UTAH DEPARTMENT OF HEALTH

Sunset Review of Anesthesia Adverse Events

STATE OF UTAH
CENTER FOR HEALTH DATA AND INFORMATICS
OFFICE OF HEALTH CARE STATISTICS
OCTOBER 13, 2021

To:	Health and Human Services Interim Committee
From:	Carl Latamendi, Director - Office of Health Care Statistics
Subject:	Sunset Review of UCA §26-1-40

Recommendations for Sunset Review

Representatives from the original anesthesia amendments workgroup that were convened February 5th, 2021, and April 30th, 2021 to discuss the findings and develop recommendations.

- Sen. Mike Kennedy, MD (was not present but sent a representative)
- Dr. Mark Bair
- Michelle McOmber
- Mark Brinton
- Iona Thraen
- Emily Salisbury
- Maryln Conti

Is the statute necessary?

Yes, the workgroup felt that more time is needed to assess the information and conduct educational outreach.

Is the program accomplishing its objective? Should it be extended?

It has started with a reporting mechanism, assessment of information, and education about reporting requirements. The program could be improved based on recommendations in the subsequent section.

Continue with the program for another 4 years*:* Overall, the recommended action is to continue with this program for another 4 years to continue to collect and assess data and conduct educational outreach efforts.

Are there ways to improve the program? What recommendations do you have for the Committee?

Continue to explore the utility of using other data sources to assess reporting completeness.

Healthcare Facilities Data (HFD) and Emergency Medical Services (EMS) data were utilized to obtain estimates of potential counts of anesthesia adverse events to compare to Redcap reporting. However, HFD is not allowed to be migrated into the anesthesia adverse event database under the governing statute 26-33a-109 (Exceptions to prohibition on disclosure of identifiable health data) or to have an individual follow-up to gather more detail on the event. At present, the statute is interpreted to disallow the Department's ability to use identifiable health data for this purpose. If the legislature wishes a more detailed follow-up of these details, per workgroup recommendation, a change to 26-33a-109 may be needed.

Continue to use Redcap Reporting.

There are several data fields captured in REDCap that are not in other datasets. Aside from an array of variables captured from the survey, Redcap also obtains narrative details of the event, which help describe the event, what went wrong and how it could have been mitigated. Other reporting sources may provide potential counts, but do not have the level of detail Redcap does. Since these systems are not interchangeable but rather complement each other, the workgroup recommended that the program not limit itself to only one single data source for this initiative.

Continue to work to improve reporting completeness.

Further foster a culture among providers of openness in providing details about these events for the purpose of learning. Conduct outreach to better inform providers of reporting requirements and the purpose of the requirements.

Form an ongoing workgroup of required reporter representatives to review data and suggest outreach education.

Provided the underlying objective of this initiative is to help inform and share practices to learn from them, which can help save Utahns' lives, there is context supplied by providers in the REDCap reporting mechanism, which may be useful for identifying if an event was potentially avoidable.

Implementation of these may need additional resources.

Currently, UDOH is allocated approximately $31,800 for the implementation of this program including staff time for Redcap maintenance, data analysis, meeting facilitation, and provider outreach. Additional requirements may need additional resources to help support as the staff working in this area already have high workloads.

Background and Overview

In 2017, H.B. 142 Administration of Anesthesia Amendments, was passed which *"amends professional licensing acts in the Division of Occupational and Professional Licensing Act to require informed consent and certain patient monitoring of patients who are sedated and establishes a database for adverse events.*[1]*"* Subsequently, in the summer of 2017, an interdisciplinary team of healthcare professionals met to determine Administrative rules (R429-3; previously codified under R434-150) that were filed and published in 2018. These rules outlined the purpose, type of event that must be reported, who was required to report, and what needed to be reported. An online reporting database was developed to receive reports using REDCAP technology. In the spring of 2018 close to 15,000 providers were notified of the reporting requirement and procedures via email and 12,000 by hard copy letter. In the fall of 2019 close to 54,441 providers were notified of the reporting requirement and procedures via email and in the spring of 2020, 9,525 providers were notified by hard copy letter. In November 2020, 57,262 email notification reminders were sent to providers. Due to a funding cut, no hard copy letters were mailed in 2020. Emails and calls were received asking for clarification of the reporting requirements. Most of these questions were related to clarifying reporting requirements from those who work in hospitals and ambulatory surgical centers versus outpatient settings. Hospital and Ambulatory Surgical Centers are covered under the Patient Safety Rule R380-200. The law and rules regarding the anesthesia amendment apply to outpatient settings only. Data collected are shared in aggregate form and reported on annually by the Utah Department of Health Patient Safety Surveillance and Improvement Program (PSSIP).

In February 2021, PSSIP reconvened the interdisciplinary team to discuss whether to recommend the continuation of U.C.A. §26-1-40 or recommend letting it sunset on July 1st, 2022.

