State of California—Health and Human Services Agency
California Department of Public Health

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Review of Federal Certification Standards as a Basis for State Licensing Standards for Ambulatory Surgery Clinics, Comprehensive Outpatient Rehabilitation Facilities, and End-Stage Renal Disease Facilities (Senate Bill 534)

Report to the Legislature

June 2017

Licensing & Certification Program
Center for Health Care Quality
California Department of Public Health

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Executive Summary

Section 1225(e) of the California Health & Safety Code (as amended by California Senate Bill 534, statutes of 2013-2014) called for a report that "describes the extent to which federal certification standards are or are not sufficient as a basis for state licensing standards. The report shall make recommendations for any California-specific standards that may be necessary." This report focuses on ambulatory surgery centers (ASCs), comprehensive outpatient rehabilitation facilities (CORFs), and end-stage renal disease (ESRD) facilities. Currently, the California Department of Public Health (CDPH) uses federal Centers for Medicare and Medicaid Services (CMS) certification standards as the sole basis for state licensing of these facilities.

CDPH contracted with the Institute for Population Health Improvement (IPHI) at the University of California, Davis to evaluate whether California's use of the federal standards constitutes adequate oversight for ASCs, CORFs, and ESRD facilities, and whether additional standards may be advised to fill in gaps. IPHI's evaluation focused on two questions: 1) what regulations are other states using to oversee these facilities, and 2) what are the known quality issues – defined broadly as concerns related to safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity?

IPHI examined state-specific regulatory language that differed from federal certification standards. No single, quality-related topic was repeatedly addressed in other states. Quality concerns identified in other states and in the literature frequently cited compliance problems with existing regulations instead of calling for expanded regulations.

IPHI's report, entitled "A Review of Regulatory Standards, Quality of Care Concerns, and Oversight of Ambulatory Surgery Clinics, Comprehensive Outpatient Rehabilitation Facilities, and End-Stage Renal Disease Facilities" (Appendix A), concludes:

- California's use of CMS certification standards as the basis for state licensure is consistent with standard practice across the nation;
- California differs from some other states in not requiring accreditation for some ASCs (i.e., California requires accreditation only for those that provide higher levels of sedation) or for CORFs, and in the requirements for specific types of facilities and services, such as for adverse event reporting;
- Better compliance with existing federal regulations would likely address many of the documented quality problems that CDPH has cited in these facilities; and
- Based on information reviewed, expanded state-specific regulations for ASCs, CORFs, and ESRD facilities would be of uncertain marginal value. (pp. 1-2).

CDPH posted the IPHI report on the CDPH Center for Health Care Quality (CHCQ) Stakeholder Forum website, presented the report and accepted public comment at the

CHCQ Stakeholder Forum on September 8, 2016, and continued to accept comments on the report via CHCQ's stakeholder mailbox through September 30, 2016.
CDPH concurs with the IPHI report's conclusions and recommends that state licensing of ASCs, CORFs, and ESRD facilities continue to rely solely on federal certification standards.

Purpose

This report summarizes the California Department of Public Health's (CDPH) findings from the evaluation of whether California's use of federal standards is sufficient as a basis for state licensing standards for ambulatory surgery centers (ASCs), comprehensive outpatient rehabilitation facilities (CORFs), and end-stage renal disease (ESRD) facilities. Currently, CDPH uses federal Centers for Medicare and Medicaid Services (CMS) certification standards as the sole basis for state licensing of these facilities. This evaluation was authorized by section 1225(e) of the California Health & Safety Code (as amended by Senate Bill 534, Statutes of 2013-2014):

> …(e) The department shall, by July 1, 2017, conduct at least one public hearing and submit a report to the appropriate legislative committees that describes the extent to which the federal certification standards are or are not sufficient as a basis for state licensing standards. The report shall make recommendations for any California-specific standards that may be necessary.

Background

CDPH is the state agency in California responsible for health facility licensing and certification, including ASCs, CORFs, and ESRD facilities. CDPH licenses these facilities using standards established by CMS for Medicare and Medicaid certification purposes. In other settings, however, CDPH licensing standards are more expansive than federal certification regulations. Given the volume of ambulatory care that Californians receive and concerns about potential quality issues, the Legislature required CDPH to report on whether the federal certification standards for ASCs, CORFs, and ESRD facilities are sufficient as a basis for state licensure.

CDPH contracted with the Institute for Population Health Improvement (IPHI) at the University of California, Davis to evaluate:

> Is California's use of federal standards sufficient as a basis for state licensing standards for ASCs, CORFs, and ESRD facilities, or are additional standards needed to fill regulatory gaps?

IPHI's evaluation focused on two questions:

1) Current regulations. *What standards and regulations are currently in place to regulate quality of care in ASCs, CORFs, and ESRD facilities?*

2) Quality issues. *What quality problems have been documented in these care settings?*

The IPHI report is attached as Appendix A and is available on CDPH's website at:

http://www.cdph.ca.gov/programs/Documents/Review-of-Regulatory-Standards.pdf

Review of Regulatory Standards and Quality of Care Concerns

Regulatory Standards

The IPHI report notes that healthcare facilities must meet federal certification requirements to participate in and receive payment from Medicare and Medicaid. IPHI additionally notes that:

> …federal standards establish a uniform, national regulatory framework, and state agencies survey facilities for compliance with certification requirements on behalf of CMS. States may also use the federal standards as the basis for state licensing, although states may have different standards for licensure. (p. 5)

IPHI examined licensing regulations in all 50 states, including a discussion of states' regulatory and rulemaking authority, facility definitions, and state licensure requirements, and noted state-specific regulatory requirements for licensing that extended beyond federal certification standards. IPHI also examined accreditation standards and compared them with CMS requirements. IPHI found that:

- No single, quality-related topic was repeatedly addressed in other states; (p. 1)
- Some accreditation standards were more detailed than CMS standards, or covered additional topics, but that it was not clear whether these differences impacted the quality of care in healthcare facilities; (p. 22)
- California's use of CMS certification standards as the basis for state licensure is consistent with standard practice across the nation; and,
- California differs from some other states in not requiring accreditation for some ASCs (i.e., California requires accreditation only for those that provide higher levels of sedation) or for CORFs, and in the requirements for specific types of facilities and services, such as for adverse event reporting. (p. 36)

Quality of Care Concerns

IPHI's report notes:

> Government oversight of healthcare facilities generally aims to ensure that patient care meets minimally acceptable standards for quality of care through diverse means, including licensure, operating standards, regulations, accreditation, public reporting of performance, and financial mechanisms (e.g., pay for performance). (p. 23)

IPHI assessed whether regulatory gaps in quality of care oversight for ASCs, CORFs, and ESRD facilities existed in six domains of healthcare quality: safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity. IPHI reviewed literature regarding quality concerns, and analyzed CDPH complaint/survey findings.
IPHI found that:

- Quality concerns identified in other states and in the literature frequently cited compliance problems with existing regulations instead of calling for expanded regulations; (p. 1)
- Quality of care issues were the most common substantiated allegations in CDPH's ASC and ESRD facility surveys; CORFs has few allegations (less than an average of 1 a year); (p. 33)
- Between September, 2005 – September, 2015, L&C surveys identified:
  - 16,592 deficiencies in 564 ASCs; the majority (73%) were federal deficiencies and commonly involved drug administration or infection-related measures;
  - 9,591 deficiencies in 537 ESRD facilities; the majority (98%) were federal deficiencies and commonly involved infection control and prevention and clinically pertinent topics such as the appropriateness of dialysis treatment; and,
  - 2,272 deficiencies in 122 CORFs; the majority (98%) were state deficiencies such as non-compliance with policies pertaining to patient care or personnel; (p. 33) and
- Better facility compliance with existing federal regulations would likely address many of the documented quality problems that CDPH has cited. (p. 37)

IPHI concluded that: "Based on information reviewed, expanded state-specific regulations for ASCs, CORFs, and ESRD facilities would be of uncertain marginal value." (p. 37).

Public Hearing

Senate Bill 534 requires that by July 1, 2017, CDPH conduct at least one public hearing and submit a report to the appropriate legislative committees that describes the extent to which the federal certification standards are or are not sufficient as a basis for state licensing standards.

CDPH posted the IPHI report on the CDPH Center for Health Care Quality (CHCQ) Stakeholder Forum website, presented the report and accepted public comment at the CHCQ Stakeholder Forum on September 8, 2016, and continued to accept comments on the report via CHCQ's stakeholder mailbox StakeholderForum@cdph.ca.gov through September 30, 2016.

The Medical Board of California and the California Ambulatory Surgery Association (CASA) provided feedback supporting the IPHI report conclusions and the continued

use of ASC federal certification standards as the basis for ASC licensure in California. CDPH did not receive any comments from stakeholders on CORF or ESRD licensing standards.

Recommendation

CDPH concurs with the IPHI report's conclusions and recommends that state licensing of ASCs, CORFs, and ESRD facilities continue to rely solely on federal certification standards.

