Research Protocol for Office-Based Surgery (OBS) Laws

Prepared by the Policy Surveillance Program Staff

August 2016
RESEARCH PROTOCOL
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Office-Based Surgery (OBS) Laws

I. Date of Protocol: August 2016

II. Scope: Compile, code and analyze state laws that impose facility and/or operational requirements on non-hospital facilities that provide office-based surgery, procedures and/or anesthesia/sedation (OBS). This cross-sectional dataset analyzes the important features of the state OBS laws, including, but not limited to, the specific conduct that triggers regulation of OBS, licensing requirements, on-site facility requirements, and types of hospital transfer arrangements required. Advancing New Standards in Reproductive Health Care (ANSIRH) and the Policy Surveillance Program (PSP) collaborated to create this dataset. This dataset complements three datasets compiling Targeted Regulation of Abortion Providers (TRAP) laws: Abortion Facility Licensing (AFL) laws, Ambulatory Surgical Center (ASC) laws, and Hospitalization Requirements (HR).

III. Primary Data Collection


b. Dates Covered in the Dataset: March 3, 1986 – August 1, 2016. This is a cross-sectional dataset analyzing OBS laws as they are in effect at one point in time, August 1, 2016. The effective date listed for each state is the date of the most recent version of the law or regulation within that state. If more than one law or regulation is included in the legal text for a state, the effective date reflects the date of the most recently amended or enacted law or regulation within the legal text. Since this dataset is cross-sectional, if the state did not have an OBS law in effect on August 1, 2016, the effective and valid-through date are listed as August 1, 2016.

c. Data Collection Methods: The Policy Surveillance Program Staff (Team) building this dataset consisted of four legal researchers (“Researchers”) and one supervisor (“Supervisor”). The American Society of Plastic Surgeons (ASPS) and Westlaw Next were used to identify which states had OBS laws in effect as of August 1, 2016. Secondary sources, including the Federation of State Medical Boards (FSMB), the Accreditation Association for Ambulatory Health Care (AAAHC), as well as a subject matter expert from ANSIRH were consulted to assist with defining the scope of the laws included in this dataset and to assist with data collection method decisions.
d. **Databases Used:** Research was conducted using Westlaw Next, state-specific legislature websites, and secondary sources from the following organizations: The American Society of Plastic Surgeons (ASPS), the Federation of State Medical Boards (FSMB), and the Accreditation Association for Ambulatory Health Care (AAAHC).

i. Full text versions of the laws were collected from each respective state legislature website.

e. **Search Terms:**

i. Keyword searches:

   a. “Office based surgery”
   b. “Outpatient surgery”
   c. “Office setting”
   d. “Office-based setting”
   e. “Surgical center”
   f. “Ambulatory surgery”
   g. “Ambulatory surgical center”
   h. “Non-hospital based ambulatory surgery”
   i. “Surgical referral site”
   j. “Ambulatory”
   k. “Freestanding surgery”
   l. “Institutional health facility”
   m. “Sedation”

ii. Search string: “TE((office or center or facility! or establishment or freestanding) /5 (surgery or procedure or liposuction or chemotherapy or catheter! or laser or cosmetic))”
   a. This search was performed for 37 jurisdictions for statutes and regulations (AL, AK, AZ, AR, CA, CO, CT, DE, DC, FL, GA, HI, ID, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OH, OK).

iii. Search string: “TE((office or center or facility! or establishment or freestanding) /5 (surgery or procedure or liposuction or chemotherapy or clinic or laser or cosmetic))”
   a. This search was performed for 14 jurisdictions for statutes and regulations (OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WV, WI, WY).

iv. Key word searches were supplemented by reviewing the table of contents chapters on OBS laws and on related surgical facility laws.

v. Once all the relevant statutes and regulations were identified for a jurisdiction, a Master Sheet was created that summarizes each relevant statute or regulation.
   a. Relevant citations were reviewed and finalized by the subject matter expert.
vi. The Master Sheet for each jurisdiction includes the most recent statutory history for each statute and regulation. The most recent effective date, or the date when a version of law or regulation becomes enforceable, are recorded for each relevant statute and regulation.

