Sedation/Anesthesia Data Collection
Requirements and Implications

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Where We’re Headed…

• “Sunset bill” – SB 313 – September 1, 2017
  – Authorizes permitting/regulation of parenteral
  – Requires rules on pre-op and emergency mgmt
  – Requires EKG for all permit levels; requires capnography for deep sedation/GA; requires add’l training for pedo and high-risk
  – Requires portable providers to report to agency
  – Requires creation of anesthesia-specific JP exam
  – Requires inspections program
  – Creates Anesthesia Advisory Committee to study anesthesia-related mortality and anesthesia-related incidents → DATA ←
Is D*ta a Four-Letter-Word?

There are three kinds of lies: lies, damned lies, and statistics.

- Benjamin Disraeli/Mark Twain/Unknown

22 Tex. Admin. Code § 108.6 (Rule)

• Dentists must submit a written report of:
  – Death of patient “which may have occurred as a consequence of the receipt of dental services from the reporting dentist” – within 72 hours of death
  – Admission of patient to hospital “as a possible consequence of receiving dental services from the reporting dentist” – within 30 days of hospitalization
Rule 108.6 Cannot Tell Us...

• The number of adverse events related to dentistry
• The number of patients who died as a result of a dental procedure
• The number of patients hospitalized as a result of a dental procedure
• The incidence of sedation/anesthesia adverse events

Blue Ribbon Panel Report

• August 2016 – Directed to establish BRP to review and report on dental anesthesia-related deaths and mishaps investigated between 2011 and 2016

• January 2017 – Final BRP report and recommendations reported to the Texas Sunset Advisory Commission
BRP Case Selection Methodology

- Electronic query of allegation codes and text-based search of complaint summary
- Elimination of cases – ongoing, no written expert report, purged, no s/a administered
- Dental Director review and summary of 123 cases
- Death/mishap defined by BRP
- Elimination of cases – BRP found no s/a death or mishap
- Dental Director extraction of data
- Resulted in specific data (48 data points) concerning 78 cases

BRP Data Points Captured

<table>
<thead>
<tr>
<th>Respondent Data</th>
<th>Investigative Data</th>
<th>Sedation/Anesthesia Treatment, Com/tol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dental school/education</td>
<td>Primary planned procedure</td>
<td>Did an emergency occur at the treatment facility? (Y/N/Unknown)</td>
</tr>
<tr>
<td>Separation permit issue date</td>
<td>Legal report</td>
<td>Pres &amp; HP (who did it, when was it done)</td>
</tr>
<tr>
<td>S/A training information</td>
<td>Age-related factors</td>
<td>Pre-op Yr</td>
</tr>
<tr>
<td>Provider</td>
<td>Mitigating factors</td>
<td>Pre-op Yr</td>
</tr>
<tr>
<td>Self-reported/peer review</td>
<td>Notes regarding emergency response</td>
<td>Pre-op anawy analysis</td>
</tr>
<tr>
<td>Highest S/A permit held</td>
<td>Written emergency protocol? Adequate? Initiated?</td>
<td>Y/N/Y</td>
</tr>
<tr>
<td>Infection</td>
<td>Duration of S/A (date, time, end time)</td>
<td></td>
</tr>
<tr>
<td><strong>Patient Data</strong></td>
<td>Anesthesia violation as per expert review</td>
<td>S/A monitoring (vital, S/A, RR, capn. EKG, etc.)</td>
</tr>
<tr>
<td>Age</td>
<td>S/A anesthesia clinical violation</td>
<td>Delivery method/route</td>
</tr>
<tr>
<td>Age category</td>
<td>S/A anesthesia monitoring or documentation violation</td>
<td>Drugs, dosage, route</td>
</tr>
<tr>
<td>Gender</td>
<td>Sedation/Anesthesia Treatment</td>
<td>Local anesthetic given</td>
</tr>
<tr>
<td>Height</td>
<td>Sedation data</td>
<td>Personal present</td>
</tr>
<tr>
<td>Weight</td>
<td>S/A level achieved? Did respondent provide S/A?</td>
<td>Airway Management - planned or emergency</td>
</tr>
<tr>
<td>BMI</td>
<td>Did respondent provide or billed to provide dental treatment? (Y/N)</td>
<td>IV access – pre-op or emergency response</td>
</tr>
<tr>
<td>Patient/ASA (respondent)</td>
<td>Was S/A provided using portability? (Y/N)</td>
<td></td>
</tr>
<tr>
<td><strong>Legal Data</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient/ASA (other source)</td>
<td>Administrator of S/A</td>
<td>Previous public Board action related to anesthesia</td>
</tr>
<tr>
<td>Additional patient information</td>
<td>Treatment facility type</td>
<td>Compliance with prior actions of the Board</td>
</tr>
</tbody>
</table>
A New Approach

• Get the right data...

• Get the data right...

• Get the data right away...

Getting the Right Data...