A Review of Regulatory Standards, Quality of Care Concerns, and Oversight of Ambulatory Surgery Clinics, Comprehensive Outpatient Rehabilitation Facilities, and End-Stage Renal Disease Facilities

June 2017

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Summary

This study was conducted at the request of the California Department of Public Health (CDPH), which was directed by Section 1225(e) of the California Health & Safety Code (as amended by California Senate Bill 534, statutes of 2013-2014) to submit a report that "***describes the extent to which federal certification standards are or are not sufficient as a basis for state licensing standards," and if not, what California-specific standards may be necessary.*** Section 1225(e) specifically focuses on this question with regard to ambulatory surgery clinic (ASC), comprehensive outpatient rehabilitation facility (CORF), and end-stage renal disease (ESRD) facilities. Currently, CDPH uses federal Centers for Medicare and Medicaid Services (CMS) certification standards as the sole basis for state licensing of these facilities.

To inform CDPH about this issue, the Institute for Population Health Improvement (IPHI) at the University of California Davis was asked to address two primary questions: ***1) what regulations are other states using to oversee these facilities,*** and ***2) what are the known quality issues – defined broadly as concerns related to safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity***? Taken together, the answers to these questions provide dual perspectives on whether California's use of the federal standards constitutes adequate oversight, and whether additional standards may be advised to fill in gaps. We undertook comprehensive, systematic reviews to identify information to answer these questions, and our findings are detailed in this report.

We identified a diverse assortment of regulatory language in other states which differed from federal certification standards. By and large, however, these differences were primarily semantic or of relatively minor consequence. The most substantive differences across state regulations pertained to the conditions under which accreditation was required, definitions of facility types, and the scope of regulations that followed from those definitions. State-specific provisions covered topics ranging from the use of flammable anesthetics to minimum staffing levels. No single, quality-related topic was repeatedly addressed in other states. Quality concerns identified in other states and in the literature frequently cited compliance problems with existing regulations instead of calling for expanded regulations. Deficiencies found through CDPH compliance surveys are consistent with this observation.

In summary, we conclude that:

- California's use of CMS certification standards as the basis for state licensure is consistent with standard practice across the nation;
- California differs from some other states in not requiring accreditation for some ASCs (i.e., California requires accreditation only for those that provide higher levels of sedation) or for CORFs, and in the requirements for specific types of facilities and services, such as for adverse event reporting;

- Better compliance with existing federal regulations would likely address many of the documented quality problems that CDPH has cited in these facilities; and
- Based on information reviewed, expanded state-specific regulations for ASC, CORF, and ESRD facilities would be of uncertain marginal value.
- Future consideration of the need for expanded regulatory oversight of ASC, CORF and ESRD facilities should be based on a more detailed, evidence-based understanding of quality problems in these facilities and how regulations would specifically address the root causes of such problems.

Acronyms

AAAASF	American Association for Accreditation of Ambulatory Surgery Facilities
AAAHC	Accreditation Association for Ambulatory Health Care
ASC	Ambulatory surgery clinic
CARF	Commission on Accreditation of Rehabilitation Facilities
CDPH	California Department of Public Health
CFR	Code of Federal Regulations
CMS	Centers for Medicare and Medicaid Services
CORF	Comprehensive outpatient rehabilitation facility
ESRD	End-stage renal disease
GAO	Government Accountability Organization
HFAP	Healthcare Facilities Accreditation Program
IPHI	Institute for Population Health Improvement
L&C	Licensing & Certification Program
OIG	Office of Inspector General

I. Background

Regulatory oversight of health care delivered in ambulatory settings is generally less rigorous than for inpatient settings because of the typically lower risk of outpatient care. Nonetheless, serious quality of care problems may occur in ambulatory settings. Relatively little is known about such problems.

The California Department of Public Health (CDPH) is the state agency in California responsible for health facility licensing and certification, including for ambulatory surgery clinics (ASC, also known as 'surgical clinics'), comprehensive outpatient rehabilitation facilities (CORF, also known as 'rehabilitation clinics'), and end-stage renal disease (ESRD) facilities (also known as 'dialysis clinics'). CDPH *licenses* these facilities using standards established by the Centers for Medicare and Medicaid Services (CMS) for federal Medicare certification purposes [Conditions for Coverage and Conditions for Participation, as documented in Title 42 of the Code of Federal Regulations (CFR)], and it also performs federal *certification*.[1]

Currently, CDPH uses the CMS certification standards as the sole basis for state licensing of ASC, CORF, and ESRD facilities, with no additional state standards. In other settings, however, CDPH licensing standards are more expansive than federal certification regulations. Given the volume of ambulatory care that Californians receive and concerns about potential quality issues, the California Senate Health Committee called for CDPH to report on whether the federal certification standards used for licensing ASC, CORF, and ESRD facilities are adequate.

Section 1225(e), Health & Safety Code (as amended by Senate Bill 534, statutes of 2013-2014) calls for a report that: 1) describes the extent to which the federal certification standards are or are not sufficient as a basis for state licensing standards, and 2) make recommendations for any California-specific standards that may be necessary.[2] The CDPH Center for Health Care Quality, Licensing & Certification Program (L&C), contracted with the Institute for Population Health Improvement (IPHI) at the University of California Davis to conduct a study and write a report. This report addresses the Section 1225(e) requirements by answering three study questions:

1) **Current regulations**. What standards and regulations are currently in place to regulate quality of care for ASC, CORF, and ESRD facilities?

2) **Quality issues**. What quality problems have been documented in these care settings?

[1] U.S. Office of the Federal Register, National Archives and Records Administration. (2015). Electronic Code of Federal Regulations, Title 42 - Public Health.
[2] Section 1225(e), California Health & Safety Code amended subsequent to Senate Bill No. 534 (statutes of 2013-2014). Retrieved from the Legislative Information database at http://www.leginfo.gov

3) **Regulatory opportunities**. Given the current regulations and quality concerns regarding ASC, CORF, and ESRD facilities, should any additional, California-specific standards be considered?

This report addresses these questions; detailed appendices are provided for reference.

- *Chapter II, Licensing Standards: 50 State Review*, describes the standards used in all states and compares them to California standards and federal regulations.
- *Chapter III, Accreditation Standards*, discusses accreditation standards that may be used for state licensure and/or certification, highlighting differences with the federal regulations.
- *Chapter IV, Quality Issues in ASC, CORF, and ESRD Facilities*, outlines quality concerns identified through a systematic literature review which examined quality based on the six domains of safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity. It also provides a snapshot of the quality issues that have been documented in California facilities via L&C surveys for the past 10 years.
- *Chapter V, Conclusions*, outlines our conclusions to the three study questions, based on findings described in Chapters II-IV.

This report focuses primarily on issues that are under CDPH's licensing and certification oversight authority. Notably, some outpatient healthcare settings fall outside of CDPH oversight, including physician-owned ASCs, which are the responsibility of the Medical Board of California. In these cases, patients receiving the same outpatient procedures may be doing so in facilities that have materially different regulatory oversight requirements. Another recent report describes the regulatory patchwork that characterizes ambulatory surgical procedures in particular.[3] Although such regulatory inconsistencies may be cause for concern, they are beyond the scope of this study.

[3] B & R Klutz Consulting. (2015). *Outpatient surgery services in California: Oversight, transparency, and quality.* Retrieved from http://www.chcf.org/publications/2015/07/limited-visibility-outpatient-surgery

II. Licensing Standards: 50 State Review

Healthcare facilities must meet federal certification requirements to participate in and receive payment from Medicare. The federal standards establish a uniform, national regulatory framework, and state agencies survey facilities for compliance with certification requirements on behalf of CMS. States may also use the federal standards as the basis for state licensing, although states may have different standards for licensure. This chapter outlines the state-specific regulatory requirements for licensing which extend beyond federal certification requirements. It identifies licensing regulations in all 50 states, including a discussion of states' regulatory and rulemaking authority, facility definitions, and state licensure requirements in comparison to California.

Methods

To identify the licensing standards pertaining to ASC, CORF, and ESRD facilities in all 50 states, we used a multi-faceted search strategy and consulted with a reference librarian to validate our strategy. Although some law and policy-focused databases are available to facilitate the search for regulations (e.g., Lexis-Nexis), the reference librarian cautioned us that such sources may be outdated, inconsistent across states, or inaccurate given the complexity of information governing health facilities regulations.

Accordingly, we drew primarily from internet-based information found on state health department and legislative websites to capture the most complete and up-to-date information. We initially reviewed the state health department's website and followed it to related sites, such as the state's general website or legislative database, in order to find where the state's licensing standards for ASC, CORF, and ESRD facilities were memorialized. We conducted this search between November 2014 and February 2015, and updated it in August 2015.

We used several other sources to validate search results against the reviews of state licensing regulations for ASC, CORF, and ESRD facilities. We reviewed an online legal research service (Westlaw) and general health law/policy sources (e.g., National Conference of State Legislatures policy database). We conducted targeted review and selective outreach to industry associations representing ASC, CORF, and ESRD facilities. We also drew upon work by the Accreditation Association for Ambulatory Health Care (AAAHC)[4] to fill in gaps, when information from state websites was lacking for ASCs.