vii. Additionally, any court decision or Attorney General Opinion affecting the enforceability of OBS provisions were also researched and included.

viii. All 51 jurisdictions were 100% independently, redundantly researched to confirm that all relevant law was being collected by the Researchers.

ix. Discrepancies were reviewed by a supervisor and sent to the Researchers. The team met to discuss and resolve all divergences (discrepancies in the original research and redundant research).

f. Initial Returns and Additional Inclusion or Exclusion Criteria: Included laws pertaining to regulation of OBS.

i. The following variables were included in the OBS dataset:
   - Triggers for OBS laws
     - Level of anesthesia/sedation: Minimal, moderate, and deep anesthesia/sedation
     - Type of procedure performed
     - Percentage of procedures performed
     - Other specified procedures (OSP)
   - Requirements for osteopathic physicians
   - Licensing requirements and exceptions
   - Penalties for violations of OBS requirements
   - Room requirements and physical facility features for facilities
   - Facility policy requirements
   - Physician qualifications and nursing staff requirements
   - Requirements related to hospital transfers and hospital admitting privileges
   - Court decisions and Attorney General opinions affecting the enforceability of OBS requirements

ii. Excluded variables include:
   - Laws regulating ambulatory surgical centers, and freestanding outpatient surgical clinics, unless by definition these laws were applicable to facilities providing office interventions
   - Laws regulating non-office settings, e.g. birthing centers, dialysis, dialysis facilities, radiation facilities
   - Laws regulating interventions by practitioners outside of the practice of medicine and/or osteopathy, e.g. cosmetologists, aestheticians, body artists (tattoo, piercing), dentists, podiatrists
• Facility laws, or requirements within facility laws, that apply only to the provision of local or general anesthesia

IV. Coding

a. Development of Coding Scheme: The project was originally conceptualized by ANSIRH in 2015. The Team worked in collaboration with ANSIRH to determine the focus of the research and the key questions to be coded. The Team conceptualized coding questions, then circulated them to ANSIRH for review. When the questions were finalized, the Team entered the questions into the Workbench, a web-based software coding platform. As the Team developed the coding scheme they recorded the dataset terminology. Dataset terminology is a set of relevant terms recorded and defined by the Team specifically for purposes of coding within this dataset.

i. Dataset terminology:
   • “Office-based surgery (OBS) laws” are laws imposing requirements on facilities that provide office-based surgery, procedures and/or anesthesia/sedation.
   • “Anesthesia/sedation” means the use of medication to change the state of an individual undergoing medical interventions.
   • “Physician” is a licensed physician qualified to perform office-based procedures through experience and training.
   • “Hospital” is a licensed hospital as defined by the law.
   • “Hospital admitting privileges” are privileges granted to a physician to admit patients to a particular hospital.
   • “Hospital staff privileges” are privileges granted to a physician that allow the physician to perform certain procedures or operations at the hospital.
   • “Transfer agreements” are agreements between an OBS-providing facility and a hospital, back-up physician and/or emergency transport service, providing that the hospital, back-up physician and/or emergency transport service will accept or facilitate the transfer of a patient from the OBS facility to a hospital if hospital-based observation or treatment of the patient is needed.

b. Coding Methods: Below are specific rules used when coding the questions and responses in the OBS dataset:

   Question: “Is there a law that regulates facilities that perform OBS generally?”