Sunset review requirements per U.C.A. §26-1-40(5)(b)

(i) the number and types of adverse events reported and (ii) the types of health care providers and locations involved

- **Number of Events:**

[1] https://le.utah.gov/~2017/bills/static/HB0142.html

    - Since the passing of the law, and establishment of the reporting mechanism at the beginning of FY2019 there have been 14 submitted reports, of which 2 were incomplete. FY2019 - two adverse events, FY2020 - five adverse events (note two of these were incomplete reports), FY2021 to 6/29/2021 - seven adverse events.
- **Types of Adverse Events:**
    - One case led to death, 1 led to intervention to sustain life, 2 led to temporary harm requiring hospitalization, 2 led to additional monitoring to prevent harm and the rest were no harm events.
    - 5 events led to the calling of EMS, two led to transfer to a higher level of care, and the rest only used rescue or reversal agents.
    - Of the 12 complete cases through the end of March 2021, 9 of them were female patients.
    - 4 were under the age of 18 years.
    - 8 of the cases occurred after the procedure.
    - 8 of the cases were related to dental procedures (wisdom teeth removal, cleaning)
    - All the cases were given intravenous moderate to deep levels of sedation.
    - All the facilities had emergency response carts available.
    - 3 cases stated that tapering the dose, starting with a lower dose or less sedation would probably have changed the outcome.
    - One case stated that considering situational information such as last taken oral opioids/sedatives, last coffee/stimulant intake, pain level, anxiety level, fatigue level, etc. might have influenced the outcome.
    - One case stated that not leaving the patient without an observer at any time would have reduced the escalation level of the outcome.
    - One case stated that sensitivity to local anesthesia due to other medications taken by patients might have influenced the outcome.
- **Types of Providers:**
    - Types of healthcare providers where the event occurred include Dentists (4), Medical Doctors (4), Oral Surgeons (2), Unspecified (2).
    - The person who administered the anesthesia, according to the reports, includes: Dentists (3), Registered Nurse (3), Certified Registered Nurse Anesthetists (5), Oral Surgeon (1).
- **Locations:**
    - Dental Office (2)
    - Physicians Office (4)
    - Oral Surgery Office (2)
    - Ambulatory Surgical Center (2)
    - Outpatient Clinic (1)
    - Private Practice (1)

(iii) the adequacy of sedation and anesthesia requirements in Sections 58-5a-502, 58-31b-502.5, 58-67-502.5, 58-68-502.5, and 58-69-502.5 related to the adverse events reported under this section; These sections have the following requirements related to unprofessional conduct for an individual licensed under those chapters to administer sedation or anesthesia intravenously to a patient in an outpatient setting that is not an emergency department without:

- Obtaining consent from the patient including the type of sedation or anesthesia is administered, identity and type of license or permit of the person performing the procedure for which sedation or anesthesia will be administered, identity and type of license or permit of the person administering anesthesia, the monitoring that will occur during the sedation or anesthesia.
    - UDOH does not have information on the adequacy of consent forms required in these Title 58 Occupations and Professions codes.

- Reporting of any adverse event under 26-1-40
    - There have been 14 adverse events reported, however, it is unclear if that number is comprehensive. There have been numerous notices sent out over the past three years to inform relevant licensed individuals of these reporting requirements.
- Having access during the procedure to an advanced cardiac life support crash cart with equipment that is regularly maintained according to guidelines established by the American Heart Association
    - As mentioned above all the facilities reported in adverse events had emergency response carts available.

(iv) the adequacy of the reporting requirements under this section and the need for additional protections for health care providers who report events under this section

- There is concern from the workgroup that there is underreporting and they have suggested exploring adverse events related to anesthesia through other data sources such as the All Payers Claims Database, Health Facilities Database, and the Emergency Medical Services data.
    - The All Payers Claims Database (APCD) contains data from health insurance carriers, Medicaid, and third-party administrators in Utah. These data consist of medical, pharmacy, and dental claims as well as insurance enrollment and health care provider data. It is estimated that the APCD has data on 65-75 percent of the population who had eligibility for at least a portion of the year. For the underlying task of identifying potentially reportable adverse anesthesia or sedation events, the APCD was not more beneficial than using the Healthcare Facilities Data (described below). Dental claims, which are within the APCD, do not have diagnosis codes, and what could be pulled from the APCD is a duplication of what is found in the Facilities database. Moreover, the Facilities database covers all encounters, whereas the APCD includes data from insurers, submitted to the State.
    - The Healthcare Facilities Database (HFD) includes all inpatient, emergency department, and ambulatory surgery encounters occurring in Utah. Facilities are not required to report anesthesia events under this rule; they would report patient safety events occurring in their facilities under the patient safety rules if they met the criteria outlined in R429-1 and R429-2. However, the data was queried to see if they could estimate the number of events that may have occurred in outpatient provider settings and then transported to the ED. Querying the HFD for emergency department encounters with a principal diagnosis related to poisoning, adverse effects, or other complications related to anesthesia that indicated healthcare-based settings as the site of injury from 2016 to 2019 yielded the following results: 2016 - 16 events, 2017 – 13 events, 2018 – 11 events, 2019 – 9 events. Additional reviews would need to be done to confirm the diagnoses, circumstances, whether these were actual reportable events under current regulation, and whether or not these were mandatory reporters under this section, or whether these may have been reported as patient safety events under R429-1 or R429-2.
- Regarding Exploration of using Emergency Medical Services (EMS) Data for Identifying Unreported Anesthesia Events
    - The team reached out to the Bureau of Emergency Medical Services and Preparedness to identify what data they collect that could be helpful
    - EMS providers may put certain information in narrative sections of reports
        - Examples, using 2020 data:
            - *Medical office* (35 cases) and *ambulatory surgical center* (6 cases) were used as the scene of the incident.
            - Using “anesth” as search term resulted in about 20 possible cases
            - Using “sedat” resulted in about 15-18
            - EMS believes there are more than 10

Contacts for questions:

- **Navina Forsythe, Director - Center for Health Data and Informatics**
- **Carl Letamendi, Director-Office of Health Care Statistics, Center for Health Data and Informatics**