For each state, we summarized information that described the: 1) regulatory agency overseeing licensing and/or certification, 2) rulemaking authority defined in state law or administrative rules, 3) facility definitions, focusing on differences between CMS and state definitions, 4) state licensure requirements (yes or no, indicating "no" for states for which we could not find any

[4] Accreditation Association for Ambulatory Health Care. (2015). Retrieved from http://www.aaahc.org/

information about licensure requirements), 5) additional state licensure requirements which were not addressed in a section of the CMS standards, and 6) additional detail contained in state standards for licensure which expanded upon language in the CFR (i.e., potentially establishing stricter state compliance requirements due to greater specificity). For the additional state standards in item six, we reviewed the CMS requirements to determine whether there were meaningful differences, erring on the side of inclusion, and we compared these additional standards to the relevant CFR section. When the CMS rules generally referred to state standards (e.g., requiring compliance with the respective state's occupational health and safety codes), we did not mark this as a "different" or new standard. Tables A1-A3 (Appendix A) detail this information for ASC, CORF, and ESRD facilities, respectively.

Definitions of ASC, CORF, and ESRD facilities vary across states. A common distinction was whether facilities were licensed as part of a general acute care hospital, or facilities that provide inpatient care lasting more than 24 hours. To be consistent with California's licensing requirements, which include these services under hospital-based licensing rules, we excluded these from the search in order to align our review with California's definition of ASC, CORF, and ESRD facilities to the extent possible**.** In anticipation of variation in facility definition, we used the following keywords to identify on state websites the health facility types of interest:

Ambulatory Surgery Clinic

- ambulatory surgery center, ambulatory surgical center, ambulatory surgical facility, ambulatory surgical treatment center, day surgery center, freestanding ambulatory surgical center, freestanding surgical clinic, freestanding surgical outpatient facility, health clinic, outpatient hospital, outpatient surgery center, outpatient surgical center, outpatient surgery facility, surgical clinic, surgicenter

Comprehensive Outpatient Rehabilitation Facility

- ambulatory care facility, health facility, general outpatient treatment center, non-residential facility, outpatient facility, outpatient physical therapy center, rehabilitation center, rehabilitation clinic

End-Stage Renal Disease Facility

- ambulatory dialysis, dialysis clinic, freestanding dialysis center, dialysis facility, free-standing dialysis facility for renal disease, free-standing specialty clinic, health clinic, hemodialysis, kidney center, kidney dialysis center, kidney dialysis unit, out-of-hospital dialysis unit, out-of-hospital out-patient dialysis unit, outpatient facility

We vetted our initial findings from this review with L&C staff, producing an interim report in July 2015. This report supersedes the interim report. Findings were updated following further review and analysis of the additional state standards that we identified in the interim report; some

of the differences that we initially identified were primarily semantic and did not effectively introduce any new regulations that extended beyond federal certification rules.

Results

Ambulatory Surgery Clinics

Federal certification standards for ASCs are outlined in 42 CFR Part 416 and described further in CMS' State Operations Manual, Appendix L.[5] They address 12 general areas, each with specific standards or requirements:

- Governing body and management
- Surgical services
- Quality assessment and performance improvement
- Environment
- Medical staff
- Nursing services
- Medical records
- Pharmaceutical services
- Laboratory and radiologic services
- Patient rights
- Infection control
- Patient admission, assessment and discharge

Table A1 (Appendix A) details the regulatory and rulemaking authority, facility definition, state licensure requirements, and additional state licensure standards beyond the federal ones for ASCs. A synopsis of the differences between California and other states for each of these subtopics follows.

Regulatory and rulemaking authority. The agency responsible for enforcing health facility licensing regulations and conducting surveys and inspections in most states is the department of health (or public health). Exceptions are Washington, DC, where the mayor's office has this role; the Agency for Health Care Administration in Florida; and the Health Authority in Oregon. As in California, some other states direct oversight for physician-owned ASCs to medical professional bodies. The New Jersey Board of Medical Examiners regulates private physician practices that have only one operating room. All but Idaho, Iowa, and Wisconsin have statutes in their respective administrative codes and legislative documents that describe minimum standards that must be met, as well as general rules for health facilities; we were unable to find such information for these three states.

[5] CMS Survey and Certification - Guidance to Laws & Regulations, Ambulatory Surgery Centers. (2012). Retrieved from www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/ASCs.html

Definition and exclusions. CMS defines ASCs as, "any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission."[6] California defines an ASC as one that is not part of a hospital and provides care for patients who stay less than 24 hours." California's specification of ASCs as being separate from hospitals, in contrast to whether the service may require hospitalization, is a notable distinction from the federal definition.

Other states' definitions of ASCs vary considerably. Most, but not all, specify that services should be outpatient, not requiring hospitalization, or provide care for less than 24 hours. Many states also note that ASCs should be freestanding facilities that are not part of a hospital facility, as with California, although a notable number do not include this requirement. Some states define specific services that are included (e.g., abortions, endoscopic procedures, pain management) or excluded in the ASC definition, although California does not. Not included as ASCs in many states are independent medical doctor, podiatrist, and dentist offices; facilities belonging to a licensed hospital; and federally owned institutions.

Additional state licensure requirements not addressed in federal standards. All states except Idaho, Vermont, and Wisconsin require state licensure, although we could not find information about whether Iowa required licensure. New Jersey requires licensure only for facilities with more than one operating room. Pennsylvania allows Class A ASCs (those which are limited to local and topical anesthesia) to be accredited but not licensed. In California, surgical clinics that are owned wholly or in part by physicians are regulated solely by the Medical Board of California. As a condition of licensure, two states (Maryland and Michigan) specifically cited federal CMS certification as a requirement. Seven states also noted that accreditation is required, with some of those states (including California) requiring accreditation only when higher levels of anesthesia (i.e., more than local and topical anesthesia) are provided.

States largely refer to CMS requirements, but 32 of the 46 states requiring licensure have additional language in their licensure provisions which address topics not covered under the CMS standards. Many of these detail specific operational requirements and restrictions. Directives for facility accreditation are also commonly found in state administrative codes. California, for instance, requires accreditation for certain unlicensed ASCs (i.e., physician-owned) when higher levels of anesthesia are provided. Examples of state-specific licensure requirements that are not linked to a section of the CMS standards are:

- **Accreditation.** Accreditation is encouraged or required, depending on various conditions such as the level of anesthesia provided (multiple states).

[6] Public Health. 42 CFR §416.2 (2015).

- **Clinical.** The use of flammable anesthetics is prohibited (Colorado, New Mexico); facilities must establish a protocol for organ donation (Virginia); a short stay record form must be used (Indiana); must have a current agreement with a blood bank (Massachusetts); examination and treatment rooms must meet minimum standards and an emergency communication connection with the surgical control station is required (New Mexico); drug administration and blood transfusion must comply with state law (North Dakota).

- **Operations.** Proof of compliance with the state fire code is needed (New Hampshire); environmental pollution control considerations must be in place (Oklahoma); smoking is not permitted (Rhode Island); no smoking signs must be posted (Tennessee); electrical work complies with state laws (Georgia); zoning requirements apply (Maine); specific signage must be visible if abortions are performed in the facility (Ohio); license is issued for specified bed size/rooms (Rhode Island, Florida); live animals are not permitted (South Carolina); extended recovery care services are not permitted for more than four patients between 10 pm and 6 am (Wyoming).

- **Food services.** A food safety system must be in place (Alabama); the food and nutrition services supervisor must be a certified dietary manager (Arkansas); a consulting dietician shall oversee special dietary needs (Hawaii); food served must be approved by the health licensing division (South Carolina); a food service establishment permit is required (Utah); nutritional services must be provided (Delaware).

- **Employee policies.** Those affiliated with the clinic must be vaccinated against influenza (Massachusetts); employees in patient care areas must wear identification badges (Maine); every position shall have a written description of job duties (Mississippi); pre-employment criminal background and registry checks are required on unlicensed staff (Nebraska); annual in-service training for nurses is needed (Oregon).

- **Staffing.** Must provide at least one physician licensed to practice in the state (Virginia).

Additional state detail for existing federal standards. Seven states have expanded upon existing CMS Conditions for Coverage. Generally, these differences address staffing and documentation issues. The additional state licensure standards for ASCs, organized by relevant section of the CFR, are:

§416.41. Governing body and management

- Alabama - A copy of the governing body meeting minutes must be kept as a permanent record of the facility.
- Delaware - A governing body with full-time director must be in place.

- Florida - A detailed emergency management plan is outlined in the administrative code.

§416.45. Medical staff

- New Jersey - The facility shall establish and implement written policies and procedures concerning the identification of the need for counseling services and referral to counseling services.

§416.46. Nursing services

- Alabama - The Director of Nursing must be a licensed graduate of a professional nursing school with one or more years of experience in surgical/recovery nursing.

§416.50. Patient rights

- Florida - A facility must notify each patient during admission and at discharge of his or her right to receive an itemized bill upon request.

§416.52. Patient admission, assessment and discharge

- Arkansas - The extended stay area must be staffed by at least two caregivers, one of whom must be a registered nurse.
- North Carolina - A post-anesthesia note containing the general condition of the patient and any instructions to the patient must be written prior to discharge.
- Utah - The physician must document the reason for admission to an extended recovery service and dietary orders.

