DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Indian Health Service
Rockville MD 20857

To: Kate Goodrich, MD
Director, Center for Clinical Standards and Quality and Chief Medical Officer, CMS

From: Michael Toedt, MD
Chief Medical Officer, Indian Health Service

RE: CMS 2567 dated 10/25/2017 for PHS Indian Hospital at Pine Ridge

Date: November 6, 2017

IHS Response to CMS Survey

This note is in response to a CMS Survey conducted on 10/17 – 10/19/2017 for PHS Indian Hospital at Pine Ridge. CMS's treatment findings for "Patient 7" are the basis of their finding of immediate jeopardy for the facility, resulting in a CMS decision to terminate the facility's participation in Medicare. I have reviewed the available medical records associated with "Patient 7" and believe findings in the survey omit significant treatment details relating the emergency treatment received by the patient. An interview with the treating physicians was conducted as a part of our due diligence, which was not undertaken in the review by CMS. The following additional findings of fact, unless otherwise noted, come directly from the medical record (to which the surveyor, who was not a physician, had complete and unrestricted access at the time of the survey). There were multiple treatment details which were not taken into account by CMS to determine whether the facility met the following applicable standard for emergency services.

Responsibilities of Medicare Participating Hospitals in Emergency Cases

Pursuant to 42 C.F.R. 489.24(a), Medicare-participating hospitals with an emergency department "must provide an appropriate medical screening examination [MSE] within the capability of the hospital's emergency department, including ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition exists…" Implementing guidance for this standard is set forth in CMS Publication 100-07 providing that "An MSE is not an isolated event. It is an ongoing process that begins, but typically does not end, with triage."

Additional Treatment Details

"Patient 7" arrived at 12:22 via Emergency Medical Service (EMS) transport, presenting with hyperglycemia, confusion, and not taking his insulin for 2-3 days. The hospital nurse performed triage immediately at 12:23 (1 minute triage time), and the nurse brought the patient into the treatment bay. The patient had a past medical history of diabetes, hypertension, atherosclerotic coronary vessel disease, and congestive heart failure. EMS noted to the treatment team that the glucometer read "HI", which is >600, so the treatment team knew that the patient had a high glucose, and the team did not require another screening fingerstick glucose, but instead ordered the appropriate confirmatory venous blood glucose test. Once confirmed, the treatment team continued to aggressively treat the hyperglycemia. The patient already had an IV in the left antecubital position, which EMS placed prior to the patient's arrival, with normal saline infusing. The nursing assessment documents normal, non-labored breathing, regular heart rhythm, pale skin color, and capillary refill of less than 3 seconds. The systolic blood pressure and heart rate were in the normal

range, although diastolic pressure was low. After completing her assessment, the nurse notified the provider of the patient arrival (12:30), and entered the vital signs that she had completed during this assessment 112/43, heart rate 63 (entered in EHR at 12:45). Signed provider orders (initiated at 13:10, signed at 13:11) document the physician order of an additional liter of IV normal saline to start infusing at 1000 cc/hr, and an order was placed for a second site of IV access. The record documents that the physician initiated treatment and diagnostic workup within 49 minutes of arrival (a dramatically shorter time than reported on the survey). Although not in the record, a follow-up interview with the provider indicates the provider observed and monitored the patient even sooner, reporting that she saw the patient on two occasions between 12:30 and 13:10. She noted that the patient was confused and nonverbal (therefore unable to give a history). The provider also stated that she recognized that the patient was receiving care in the form of IV fluid fluids.

It is documented in the record that at 13:11 the provider ordered establishment of additional IV access and diagnostic labs as part of her medical screening examination including ammonia, basic metabolic profile (which includes blood glucose), C-reactive protein, urine analysis, beta-hydroxybuterate, magnesium, ethanol, urine drug screen, and CBC. The staff encountered difficulty in establishing additional IV access and drawing peripheral venous blood sample, but upon arrival of a second physician at 14:00, successfully established additional IV access via an external jugular (neck) IV at 14:05. Staff successfully collected the labs at the time of the external jugular vein catheter insertion. The provider ordered insulin to be added to the IV fluids.

The patient received this significant attention and treatment despite the fact that there were five other critical patients receiving care in the ED, including a patient with a hand infection, a patient with leg osteomyelitis (bone infection), a patient with abdominal pain, a patient with hallucinations and methamphetamine use, and a patient with left shoulder pain. This is confirmed by review of the emergency department log, which was available to the surveyor at the time of the survey. The provider did not recall that she had not entered a note on the patient, noting that the second provider who arrived at 14:00 and continued care, entered his history and physical examination, assessment, and plan.

Through the two IV sites (the antecubital and external jugular), the patient received a total of 4 liters of IV normal saline fluid (in addition to the liter initiated by EMS). At 14:51, an arterial blood gas (ABG) was ordered results were pH 7.128 (markedly acidotic, with normal being 7.35–7.45), pO2 105.5, pCO2 17.2, total bicarbonate 6.3, O2 sat 96.1%. At 15:58 a repeat basic metabolic panel was ordered (which includes blood glucose). Again the treatment team noted difficulty in drawing the blood, but the labs were successfully collected from the patient at 16:30.

In addition to the 1 liter of IV normal saline initiate by EMS, there were a total of 4 liters of IV normal saline fluid resuscitation initiated by the treatment team. During the ED course, the patient was placed on a cardiac monitor, oximeter (measures O2 saturation), IV antibiotics (Cipro) and an insulin drip. In addition, the record indicated the ED staff inserted a Foley catheter. Due to continued low blood pressure and failure to respond to IV fluid boluses, the patient was started on medication for blood pressure support (levophed) and the patient was transferred via air ambulance because Pine Ridge does not have an ICU.

The patient arrived at the tertiary care facility on 10/16 at 18:15. The flight crew reported that he was noticeably more alert. The blood pressure had improved to 132/97 on arrival. Further diagnostic workup at the tertiary care receiving facility (CT) revealed pneumatosis (gas within the walls) of loops of small bowel and portal venous gas within the liver (typical of ischemic bowel). The patient underwent diagnostic laparoscopy on hospital day 2 at the receiving facility, which revealed “extensive small bowel necrosis with frankly necrotic changes” (dead bowel). The surgeon stated: “Findings were considered incompatible with life.”

In summary, the patient received prompt initiation of resuscitative care and treatment by a team of multiple physicians and nurses during the ED course at Pine Ridge Hospital that resulted in patient improvement on arrival to the tertiary care center. As noted in the survey, the patient unfortunately succumbed to the severity of his condition at the tertiary medical center on hospital day two, after diagnostic surgery revealed the patient had a terminal condition incompatible with life. The patient's condition was improved on arrival to the tertiary care center due to the actions and treatment initiated at Pine Ridge Hospital. Many factors could contribute to the patient's outcome, including comorbidities and care in another facility, and it is not possible to draw a direct conclusion from the care received at Pine Ridge Hospital to the patient's ultimate outcome.

While longstanding challenges remain for the IHS Great Plains Area, it is essential that all relevant treatment information be considered in reaching an informed decision on this matter. The additional information provided that was not discovered or included in the survey process demonstrate that another conclusion is possible.

Respectfully submitted,

Michael E. Toedt -S

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