   • States were coded as “yes” if there was a law or regulation that imposed requirements on facilities performing OBS.
   • States were coded “no” where states regulated interventions by practitioners outside of the practice of medicine and/or osteopathy or regulated non-office settings.
• States were coded as “no, but medical board has issued guidelines, policy, or position statement for OBS generally” if the guidelines promulgated by a medical board or by a professional association did not have the force of law, but were aspirational standards.
• States were coded as “no, but the state has a law regulating a specific surgery/procedure other than abortion” where states did not have regulations governing OBS generally, but had facility and/or licensing requirements for some specified procedure(s) other than abortion.
  o see Maryland (MD)

Question: “What conduct triggers regulation under the law? (Text response)”
• Where facilities performing OBS (either OBS generally or a procedure other than abortion specifically) were subject to regulation based on use of anesthesia (other than local or general anesthesia), type of procedure, number of procedure, or percentage of procedures that information was coded in the text box.
• Where requirements for osteopathic physicians performing OBS were the same as general OBS requirements, the legal text was collected but requirements were not specifically cited.
• Where OBS requirements for osteopathic physicians differed from general OBS requirements, the difference was captured in a caution note.

Question: “What type of procedure triggers regulation?”
• This question was coded where regulation was triggered by performing specific surgical procedures, such as cosmetic procedures or liposuction.
• “Cosmetic procedures” includes both surgical and non-surgical cosmetic procedures.
• Where the type of procedure performed did not impact requirements, “Regulation is not triggered by types of procedures” was coded.

Question: “What percentage of procedures triggers regulation?”
• Where regulation was triggered by performing a certain amount of surgical procedures, “More than 50 percent of facility activities are surgical procedures” was coded
• Where the percentage of procedures did not trigger regulation, “Regulation is not triggered by percentage of procedures” was coded.

Question: “What level of sedation triggers regulation?”
• “Minimal sedation” was coded when the law was triggered by the use of minimal sedation.
• “Moderate sedation” (also known as conscious sedation) was coded when the law was triggered by the use of minimal sedation, as defined by ASA.
• “Deep sedation” was coded when the law was triggered by the use of minimal sedation, as defined by ASA.
• When a jurisdiction did not explicitly use the terms “minimal,” “moderate,” or “deep” to describe sedation level, the state’s sedation regulations were compared to the sedation definitions of the American Society of Anesthesiologists, described above. See ASA definitions: http://www.asahq.org/~media/sites/asahq/files/public/resources/standards-guidelines/continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedation-analgesia.pdf.
  o The level of sedation was coded as “minimal,” “moderate,” or “deep” based on which ASA definition of sedation level was most closely aligned with state definitions.
  o For states where there were different requirements depending on the level of sedation used, the questions following were coded using the most restrictive requirements. Any less restrictive requirements were noted in caution notes.

• Laws triggered only by general or local anesthesia were out of the scope for the dataset and were not included. Where laws included within the dataset contained particular requirements applicable only to the use of local or general anesthesia, those requirements were out of scope and not coded in the dataset.

• Laws triggered regardless of the level of sedation/anesthesia used in a facility were coded as “Regulation is not triggered by sedation level” and were included in the dataset. States that describe levels of sedation as Level I, Level II, or Level III were coded as minimal, moderate, or deep based on the ASA definitions comparison.

Question: “Is the facility required to be licensed?”
  • Where the practice of OBS required the facility to be licensed by the state department of health this question was coded as “Yes.”
  • Registration and/or certification requirements were coded as “no” but the requirements were included in caution notes.

Question: “Is the facility required to be accredited?”
  • Where the practice of OBS required the facility to be accredited by a private accreditation organization this question was coded as “Yes.”
  • Where accreditation or an alternative to accreditation was required, this question was coded “no” with requirements captured in a caution note.

Question: “What are the penalties for non-compliance with OBS requirements?”
  • This question was coded “criminal penalties” where the law explicitly provided criminal penalties for violations of OBS requirements
  • This question was coded “fines” where the law explicitly provided fines for violations of OBS requirements, which are generally imposed against the facility itself (i.e. licensee) but may also be against an individual (non-licensee) violator.
  • “Licensing sanctions against a facility” was coded where licensing sanctions may be imposed against the license of an OBS facility. Licensing sanctions against an individual physician’s medical license were out of scope for the dataset and not coded or included.
Where the law provided for no penalties or for penalties outside of the scope of this dataset, the question was coded as “None.”