Comprehensive Outpatient Rehabilitation Facilities

Federal certification standards for CORFs are outlined in 42 CFR and described further in CMS' State Operations Manual, Appendix K.[7] CMS certification standards address six general areas:

- Governing body and administration
- Comprehensive rehabilitation program
- Clinical records
- Physical environment
- Disaster procedures
- Utilization review plan

[7] CMS Survey and Certification - Guidance to Laws & Regulations, Comprehensive Outpatient Rehabilitation Facilities. Retrieved from http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/CORF.html

Table A2 (Appendix A) details the regulatory and rulemaking authority, facility definition, state licensure requirements, and additional state licensure standards beyond the federal ones for CORFs. The primary differences between California and other states for each of these six areas are noted below.

Regulatory and rulemaking authority. The regulatory agency overseeing CORF licensing is similar to that of ASCs, although we could not find policies or regulations outlining CORF regulations for 40 states and the District of Columbia. In contrast to ASCs, the Medical Board has no responsibility for overseeing CORFs in California.

All states but Idaho, Iowa, and Wisconsin describe minimum standards that must be met, as well as general rules for health facilities; we were unable to find such information for these three states.

Definition and exclusions. CMS defines a CORF as a "nonresidential facility established and operated for the purpose of providing therapeutic and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons at a single fixed location and by a physician/under physician supervision."[8] California defines a CORF as "a clinic that, in addition to providing medical services directly, also provides physical rehabilitation services for patients who remain less than 24 hours." It additionally specifies that at least two of the following rehabilitation services must be provided: physical therapy; occupational therapy; or social, speech pathology, and audiology services. It also notes that a CORF excludes the offices of a private physician in individual or group practice. California's definition is more specific than the federal one in the services included, and it excludes private physician offices. In other states, a CORF typically does not include certified home health agencies or the offices of a private physician in individual or group practice.

Most states do not specifically define a CORF, and when they do, it closely mirrors the CMS definition. Ten states offer additional details about exclusions and services provided. In the definitions for Alabama, California, Georgia, Kentucky, Ohio, and Washington, physical therapy, occupational therapy, and speech pathology are specified as services provided; in Georgia and Ohio these services may be provided off-site. Wyoming also includes therapy for persons with brain injury in its definition. Mississippi, New Jersey, and Pennsylvania further stipulate that social or psychological services must be provided in a coordinated manner.

[8] Public Health. 42 CFR §485.51 (2015).

Additional state licensure requirements not addressed in federal standards. The majority of states either do not require licensing of CORFs or their websites do not contain information on state-specific CORF regulations. We found such information in only seven states (Alabama, Arizona, California, Kentucky, Maryland, New Jersey, and Wyoming).

Three states specify that CMS certification is required (Louisiana, Missouri, and Oklahoma); CORFs in New Jersey are required to be certified or eligible for certification. Two states require accreditation (Maryland and Wyoming), although in Texas CORFs are not eligible for accreditation. Examples of state-specific licensure requirements that are not linked to a section of the CMS standards are:

- **Accreditation**. Accreditation by the Commission on Accreditation of Rehabilitation Facilities is required (Maryland); rehabilitation facilities providing services to adults with developmental disabilities must maintain accreditation (Wyoming).

- **Operations**. Requirements for communication systems and narcotic permits are outlined in the administrative code (Alabama); must keep records and make reports in accordance with Secretary requirements (Maryland); general construction rules for healthcare facilities apply (Montana, Nebraska, Utah).

Additional state detail for existing federal standards. Only two states (Alabama and Maryland) add to language in the CMS standards. Alabama's administrative code expands considerably on CMS standards, particularly regarding standards for the physical environment. It requires designated space for an admission office, a waiting room, and a janitorial closet, as well as written procedures detailing housekeeping and decontamination techniques. It also requires an emergency call system. Maryland mandates licensees to follow recordkeeping instructions prescribed by its Secretary of Health. The additional state licensure standards for CORFs, organized by relevant section of the CFR, are:

§ 485.60. Clinical records

- Maryland - Licensees must keep records and make reports in the manner and form as the Secretary shall prescribe and be open to inspection by the Secretary.

§ 485.62. Physical environment

- Alabama - Extensive guidelines for the provision of an admissions office, waiting room, and housekeeping, set forth in the state administrative code.

§ 485.64. Disaster procedures

- Alabama - There shall be an adequate number of telephones to summon help in case of fire or other emergency, and these shall be located so as to be quickly accessible from all parts of the building.

End-Stage Renal Disease Facilities

Federal certification standards for ESRD facilities are outlined in 42 CFR Part 494 and described further by the CMS Conditions of Participation.[9] The CMS standards cover 15 general areas, each with specific standards or requirements:

- Infection control
- Water and dialysate quality
- Reuse of hemodialyzers and bloodlines
- Physical environment
- Patients' rights
- Patient assessment
- Patient plan of care
- Care at home
- Quality assessment and performance improvement
- Special purpose renal dialysis facilities
- Laboratory services
- Personnel qualifications
- Responsibilities of the medical director
- Medical records
- Governance

Table A3 (Appendix A) details the regulatory and rulemaking authority, facility definitions and exclusions, state licensure requirements, and additional state licensure standards beyond the federal ones for ESRD facilities. The primary differences between California and other states for each of these 15 areas are noted below.

Regulatory and rulemaking authority. The agencies that enforce state regulations for ESRD facilities are the same as those for CORFs and ASCs. California law does not raise issues of physician ownership or Medical Board oversight for ESRD facilities, as it does with ASCs. Additional regulatory information regarding ESRD facilities is sparse.

[9] CMS Survey and Certification - Guidance to Laws & Regulations, Dialysis. Retrieved from http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Dialysis.html

Definition and exclusions. CMS defines an ESRD facility as "an entity that provides outpatient maintenance dialysis services, or home dialysis training and support services, or both. A dialysis facility may be an independent or hospital-based unit that includes a self-care dialysis unit that furnishes only self-dialysis services."[10] California defines an ESRD facility as "a free-standing specialty clinic, which provides less than 24-hour care for the treatment of patients with ESRD." The free-standing component of California's definition makes it more restrictive than the federal definition, which includes hospital-based dialysis.

While ESRD facilities are generally referred to as non-hospital-based facilities, outpatient renal dialysis facilities may be hospital-based clinics in Colorado, Iowa, Kentucky, Ohio, and Vermont.

Additional state licensure requirements not addressed in federal standards. The District of Columbia and 25 states (including California) have statutory licensing requirements for ESRD facilities. Licensing is not required in Oklahoma, but CMS certification is. We were unable to find information on licensing or certification for ESRD facilities in Alaska, Iowa, Michigan, Mississippi, Montana, New York, and North Dakota.

State licensure of ESRD facilities usually follows federal standards with no additional requirements. Two states and the District of Columbia specify additional licensing conditions; New Jersey is the only one with extensive additional requirements. State-specific licensure requirements not linked to a section of the CMS standards are:

- Colorado - Outpatient hemodialysis treatment of a non-ESRD patient is not permitted without referral for treatment from a board-certified or board-eligible nephrologist licensed in the state.
- District of Columbia - State standards and procedures cannot be less stringent than the guidelines in the Association for Advancement of Medical Instrumentation Recommended Practice or Centers for Disease Control and Prevention recommendations.
- New Jersey - Facilities must have transfer agreements with at least one CMS-certified hospital to provide inpatient dialysis and with one state-licensed renal transplantation program. Policies related to criteria for handling of aggressive patients and orientation of new patients are required. Patients are prohibited from bringing food into the facility.

Additional state detail for existing federal standards. Three states and the District of Columbia expand upon the CMS regulations. ESRD facilities have long been subject to substantial federal oversight; additional state regulation has been limited. State expansion of the CMS standards include:

[10] Public Health. 42 CFR §494.10 (2015).

§494.30. Infection control

- Massachusetts - The unit shall obtain blood from a blood bank immediately prior to its administration. All blood so obtained shall be identified, stored, handled and administered in accordance with 105 CMR 135.000: Use of Blood, Blood Components and Derivatives for the Purpose of Transfusion.
- Utah - Facilities must establish a written health surveillance and evaluation program for facility personnel (according to the Communicable Disease Rule, R386-702; Tuberculosis Control Rule, R388-804; and OSHA guidelines for blood-borne pathogens) that includes a health status exam.

§494.50. Reuse of hemodialyzers and bloodlines

- District of Columbia - Reuse of tubing or transducer protectors and reuse of hemodialyzer or dialyzer caps without express written consent of the patient are not permitted.

§494.60. Physical environment

- Massachusetts - A minimum of 110 square feet of floor space per station is required.
- New Jersey - Facilities must provide at least six dialysis stations and an emergency generator and water supply.

Data Limitations

State government websites and administrative codes may not always be kept current, may not completely capture all information about licensing requirements, or may not make all pertinent information readily available. During our review we found multiple sources of regulatory information within state websites, raising the possibility that the sources used for this report may not have been absolutely current and complete. Sometimes there was insufficient detail on policies and procedures to allow for definitive determination of requirements listed on state websites, particularly with regard to CORFs and ESRD facilities.

