this area. https://cjasn.asnjournals.org/content/early/2020/04/27/CJN.05180420

- 3) <u>Vascular Access Procedures</u>: CMS request to quantify and identify regions where surgeons/hospitals do not consider vascular access procedures an essential procedure.
 - The Forum is collaborating with Network MRBs to determine scope of problem

Discussion:

Through the Network MRBs and Forum MAC members, the Forum was able to gather data regarding vascular access procedures. Dr. Henner reported that as of the call, 15 of 18 Networks had responded to the inquiry. 14 have reported significant issues with getting VA procedures performed. Of the 28 states included in this reporting, 25 states reported having issues, only 3 states reported no issues. Overall, the common theme is that most states are viewing vascular access procedures as elective surgery, even with the previously released CMS statements. Attendees also discussed the backlog of elective procedures, including vascular access procedures, once the restrictions are loosened.

Mr. Forfang shared that during recent conversations with many of his fellow patients, many are worried about the access to surgery if they should have problems with the access or were scheduled for placement of an access.

ACTION: Ms. LeDuc will forward the detailed spreadsheet to CMS.

Footnote 04/20/2020: Networks report that LDOs have resumed batch submission into EQRS.

- 4) LDO data reporting at the national level:
 - Is there any follow up to the referenced call between CMS and DaVita leadership that can be shared?
- 5) Tracking Nursing Home residents in EQRS:
 - CMS is working on this, any updates to share?

Discussion: Ms. Rees reported CMS continues to work on this request.

- 6) <u>Transparency of sharing COVID test results</u> between dialysis facilities/healthcare providers and nursing homes
 - Any updates from CMS that can be shared?

New Topics for Consideration:

1) <u>Triage Documents</u> that put dialysis patients at a real disadvantage especially when the main determinant is a SOFA score that is heavily weighted against those with high Cr.

Briefly, the issue is that Triage documents are prepared by states and health systems to help guide which patients receive ICU care during an emergency situation like a pandemic where critical care resources are compromised. Many of these documents specifically exclude ESRD patients and even the presence of acute kidney injury may count against a patient (SOFA score). The NKF recently released a statement about this as well:

 $\underline{https://www.kidney.org/news/national-kidney-foundation-urges-america-s-hospitals-and-health-systems-to-not-implement}$

2) Transplant Metrics: The decline of transplants performed & increased use of telehealth for waitlist referrals

Discussion:

Mr. Huff inquired about the preservation of transplant practices during the pandemic. Dr. Molony noted a substantial reduction of living donor transplantation in Texas.

Dr. Howard shared the most recent UNOS data regarding adult kidney transplant trends (living and deceased donor) and the impacts on the adult kidney transplant waitlist. Total adult kidney transplant are typically in excess of 400 per week but dropped to just over 200 in late-March/early-April; this past week there were a reported 317 kidney transplants. Living donor kidney transplants dropped from just over 100 per day to just 19 this past week.

There has been a significant increase in the number of inactivations on the waitlist, primarily due to COVID-19 precautions, and most importantly to Networks and their QIAs there has been a progressive decrease in new additions to the waitlist.

ACTION: Ms. LeDuc will send these graphs to CMS leadership.

Due to time constraints the remaining topics were not discussed, and the call adjourned at 4:30.