**Question:** “What are the authorized fines?”
- This question was coded where fines were imposed against a person or entity for violations of OBS facility provisions.
- Only the highest authorized fine for a first-time violation was coded.
- Where the law provided for a range of allowable fines for a first-time violation, only the highest allowable fine was coded.
- Where the law provided that each day of non-compliance, or each instance of violation, constitutes a separate violation which may be fined, this information was captured in a caution note.

**Question:** “What are the authorized criminal penalties?”
- This question was coded where criminal penalties were authorized for violations of OBS facility provisions.
- The highest authorized criminal penalty for a first-time violation was coded.
- Specific classes of misdemeanors, i.e., “class A misdemeanors,” were coded only as “misdemeanor.”

**Question:** “What are the authorized licensing sanctions?”
- Where the law explicitly authorized revocation, suspension, or probation of a facility’s license as a penalty for violations, this question was coded.
- Sanctions against the medical license of a physician were not captured.

**Question:** “Can facilities seek exceptions from specific OBS requirements?”
- Where the law authorized facilities performing OBS to seek a waiver, variance, or other exemption from OBS requirements, this question was coded “yes.”

**Question:** “Which types of facilities, if any, are explicitly excluded from OBS requirements?”
- Where facilities performing OBS were exempt from OBS requirements if the facility is accredited by a private accreditation organization, “accredited facilities” was coded.
- Where hospitals or other healthcare facilities were excluded from OBS requirements, this question was coded as “Facility is already licensed as another class of facility.” Where the law specified specific types of excluded healthcare facilities, this was captured in a caution note.
- Where physician’s offices performing OBS were explicitly excluded from facility licensing requirements, this question was coded as “Private physician practice.”
- Where the law did not specify that certain facilities were excluded from licensing requirements, “No facilities are excluded” was coded.

**Question:** “What types of rooms must the facility have on-site?”
• Requirements related to areas, i.e. recovery area, were not coded as room requirements.
• Where the law provided room requirements outside the scope of this dataset, this question was coded as “Room types are not specified.”
• Where a separate operating room, procedure room, instrument sterilization room, or recovery room was not required, “Room types are not specified” was coded.
• Laws or regulations that merely mentioned an operating room, procedure room, recovery room, or sterilization rooms, were not coded as requirements. There must be an explicit requirement for a separate room to code a specific room type as required.

Question: “What size is the operating room required to be?”
• Requirements related to total square footage of the operating room were coded. Where required dimensions of rooms were given, those measurements were converted to total square footage. For example, a room requirement of 12 ft x 12 ft was coded as “144 sq ft.”
• Where an operating room was required but the size was not specified, “Operating room size is not specified” was coded.

Question: “What size is the procedure room required to be?”
• Requirements related to total square footage of the procedure room were coded. Where required dimensions of rooms were given, those measurements were converted to total square footage. For example, a room requirement of 12 ft x 12 ft was coded as “144 sq ft.”

Question: “What size is the recovery room required to be?”
• Requirements related to total square footage of the recovery room were coded. Where required dimensions of rooms were given, those measurements were converted to total square footage. For example, a room requirement of 12 ft x 12 ft was coded as “144 sq ft.”
• Where a recovery room was required to be “adequate” or “sufficient” in size, this question was coded as “Adequate or sufficient.”
• Where a recovery room was required but the size was not specified, “Recovery room size is not specified” was coded.

Question: “What on-site features of the facility are regulated?”
• This question was coded where the regulatory scheme for facilities performing OBS specified requirements for hallway and/or doorway width, emergency power source, or ventilation and/or temperature requirements.
• Where the law provided ventilation requirements and/or temperature requirements, “Facility must meet ventilation and/or temperature requirements” was coded.
• Where the law provided facility feature requirements outside the scope of the dataset, this question was coded as “On-site features are not specified.”
Where facility requirements only applied to new construction or renovations, this question was coded as “On-site features are not specified.”

**Question:** “What type of ventilation is required?”
- Requirements for ventilation that were general, such as “adequate”, “sufficient”, “comfortable”, or “satisfactory” were coded as “Adequate or sufficient.”
- Requirements for ventilation “to ensure the health and safety of a patient” were coded as “Adequate or sufficient.”
- Specific requirements related to number of air changes, filter efficiencies, etc. were coded as “specific ventilation requirements”, with details of the ventilation requirements captured in a caution note.
- Ventilation requirements for toilet or storage areas were not coded.