Adverse event reporting requirements were not typically described as part of the regulatory language pertaining to general licensure requirements, so we did not report on this, although some states require all licensed healthcare facilities to report on adverse events. Other state-based requirements documented separate from general healthcare licensure provisions, might have been missed in this review. A survey of state agencies responsible for overseeing ASC, CORF, and ESRD facilities would be helpful to validate the completeness and currency of our information, but this was beyond the scope of our work.

Conclusions

Overall, we did not find significant state licensing requirements addressing clinical quality or safety additional to CMS certification standards for ASC, CORF, and ESRD facilities. ASC and ESRD facilities were subject to additional licensing requirements in some states, though these primarily addressed facility operational matters. A few states addressed clinical practice issues in ASCs. Additional state ESRD facility standards were more clinically focused, though New Jersey was the only state that included a substantive set of state regulatory requirements for these facilities. We identified almost no additional state standards for CORFs. Variations in state administrative procedures, implementation guidance, or unpublished updates may introduce differences that were not readily apparent through the information we reviewed.

III. Accreditation Standards

Accreditation provides an alternative approach to external quality oversight for healthcare facilities. CMS grants certain accrediting organizations authority to *deem* a facility as meeting minimum standards. Currently, ASCs and CORFs are eligible for this process, but not ESRD facilities. Accredited facilities satisfy minimum CMS' certification requirements by virtue of their *deemed status.* Facilities may opt for accreditation instead of certification, and the accreditation process can include quality improvement support that the regulatory certification/licensure survey process typically does not. Some states require accreditation as a condition of licensure. A consideration of whether the current state regulatory provisions are adequate should consider accreditation standards, which may be used in lieu of federal certification standards. This chapter describes the various organizations that accredit ASC, CORF, and ESRD facilities, and it compares their respective standards with the CMS requirements.

Methods

To identify additional external quality oversight standards, we conducted targeted searches and consulted with industry experts on regulation in these settings. We first conducted Internet searches (between August and October 2015) to identify accreditation organizations for ASC, CORF, and ESRD facilities. We focused primarily on organizations that had deemed status from CMS, and sought resources that compared accreditation and certification standards (e.g., recent crosswalk comparisons done by professional groups, and examples of selected content from standards manuals – the full accreditation standard manuals were typically not available online).

Accreditation standards are usually lengthy, sometimes encompassing hundreds of pages and multiple manuals. A line-by-line comparison was not practical, and we did not obtain the full accreditation manuals if they were not readily available. Instead, we used selected examples to get a general sense of how CMS and accreditation standards may differ.

We met with staff from professional and industry groups that represent ASC, CORF, and ESRD facilities, and who have a strong working knowledge of regulations in those settings. These groups included the California Ambulatory Surgery Association and California Medical Association for ASCs and the Health Services Advisory Group (California ESRD Network 18) for ESRD facilities. While we also contacted DaVita Kidney Care, a major dialysis provider, we did not receive a response. No professional organizations specifically for CORFs were identified. CDPH's L&C subject matter expert staff provided interim feedback as well. We used these meetings to learn about the regulations and quality oversight processes, validate our understanding of accreditation issues, and identify relevant resources that compared accreditation and CMS standards.

Results

Ambulatory Surgery Clinics

Seven states require ASCs to obtain accreditation as a condition of state licensure: Delaware, Georgia, Nevada, North Carolina, Pennsylvania, and Rhode Island. Accreditation is required in California for physician-owned ASCs that use general anesthesia. There are four accreditation organizations with deemed status from CMS for ASCs.

American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF). AAAASF is one of the nation's largest accrediting organizations, accrediting more than 2,000 facilities nationwide. The AAAASF Medicare ASC Standards and Checklist[11] addresses:

- Basic mandates
- Operating room policy, environment, and procedures
- Recovery room environment, policy, and procedures
- General safety in the facility
- Intravenous fluids and medications
- Medical records
- Quality assessment / quality improvement
- Personnel
- Governance
- Anesthesia

The AAAASF standards contain the same general elements of the CMS requirements, but we found some examples where the accreditation standards were more detailed. For example, the AAAASF standard stipulates a minimum height and width for hallways, ramp requirements, and door opening sizes; the CMS standards do not include such specifications.

Accreditation Association for Ambulatory Health Care (AAAHC). AAAHC accredits a broader set of facilities than the AAAASF, including ASCs, community health centers, medical and dental group practices, medical homes, and managed care organizations. It is currently the predominant accreditation body for ASCs in California. It can grant ASCs deemed status. The seven core areas covered by its ASC accreditation standards are:

- Rights of patients
- Governance
- Administration
- Quality of care provided

[11] American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (2014). Medicare Standards and Checklist for Accreditation of Ambulatory Surgery Facilities. Retrieved from http://www.aaaasf.org/Surveyor/cms_web/PDF/FILES/ASC/PDFS/ASC/Standards.pdf

- Quality management and improvement
- Clinical records and health information
- Infection prevention and control and safety
- Facilities and environment

The AAAHC standards[12] are mostly identical to the CMS standards. Some AAAHC standards have more detailed or stringent requirements.[13] For example, the AAAHC requires emergency preparedness drills at least quarterly, compared to a minimum yearly requirement by CMS.

The Joint Commission. The Joint Commission has CMS recognition to provide deemed status and is the largest accrediting body for healthcare organizations overall, covering a range of ambulatory care settings (including ASCs and office-based surgery, imaging, urgent care), hospitals, laboratories, behavioral health facilities, home care, nursing facilities, and more. Hospitals that are accredited by The Joint Commission could have their outpatient surgical services covered under the hospital accreditation standards; here, we focus on standards that apply for accreditation as an ambulatory care facility. The Joint Commission ambulatory care standards address 14 general areas, including sentinel events which are applicable in multiple accreditation standards:[14,15]

- Environment of care
- Emergency management
- Human resources
- Infection prevention and control
- Information management
- Leadership
- Life safety
- Medication management
- National Patient Safety Goals
- Provision of care, treatment, and services
- Performance improvement
- Record of care, treatment, and services
- Rights and responsibilities of the individual
- Sentinel events

[12] Accreditation Association for Ambulatory Health Care. (2015). *Accreditation Handbook for Office-Based Surgery Including Review Guidelines.*
[13] Accreditation Association for Ambulatory Health Care. (2012). *2012 AAAHC/CMS Crosswalk*. Retrieved from https://www.aaahc.org/Global/2012/AAAHC-CMS/Crosswalks/7-16-12.pdf
[14] The Joint Commission. (2015). *Comprehensive Accreditation Manual for Ambulatory Care.* Retrieved from https://www.jcrinc.com/assets/1/14/CAC15_Sample_Pages.pdf
[15] Joint Commission. (2010). *Standards Sampler for Ambulatory Surgery Centers*. Retrieved from http://www.jointcommission.org/assets/1/18/ASC_Standards_Sampler.pdf

- Transplant safety
- Waived testing

We also found examples of some noteworthy differences between The Joint Commission and CMS standards. Whereas the CMS standards for peri-operative anesthesia monitoring refer generally to current clinical guidelines, the Joint Commission language requires ongoing monitoring for higher risk procedures or those with moderate to deep sedation or anesthesia, including continuous monitoring of the patient's oxygenation, ventilation, and circulation. Moreover, The Joint Commission standards address broader topics that are not covered in the CMS standards, including a specific set of National Patient Safety Goals, as well as detailed procedures for medication management.

American Osteopathic Association, Healthcare Facilities Accreditation Program (HFAP). Originally created to review services provided by osteopathic hospitals, HFAP also has deeming authority to accredit ASCs. Detailed information about the HFAP standards was not available.[16]

Comprehensive Outpatient Rehabilitation Facilities

Maryland and Wyoming are the only states which require accreditation for CORFs, and Texas is the only state where facilities are ineligible for accreditation. There are two accreditation organizations for CORFs.