22 Tex. Admin. Code § 107.400 (Rule)

(a) All information related to an investigation is confidential, except that the agency shall provide information on a quarterly basis to the Board and the Anesthesia Committee of the Board, and to legislative offices upon request. This information shall consist of de-identified, case specific data reflecting information about jurisdictional, filed complaints involving sedation/anesthesia that were resolved during the reporting period, including, at a minimum, the following data points:

(1) Source of initial complaint -- public, other agency, self-report of death, self-report of hospitalization, or initiated by the Board.

(2) Information about licensee:
   (A) Whether respondent is Medicaid provider;
   (B) Respondent's highest sedation/anesthesia permit level;
   (C) Whether respondent holds portability privileges; and
   (D) Respondent's self-reported practice area.

(3) Information about patient:
   (A) Patient ASA, as identified in respondent's dental records and/or determined by Dental Review Panel;
   (B) Patient age -- 13 and under, between 13 and 18, between 19 and 75, and over 75;
   (C) Location of the treatment investigated by the agency -- dental office, hospital, ASC, office of other practitioner;
   (D) Level of sedation/anesthesia administered -- Local, Nitrous, I, II, III, IV (determined by Dental Review Panel);
   (E) Sedation/anesthesia administrator -- respondent, other dentist, MD, CRNA (determined by Dental Review Panel); and
   (F) Whether treatment investigated by the agency was paid by Medicaid.

(4) Information about investigation:
   (A) Allegation categories identified in preliminary investigation;
   (B) Disposition of official investigation -- Dismissed by Enforcement, Dismissed by Legal -- No Violation, Dismissed by Board Vote, Closed by Administrative Citation/Remedial Plan/Disciplinary Action; and
   (C) If disposition is public action (Administrative Citation, Remedial Plan, or Disciplinary Action), the violations identified in the public action resolving the official investigation.

Effective March 20, 2017.
Sec. 258.206. COMPILATION AND ANALYSIS OF INFORMATION.

(a) The board shall identify complaints resolved by the board that involve anesthesia-related deaths or incidents and compile confidential, de-identified information derived from the investigative files on each complaint identified under this subsection.

(b) The board shall provide information compiled under Subsection (a) to the advisory committee. The advisory committee shall analyze the information compiled under Subsection (a) to identify any trends and submit a report to the board at least annually on:

(1) the advisory committee's findings; and
(2) any recommendations for changes to board rules or this subtitle based on the advisory committee's analysis...

Effective September 1, 2017.

(c) Compilation of Information by Agency. The agency shall identify investigations and provide confidential, de-identified information regarding the investigations to the advisory committee as described below:

(1) By September 30 of each year, the agency shall identify official investigations in which the preliminary investigation was initiated after September 1, 2016, and the official investigation was resolved by the board in the preceding fiscal year, which involve anesthesia-related deaths or incidents. A death shall be considered anesthesia-related if the dental treatment involved the administration of an anesthetic or sedative agent in the dental office, including local anesthesia, and a death occurred. An incident shall be considered anesthesia-related if the dental treatment involved the administration of an anesthetic or sedative agent in a dental office, including local anesthesia, and the Dental Review Panel identified a complication associated with the administration of the anesthetic or sedative agent.

Effective October 19, 2017.
Getting the Right Data…
22 Tex. Admin. § Code 100.12(c) (Rule)

(2) By November 30 of each year, the agency shall compile confidential, de-identified information on each investigation identified under paragraph (1) of this subsection, including, but not limited to, the following information:

(A) Information about respondent:
   (i) Whether respondent is a Medicaid provider;
   (ii) Respondent’s highest sedation/anesthesia permit level;
   (iii) Whether respondent reported providing anesthesia services in more than one location on the licensee’s application or latest renewal;
   (iv) Respondent’s self-reported practice area; and
   (v) Whether the investigation was initiated as the result of a complaint submitted by a patient or member of the public, a self-report to the agency required by Board Rule 108.6, or both.

(B) Information about patient:
   (i) Patient ASA, as identified in respondent’s dental records and/or determined by Dental Review Panel;
   (ii) Patient age -- under the age of 13, 13 and over but under 18, 18 and over but under 75, and 75 and over;
   (iii) Location of the treatment investigated by the agency -- dental office, hospital, ASC, office of other practitioner;
   (iv) Level of sedation/anesthesia administered -- Local, Nitrous, I, II, III, IV (determined by Dental Review Panel); and
   (v) Whether treatment investigated by the agency was paid by Medicaid; and

(C) The Dental Review Panel report designated as the final report by the Dental Review Panel.
Getting the Data Right Away...

• 108.6 data compiled before the treatment was evaluated by experts
• BRP data compiled after the treatment was evaluated by experts
• Sedation/anesthesia data now compiled *while* the treatment is evaluated by experts

Confidentiality of Derived Data

Sec. 254.006. BOARD RECORDS AND CONFIDENTIALITY OF RECORDS. (a) Except as provided by this section, the investigation files and other records of the board are public records and open to inspection at reasonable times. (b) Investigation files and other records are confidential, except the board shall inform the license holder of the specific allegations against the license holder. The board may share investigation files and other records with another state regulatory agency or a local, state, or federal law enforcement agency.

• OR2016-11287
  – "the submitted responsive information consists of 'case-specific investigative information' derived from investigation files of the board...we conclude the board must withhold the submitted responsive information..."
Thank you!

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