**Question:** “What hallway width is required?”
- All required hallway or corridor widths were coded as a measurement in inches. If the law or regulation provided the requirement in feet, this requirement was converted to inches.

**Question:** “What doorway width is required?”
- All required doorway widths were coded as a measurement in inches. If the law or regulation provided the requirement in feet, this requirement was converted to inches.

**Question:** “What are the emergency power system requirements?”
- Where an emergency power system was required in the law, but not specified as to operating time, emergency lighting, or power in operating or procedure rooms, this question was coded as “Emergency power system requirements are not specified.”
- Where emergency power systems were required to power equipment and/or lights in the operating room, “System must power operating room” was coded.
- Where emergency power system requirements were outside the scope of the dataset, this question was coded as “Emergency power system requirements are not specified.”
- Requirements that the emergency power system be available to protect the health of the patient were coded as “Emergency power system requirements are not specified.”

**Question:** “What policies must a facility have in place?”
- Where required policies were outside the scope of the dataset, this question was coded as “Policies are not specified.”
- Where no policies were required, this question was coded as “Policies are not specified.”
- Quality improvement or quality assessment programs were coded as “Quality assurance.”
• Emergency or natural disaster preparedness programs were coded as “Disaster preparation.”
• Functional and/or routine maintenance of equipment was coded as “Preventative maintenance.”
• Policies related to sterilization of infectious waste were coded as “Infection control.”

**Question:** “Do physicians need additional qualifications beyond state licensing, training and experience?”
- This question was coded “yes” where requirements for hospital staff privileges, board certification and/or specific residency training were imposed on physicians performing OBS.

**Question:** “What additional qualifications are required?”
- This question was coded where requirements for hospital staff privileges, board certification and/or specific residency training were imposed on physicians performing OBS.
- Where proof of competency could be met through more than one option, i.e. either hospital staff privileges or board certification, the answer choice “Proof of competency by one of multiple options” was coded and specific requirements were captured in a caution note.
- Advanced cardiac lifesaving training was not considered a certification or training that was within scope.

**Question:** “Are specific levels of nursing staff required to perform specified functions in the facility?”
- Regulations related to nursing staff were coded only when specific levels of nursing staff were required, rather than permitted, to perform certain functions.
- Nursing staff requirements specific to certified nurse anesthetists and/or the administration of anesthesia were not coded.

**Question:** “Are there any requirements related to transferring a patient to a hospital?”
- This question was coded “Yes” where the law imposed requirements related to transfer agreements, transfer plans or protocols, and/or hospital admitting privileges on facilities.

**Question:** “What type of relationship, if any, is the facility, required to have related to patient hospital transfers?” (Text response)
- Details of requirements related to transfer agreements, transfer plans or protocols, and/or hospital admitting privileges were coded in the text box.

**Question:** “What type of relationship, if any, is the facility required to have related to patient hospital transfers?”
- Requirements to have an “arrangement” related to hospital transfers were coded as “transfer agreements.”
• Requirements to have a “written agreement” related to hospital transfers were coded as “transfer agreements.”
• Requirements to “arrange” a transfer were coded as “Plan/protocol.”
• Selecting more than one answer choice indicates that all of the selected requirements apply.

Question: “Has the law been held unenforceable in whole or in part?”
• This question was coded “Yes” where there was a relevant court opinion or attorney general opinion affecting the enforceability of one or more of the requirements coded.

Question: “Has the law been limited by a court decision?”
• This question was coded “yes” where there was a relevant court opinion affecting the enforceability of one or more of the requirements coded.
• A brief summary of the opinion’s ruling, including which provisions were affected by the ruling, were captured in a caution note.
• Where related court opinions were not in scope of the dataset, this question was coded as “No.”