The Joint Commission. CORFs that seek deemed status through Joint Commission accreditation are subject to the general ambulatory care accreditation standards which were discussed in the ASC section. Disease-specific care certification is also available for the following rehabilitation programs:[17]

- Amputee
- Brain injury
- Cardiac
- Hip fracture
- Intractable chronic pain
- Multiple sclerosis
- Oncology
- Orthopedic
- Parkinson's disease
- Pulmonary

[16] *Health Facilities Accreditation Program, Ambulatory Surgical Center Program*. (2015). Retrieved from http://www.hfap.org/AccreditationPrograms/amb_surgical.aspx
[17] The Joint Commission. (2015). *DSC Physical Medicine/Rehabilitation*. Retrieved from http://www.jointcommission.org/certification/dsc_physical_medicine_rehabilitation.aspx

- Spinal cord injury
- Stroke
- Traumatic brain injury

Each of these rehabilitation programs is associated with clinical practice guidelines specific to the care provided. Disease-specific care certification addresses the following categories:[18]

- Program management
- Delivering or facilitating clinical care
- Supporting self-management
- Clinical information management
- Performance measurement

Commission on Accreditation of Rehabilitation Facilities (CARF). CARF is an international accreditation organization whose programs cover medical and vision rehabilitation, behavioral health, aging services, child and youth services, opioid treatment, and others. CORFs may voluntarily seek accreditation through CARF,[19] though CARF does not have deemed status. Its accreditation standards include several program-specific standards (e.g., adult day services, assisted living, and case management) and specialty guidelines for dementia care and stroke rehabilitation. They also require common elements for the program/service structure. The bulk of the CARF standards are organized around a quality improvement framework, addressing:

- Leadership
- Governance
- Strategic planning
- Input from persons served and other stakeholders
- Legal requirements
- Financial planning and management
- Risk management
- Health and safety
- Human resources
- Technology
- Risks of persons served
- Accessibility
- Performance measurement and management
- Performance improvement

[18] Eickemeyer, D. (2015). *Part 1: Quick Steps to Certification: Disease-Specific Care Preparation.* Retrieved from http://www.jointcommission.org/assets/1/18/Quick_Steps_Webinar_10-01-2015_rev.pdf
[19] Commission on Accreditation of Rehabilitation Facilities. (2015). *2015 CCAC Standards Manual*. Retrieved from www.carf.org/WorkArea/DownloadAsset.aspx?id=23968

End-Stage Renal Disease Facility

We did not identify any states that required ESRD accreditation as a condition for licensure, including California. ESRD facilities may choose to be accredited through The Joint Commission's ambulatory care accreditation program (discussed previously) for the purpose of internal quality improvement. They may also participate in its Disease-Specific Care certification program, for ESRD care.

Data Limitations

Our evaluation of accreditation standards primarily drew from available online resources, including samples of specific standards, tables of contents for accreditation manuals, and informal documents (e.g., crosswalks, presentations) produced by other organizations that have done comparisons of the standards. These resources may provide only a high-level view of the standards, and they may not be fully up-to-date. We did not review accreditation and certification manuals in full detail, given their length and complexity, so these results do not represent a detailed crosswalk comparison between standards.

Conclusions

Accreditation provides an alternative path to satisfy minimum CMS certification requirements, and in some cases, to meet additional state licensing requirements. We found some examples in which accreditation standards were more detailed or stringent, and/or covered additional topic areas entirely. It is unclear whether these differences materially impact the quality of care in healthcare facilities. Although research has established a link between accreditation status and quality,[20-21] the marginal value of accreditation in addition or in lieu of certification has not been discussed in the literature.

Some states have supported accreditation as a licensure requirement, most notably in ASCs and to a very limited extent in CORFs. Policies that seek to expand state licensure in California to require accreditation for a broader set of facilities would benefit from a focused examination of those states' experiences to date.

[20] Greenfield, D., & Braithwaite, J. (2008). Health sector accreditation research: A systematic review. *International Journal for Quality in Health Care*, *20*(3), 172-183.
[21] Alkhenizan, A., & Shaw, C. (2011). Impact of accreditation on the quality of healthcare services: A Systematic Review of the literature. *Annals of Saudi Medicine, 31*(4), 407-416.

IV. Quality Concerns in ASCs, CORFs, and ESRD Facilities

Healthcare quality may be viewed through six distinct domains: ***safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity***.[22] Government oversight of healthcare facilities generally aims to ensure that patient care meets minimally acceptable standards for quality of care through diverse means, including licensure, operating standards, regulations, accreditation, public reporting of performance, and financial mechanisms (e.g., pay for performance). To provide an evidence-based foundation for understanding where regulatory gaps in quality of care oversight may exist, this chapter describes quality concerns from two vantages: 1) a review of the literature regarding quality concerns in ASC, CORF, and ESRD facilities, and 2) an analysis of complaints and L&C survey findings in California ASC, CORF, and ESRD facilities.

Methods

Literature Review

To provide an evidence-based foundation for understanding where gaps in quality of care oversight might exist for ASC, CORF, and ESRD facilities, we conducted a systematic review of the peer-reviewed professional literature, grey literature (e.g., government and consultant reports), general literature, and news media reports. To be consistent with California's definitions of these facilities, we excluded literature about hospital-based facilities and inpatient care settings.

Professional peer-reviewed literature. We searched PubMed for literature (all types) and the Cochrane database for systematic reviews in March 2015. The search was limited to English-language literature about human-based studies dated between January 1995 and March 2015. We excluded studies that focused narrowly on technical descriptions or evaluations of specific clinical procedures or treatments.

Although relevant to the quality domain of effectiveness, including these types of studies would entail innumerable comparative effectiveness evaluations across a broad range of clinical topics, which was beyond the scope of this analysis. We used the following search terms to identify literature that met criteria for the type of facility and the quality issue(s) of interest, with some additional exclusion criteria specific to the facility type:

Ambulatory Surgery Clinic

- **Facility keywords:** ambulatory surgical clinic, ambulatory surgery center, surgicenter, ambulatory surgical procedure, surgical procedure, ambulatory care, outpatient surgery

[22] Institute of Medicine (2001). *Crossing the quality chasm: A new health system for the 21st century*. Washington, DC: National Academy Press.

- **Quality of care keywords:** quality of care, quality of care issue, quality of health care, patient safety, medical error, postoperative complication, preoperative complication, adverse event, outcome
- **Additional exclusions:** office-based surgery/procedure

Comprehensive Outpatient Rehabilitation Facility

- **Facility keywords:** rehabilitation, rehabilitation center, ambulatory care, outpatient rehabilitation, occupational therapy, physical therapy
- **Quality of care keywords:** quality of care, quality of care issue, quality of health care, patient safety, outcome
- **Additional exclusions:** long-term care facility (including nursing home), rehabilitation facility other than physical rehabilitation (e.g. substance abuse and mental illness), tele-rehabilitation, physician-owned clinic

End-Stage Renal Disease Facility

- **Facility keywords:** dialysis clinic, outpatient dialysis, hemodialysis, kidney disease, kidney failure, renal dialysis, dialysis
- **Quality of care keywords:** quality of care, quality of care issue, quality of health care, patient safety, outcome, adverse event
- **Additional exclusions:** Intensive care unit setting, primary care setting, kidney transplant

Grey literature. Since quality issues are frequently addressed outside of the formal peer-reviewed professional literature, we also searched the "grey literature" for information about: 1) general quality issues in ASC, CORF, and ESRD facilities, and 2) policy/regulatory analyses pertaining to quality issues in these care settings. The grey literature includes, among other things, state and federal government reports; consultant, professional association, and philanthropy sponsored reports; and trade association and manufacturer reports. We applied the same search terms and inclusion/exclusion criteria as for the peer-reviewed literature. We searched the following general grey literature sources: LexisNexis, New York Academy of Medicine grey literature database, and Congress.gov. We also conducted targeted searches of selected websites (i.e., state legislative websites, Agency for Healthcare Research and Quality, Institute of Medicine).

General literature and news reports. High-visibility cases of egregious patient safety and quality incidents may prompt licensing agency investigations and lead to new state regulations but not be documented in either peer-reviewed or grey literature reports. To capture this information, we searched LexisNexis and Google News for articles that linked new state regulatory standards to publicized cases of quality or safety incidents, using the basic query structure: “[state]” AND “law OR regulation” AND “[facility type]” AND “quality OR safety.”

Additionally, we conducted a targeted search in Google News to see whether any of the ASC, CORF, or ESRD facilities that had been frequently cited by CDPH were reported in the California news media for quality of care or safety concerns. CDPH provided us with data from its Automated Survey Processing Environment (ASPEN) system that summarized the number of complaints and incidents in the three facility types of interest between 2000 and 2014. We identified 41 facilities in this search (mostly ESRD facilities), and we searched for those facility names in connection with quality and safety keywords.

L&C Survey Findings

We analyzed data provided by L&C from ASPEN on the frequency and general nature of deficiencies and allegations that have been noted in California ASCs, CORFs, and ESRD facilities. We used the ten most recent years of data (September 16, 2005 through September 16, 2015). L&C identifies regulatory deficiencies through various activities, including surveys done for routine licensure/certification, follow-up visits to assess whether deficiencies were corrected, and responses to public complaints or entity-reported incidents. When the same deficiency was noted multiple times in a series of follow-up surveys at the same facility, it was counted once. Multiple deficiencies are often found in a single survey, and a facility may be subject to a series of surveys for a particular issue.

We also reviewed data on allegations that were found to be substantiated with deficiencies, which are a subset of deficiency data. Allegations arise from complaints (e.g., by patients or submitted on their behalf) or incidents that facilities self-report to CDPH (e.g., breach of medical information). Detailed data about the nature of these deficiencies and allegations were not available, so only the general category or description is presented. The analysis provides a high-level, descriptive overview of the scale of compliance issues and associated quality concerns that have been documented through L&C activity.

Results

Quality Issues from the Literature

We initially identified 2,245 sources of information about potential quality concerns in ASCs, CORFs, and ESRD facilities; 92 (4.1%) of those sources met inclusion criteria (Table 1). Professional journal articles were the primary source of relevant information. ASCs and ESRD facilities had the largest number of sources. Very little relevant information on CORFs was found. Few pertinent news reports and policy/legislative sources were identified. We did not find any news articles discussing quality problems in the 41 selected California facilities that were most frequently cited by CDPH, with the exception of news coverage about one facility that had paradoxically received a quality award.