Question: “Has the law been limited by an attorney general opinion?”
• All jurisdictions were coded “No” for this question.
• This question would have been coded “Yes” if there was a relevant attorney general opinion affecting the enforceability of one or more of the requirements coded.

V. Quality Control

a. Quality Control – Background Research: All 51 jurisdictions were 100% redundantly researched to confirm that all relevant laws were collected by the Researchers. The Researchers consulted a combination of secondary sources to verify whether states had OBS regulations within scope of the dataset.

i. The research produced the following breakdown regarding the presence of OBS requirements across all jurisdictions:
1. Twenty-five (25) jurisdictions have OBS requirements that carry the weight of law (AL, AR, AZ, CA, CT, DC, DE, FL, IL, IN, KS, LA, MS, NJ, NV, NY, OH, OR, PA, RI, SC, TN, TX, VA, WA).
2. Seven (7) jurisdictions have guidelines that do not carry the weight of law (AK, CO, GA, KY, MA, NC, OK).
3. One (1) jurisdiction has OSP requirements but no general OBS laws (MD).
4. Eighteen (18) jurisdictions have no OBS or OSP requirements or guidelines within scope (HI, IA, ID, ME, MI, MN, MO, MT, ND, NE, NH, NM, SD, UT, VT, WI, WV, WY).

b. Quality Control – Original Coding: Quality control of the original coding consisted of the Supervisor exporting the data into a Microsoft Excel document each day the
Researchers completed coding to examine the data for any missing responses, citations, and caution notes.

c. **Quality Control – Redundant Coding**: The redundant coding process includes independent coding of each jurisdiction by two Researchers.

Quality control of the redundant coding consisted of the Supervisor exporting the data into a Microsoft Excel document each day the Researchers completed redundant coding to calculate divergence rates. 100% of the records were redundantly coded throughout the life of the project.

25 states had OBS regulations that were in scope. After coding the first ten OBS jurisdictions, the rate of divergence was 15.9% on February 21, 2017. A coding review meeting was held and all divergences were resolved. Divergences (discrepancies in the original coding and redundant coding) are resolved through consultation and discussion with subject matter experts and the Supervisor. Questions that were causing confusion were edited for clarity. The Supervisor assigned the next 18 OBS jurisdictions for redundant coding and the rate of divergence dropped to 9.2%. Again, a coding review meeting was held and all divergences were resolved.

In April 2017, the scope of the dataset was expanded to include laws that impose additional legal requirements on office-based facilities or clinics where specific outpatient procedures within the general practice of medicine are performed (OSP). After finding that one jurisdiction (MD) was within the scope of OSP, the relevant law was collected and coded. After the Researchers coded the new state record, the Supervisor assigned MD to be redundantly coded. The divergence rate for MD was 13.3% on May 16, 2017. The Team met to discuss all divergences and resolved each one individually. The Supervisor deleted the redundant coding records and did a final check of the data.

| Table 1. Coding Quality Control |
|-------------------------------|------------------|------------------|
| **Dataset** | **Batch** | **Divergence Rate** |
| OBS laws | 1 (10 states) | 15.9% |
| | 2 (18 states) | 9.2% |
| Other specific procedure laws | 1 (1 state) | 13.3% |

Note. The number of states that were redundantly coded may be greater than the total number of states included in the final dataset, as state was later excluded.

d. **Quality Control – Post-Production Statistical Quality Control (SQC)**: As part of the policy surveillance process, the Supervisor typically runs SQC after all original and redundant coding is completed to assess the overall error rate of the dataset. However, the Team did not perform SQC for this dataset due to the fact that this dataset was redundantly coded at 100% redundancy and the subject matter expert checked each coded variable.

e. **Quality Control – Final Data Check**: The Team completed a final check against the secondary sources listed above (III.(d)). Any divergences between our coding and the secondary sources were discussed and resolved as a Team. Prior to publication, the
Supervisor downloaded all coding data into Microsoft Excel to do a final review of coded responses, statutory and regulatory citations, and caution notes. Unnecessary caution notes were deleted, and all necessary caution notes were edited for publication.