Table 1. Literature Review Search Results

Reference Type	Facility Type						Total	
	ASC		CORF		ESRD			
	# initial hits	# included	# initial hits	# included	# initial hits	# included	# initial hits	# included
Journal	797	20 (2.5%)	712	5 (0.7%)	469	31 (6.6%)	1,978	56 (2.8%)
Report/grey literature	106	9 (8.5%)	99	2 (2.0%)	4	4 (100%)	209	15 (7.2%)
Policy/legislative	15	2 (13.3%)	1	0 (0.0%)	2	2 (100%)	N/A	4
News	357	18 (5.0%)	0	0 (0.0%)	28	6 (21.4%)	385	24 (46.3%)
Total	1275	49 (3.8%)	812	7 (0.9%)	503	43 (8.5%)	2,590	99 (3.8%)

Ambulatory Surgery Clinics

We identified and reviewed 49 relevant sources about quality concerns in ASCs (Appendix B, Table B1). We organized the information into pre-, peri-, and post-surgical issues. Pre-surgery-themed literature that we identified addressed candidate selection for outpatient surgery and preoperative testing, with a goal of ensuring that care was clinically appropriate for the ASC setting. Literature concerning peri-operative issues included patient burns, prophylactic intravenous antibiotic timing, patient falls, and adverse events. Post-surgical quality issues focused on nausea/vomiting, pain control, and unanticipated hospital admission. The overwhelming majority of the initially identified sources were excluded because they were not relevant to the issues we were evaluating. For instance, they were reports about clinical or technical studies (e.g., randomized controlled trials comparing two forms of anesthesia medication).

The journal articles that we included primarily addressed the quality domains of efficiency, safety, and effectiveness, with limited to no discussion of the other quality domains. Reports primarily concentrated on safety and general oversight issues, while news articles and legislative/policy documents focused primarily on safety.

Safety. We reviewed five journal articles and five reports that described safety issues in ASCs. The journal articles primarily addressed adverse events, patient screening and selection for outpatient surgery, and surgical site infection (SSI). The reports provided recommendations on how to reduce adverse events and SSIs. We included 14 news reports, which primarily discussed infection and general safety concerns and deaths following lap-band surgery and the highly publicized death of comedian Joan Rivers. We also included two legislative/policy documents that described the regulatory environment in Washington and Oregon.

A 2008 study of 1.14 million ambulatory surgical procedures found that procedures performed by board-certified surgeons in accredited ASCs had mortality rates comparable to hospitals. A more recent study of national day-case surgery data had similar findings. However, state reports of adverse events raised concerns about the occurrence of serious safety events (e.g., SSIs, retained surgical items, and wrong patient, site, or procedure surgery) in ASCs. These are also concerns in the hospital setting. Data from one analysis of medical errors concluded that death from office-based lipoplasty was unacceptably high. A sixth journal article that we found incidentally, but which did not appear in our search results, noted that in seven years of mandatory adverse event reporting for medical office-based procedures in Florida, there were 174 events and 31 deaths.[23] Plastic surgery procedures accounted for most of the deaths.

Numerous sources addressed SSI and concerns about noncompliance with facility and physician oversight standards. Several news reports highlighted non-compliance with infection control requirements. One report noted that state inspectors found more "immediate jeopardy" level safety concerns in unlicensed ASCs than in licensed ASCs. Some reports cited concerns about inadequate training or equipment to deal with emergencies, insufficient facility or practitioner competence to perform complex or risky procedures, and the lack of practitioner oversight and peer review.

Effectiveness. We reviewed eight journal articles on effectiveness. They addressed post-operative unplanned hospital admissions and pain management issues; peri-operative adverse events; and pre-operative patient anxiety.

General surgery, gynecology, urology, and orthopedic procedures done in ASCs account for the vast majority of unplanned hospital admissions; plastic surgery has a relatively low rate of admissions. Common reasons for unplanned hospital admission after an ASC procedure were bleeding and wound management issues, cardiopulmonary problems, nausea and vomiting, and pain. Multiple reports cited problems with patients experiencing nausea, vomiting, and/or pain after ASC procedures. Hospital admissions following ASC procedures were frequently initiated through the emergency department. Better ASC postoperative management and patient discharge procedures could reduce the need for these admissions.

Patient-centeredness. Literature on patient-centeredness was limited. We included only one journal article, which reported on patient satisfaction in freestanding ASCs compared to hospital-based ASCs. Patient satisfaction and anxiety were reported to be similar between hospital and ASC-based procedures.

Timeliness. We did not find any literature addressing this quality domain.

[23] Coldiron, B. M., Healy, C., & Bene, N. I. (2008). Office surgery incidents: What seven years of Florida data show us. *Dermatologic Surgery*, *34*(3), 285-291.

Efficiency. We reviewed six journal articles on efficiency – three reviews and three original analyses. Several articles addressed the appropriate and efficient use of pre-operative patient evaluations to assess candidacy for outpatient surgery. One journal article evaluated whether pre-operative anxiety medication delayed discharge, and another examined the link between ASC structure and specialization with quality outcomes.

Some studies raised concerns about potential overuse of pre-operative testing. Pre-operative testing occurs in the majority of patients undergoing elective surgery, even if the patient does not present with comorbidities that offer clear indications for it (e.g., as outlined by the National Surgical Quality Improvement Program). However, abnormal results in preoperative tests performed in ambulatory surgery settings rarely prompt management changes or affect patient outcomes. The reports did not allow us to determine whether overuse of pre-operative testing was due to practice traditions, lack of communication between physicians, fear of malpractice litigation, or lack of awareness of evidence and guidelines.

Equity. We did not find any literature addressing this quality domain.

General. We reviewed four reports and four news stories about general patient safety policy issues. Three of the reports were highly relevant investigations by the Office of the Inspector General (OIG), U.S. Department of Health and Human Services, which evaluated whether government and accreditation agency oversight of ASCs was adequate; one report described state licensing issues in New Jersey. The news reports highlighted concerns about the adequacy of state regulatory oversight.

The OIG raised numerous concerns in its 2002 reports about the adequacy of existing ASC oversight, urging stronger oversight by federal and state regulators and accrediting bodies. The report noted that outpatient surgery is increasingly common, and that the procedures being performed in these settings are increasingly complex and high-risk. The OIG called for, at a minimum, changes to the CMS Conditions of Coverage to include patient rights and continuous quality improvement. The OIG concluded that “Medicare’s system of quality oversight is not up to the task,” and it urged CMS to hold state agencies and accreditors accountable for noncompliance. CMS standards for ASCs have been extensively revised and expanded since the 2002 OIG reports were released.

General news stories reported on the citation of numerous licensed facilities for “immediate jeopardy violations” and safety concerns due to unlicensed clinical practices. Both the OIG and the news media reports advocated for more comprehensive regulations and more meaningful compliance with those standards.

The California HealthCare Foundation produced two reports which were not captured in our review but are relevant. The first was a brief that highlighted the growing need for, but lack of,

public data about outpatient surgery.[24] The second was a report that outlined the regulatory structure for all outpatient surgery settings in California (including but not limited to ASCs). It noted the complex patchwork of state requirements and described multiple opportunities for regulatory improvements.[25] The work raises important points about the need for better regulatory consistency across various outpatient surgery settings, and it addresses topics that were outside the scope of our analysis – which focused on regulatory opportunities within the current framework of CDPH oversight.

Comprehensive Outpatient Rehabilitation Facilities

We reviewed seven journal reports about quality concerns in CORFs (Appendix B, Table B2). There were no news reports, policy evaluations, or other relevant sources. Literature regarding quality in CORFs was sparse, with 99% of the initially identified literature failing to meet inclusion criteria. Many of the excluded results pertained to mental health and drug abuse rehabilitation facilities or descriptions of specific therapeutic methods.

Access to care was the most common topic discussed in the CORF-related literature, and access issues spanned multiple quality domains. Topics included clinical education of caregivers, racial/ethnic disparities in stroke rehabilitation, outcome measures, research needs, and adherence to clinical guidelines. A few sources addressed patient-centeredness and effectiveness, but there was almost nothing on the other quality domains for CORFs.

Safety. We did not find any literature addressing safety.

Effectiveness. We reviewed two journal articles and one report about effectiveness. These sources discussed clinical education about rehabilitation needs, state regulation of allied health professional practice, and research needs for measurement.

The journal articles asserted that quality of care in CORFs was compromised by insufficient rehabilitation training for resident physicians, particularly in cancer-survivor populations. One journal article cautioned about whether states should allow physical therapists to be substituted with physical therapy assistants and therapy aids, which may decrease care quality. A report about a two-day symposium to discuss the state-of-the-science on post-acute care rehabilitation noted that little is known about how to achieve optimal outcomes and cited the need for more research.

Patient-centeredness. We identified one journal article related to patient-centeredness, which reported on a survey of 21 women's experiences with care access after brain injuries. All the

[24] California HealthCare Foundation. Ambulatory surgery centers: Big business, little data. *California Health Care Almanac, June 2013*. Retrieved from http://www.chcf.org/publications/2013/06/ambulatory-surgery-centers
[25] B & R Klutz Consulting. (2015). *Outpatient surgery services in California: oversight, transparency, and quality*.

women faced barriers to rehabilitation care access, including cost, transportation, knowledge, and coordination of care issues. These barriers may result in underuse of services.

Timeliness. We identified one journal article relating to timeliness. It examined whether stroke survivors received timely and adequate care, finding that patient outcomes and quality of life could be improved if more patients received recommended care.

Efficiency. We did not find any literature addressing efficiency.

Equity. We identified one journal article relating to equity. It described widespread racial and ethnic disparities in stroke care, including use of outpatient rehabilitation, access, treatment quality, and research participation.

General. We reviewed one journal article about general quality issues. It reviewed various outcome measures for rehabilitation care and discussed the challenges in achieving consensus around a common set of standards.

End-Stage Renal Disease Facilities

We reviewed 43 literature sources discussing quality concerns in ESRD facilities, and discarded 91% of the sources (Appendix B, Table B3). The excluded results could not be linked to one of the six quality domains and discussed topics such as Medicare reimbursement rate schedules, laboratory experimentation, and genetic factors. We included 31 journal articles, four reports, six news reports, and two policy/legislative documents. Most literature fell under the quality domain of effectiveness, though we found information in all quality domains except timeliness. Common topics in ESRD facilities were quality measurement, organizational structure (e.g., non-profit vs. for-profit status), vascular access, and adverse events. News media reports heavily focused on safety issues due to faulty equipment or non-compliance with CMS guidelines.

The Institute of Medicine Committee for the Study of the Medicare End-Stage Renal Disease Program published a seminal 1991 report about the government's role in ESRD facility quality.[26] This was outside of our search timeframe for inclusion, but it is worth noting since the report formed the basis for much of the current regulatory oversight that is in place. The report detailed concerns about disparities in access to care, declining quality in the face of diminished reimbursement, and quality oversight needs.

Safety. We reviewed two journal articles, six news reports, and two policy/legislative documents related to safety. One journal article and one report discussed the epidemiology of healthcare-associated infections in ESRD facilities. The type of vascular access used for dialysis is related to infection. The second journal article reported on vascular access complications based on the

[26] Institute of Medicine Committee for the Study of the Medicare End-Stage Renal Disease Program. (1991). *Kidney Failure and the Federal Government.* In R. A. Rettig & N. G. Levinsky (Eds.). Washington, DC: National Academies Press.

technology at the time, though it was published nearly 20 years ago and is of uncertain relevance today; the other journal article described more recent vascular access infection risk factors.

News media reports discussed several serious adverse event incidents, which were linked to employee error, defective equipment, and continued use of recalled products. A number of news reports recounted an instance of healthcare serial murder in Texas at a dialysis clinic; this instance was also described in a peer-reviewed journal article on healthcare serial murder.[27] One report pointed to disproportionately high morbidity in some San Gabriel Valley clinics that had inspection citations. Others raised general concerns following ESRD facility conversion from non-profit to for-profit. A Government Accountability Organization (GAO) report further substantiated news report concerns about noncompliance, finding that many facilities surveyed for Medicare participation should have been terminated from the program due to serious quality problems. Moreover, state inspections were not frequent enough to detect or result in correction of many violations.

Effectiveness. We included 17 journal articles and four other reports about effectiveness. The prevailing topic within effectiveness was quality measures, though organizational structure, dialyzer reuse, vascular access, and dialysis care issues were also discussed.

Multiple studies linked improved efficiency and patient outcomes to better performance on quality of care measures and closer adherence to clinical guidelines. A number of reports found that many ESRD facilities failed to meet minimum clinical targets. Serious problems identified during inspections included medication errors and water contamination – problems that, if left uncorrected, could lead to termination from Medicare participation. A 2010 panel recommended several additional areas for measurement of ESRD care quality.

Studies found mixed results about the relationship between mortality and facility for-profit/not for profit status, but a systematic review concluded that mortality was higher in private for-profit facilities than in non-profit facilities. Other studies linked higher mortality in dialysis care to factors such as less physician supervision; free standing instead of hospital-based clinic structure (though authors noted that their findings differed from a prior study); lower dialysis adequacy (as measured by urea reduction ratio); type of vascular access method (catheter and graft-based access were reported to be problematic); ongoing vascular access monitoring; and pre- and post-dialysis care.

Patient-centeredness. We reviewed one journal article on this quality domain; it addressed patient satisfaction. The study found that patient satisfaction increased with greater nurse-patient

[27] Kizer, K. W. & Yorker, B. C. (2010). Health care serial murder: A patient safety orphan. *The Joint Commission Journal on Quality and Patient Safety*, *36*(4), 186-191.

interaction, more information and instruction provided by staff, a more personalized atmosphere of the facility, and the efficiency of delivery of the dialysis supplies. The dialysis regimen itself was the greatest cause of patient dissatisfaction.

Timeliness. We did not find any information on this quality domain.

Efficiency. We reviewed four journal articles focusing on efficiency. Three of the articles explored issues relating to staffing levels, and one discussed Medicare reimbursement changes.

Studies found large regional differences in patient-nurse staffing ratios, and staffing levels were significantly associated with clinical outcomes. High patient-to-nurse ratios were linked to an increased number of adverse events. Medicare reimbursement changes in 2005 were not linked to changes in clinical quality measures.

Equity. We included five journal articles pertaining to equity. These articles addressed issues of access to care and quality measures.

Dialysis care access varies widely based on patient characteristics, and even after controlling for these variables across facility types. One study found variation in ESRD care access that was linked to gender, race, and hemoglobin and serum albumin levels, as well as clear regional variations in catheter utilization. Another study found that physician visit volume was driven by geography and facility location, rather than patient health status or illness acuity; patients had fewer nephrologist visits in small towns and rural areas compared to large towns and urban areas. In addition, facility quality and patient survival were shown in one study to be markedly worse in neighborhoods with a higher proportion of African-Americans.

Compliance Violations in California: L&C Survey Findings

In order for regulatory oversight of healthcare facilities to be effective, the standards must be comprehensive and well-defined, and facilities must comply with those standards. The focus of this study is the former, but much of the literature addresses problems with the latter. As such, we also report on the number of compliance violations which resulted in federal or state deficiencies that have been identified in L&C surveys (Figures C1-C3). The data represent issues that L&C found via on-site surveys, including those that were part of routine surveillance and in response to consumer complaints, over a ten-year period, September 2005 to September 2015. These issues represent opportunities to improve quality and general facility conditions in ASCs, CORFs, and ESRD facilities that do not entail new requirements, but rather through improvements for known compliance problems.

***Ambulatory Surgery Clinics*.** L&C identified 16,592 discrete deficiencies in 564 ASCs between September 2005 and September 2015, an average of 1,659 per year (Figure C1). The majority (73%) were federal deficiencies, and a minority (15%) violated CMS conditions of participation. State deficiencies usually cited violations of the life safety code standards (e.g., building fire

codes); these are also part of federal standards, but CMS may defer to existing state rules. Federal deficiencies were diverse, but commonly involved drug administration or infection-related measures.

Of the deficiencies that L&C identified in substantiated allegations (n=155, averaging about 16 per year), quality of care was the general type of allegation that surveyors cited most often. Examples of the most serious allegations included surgical and procedural adverse events: three wrong part surgeries, two wrong procedures, and one death linked to anesthesia in an otherwise healthy patient, over 10 years. Acute care hospitals report many more surgical adverse events than ASCs: more than 600 substantiated retained surgical items in seven years of reporting, though some of these cases may not have deficiencies;[28] compared to zero retained surgical items in ASCs that were substantiated with deficiencies. Importantly, from the information available, we could not determine whether the low number of adverse events reported from ASCs was due to reporting practices and requirements or truly fewer events. Physician-owned ASCs were only required to report adverse events to CDPH between 2012 and 2014; they are currently required to report adverse events to the Medical Board of California. Compliance with the reporting requirement is unclear, although non-reporting is generally believed to be widespread.

Comprehensive Outpatient Rehabilitation Facilities. L&C identified 2,272 discrete deficiencies in 122 CORFs between September 2005 and September 2015, an average of 227 per year (Figure C2). In contrast to ASCs, the overwhelming majority (98%) were state deficiencies. A minority (11%) violated CMS conditions of participation. (State and CMS COP deficiencies are not mutually exclusive, resulting in the total of the two categories exceeding 100%.) State deficiencies often cited non-compliance with policies, such as those pertaining to patient care or personnel. Few noteworthy allegations were documented for CORFs, less than one per year on average.

End-Stage Renal Disease Facilities. L&C identified 9,591 discrete deficiencies in 537 ESRD facilities between September 2005 and September 2015, an average of about 959 per year (Figure C3). The majority (98%) were federal deficiencies, and a small minority (2%) violated CMS conditions of participation. State deficiencies usually cited violations of the life safety code standards (e.g., building fire codes); these are also part of federal standards, but CMS may defer to existing state rules. Federal deficiencies were diverse, but commonly addressed infection control and prevention, though compared to the other two settings, clinically pertinent topics such as the appropriateness of dialysis treatment were also frequently cited.

[28] Wu, H. W. & Kizer, K. W. (2016). *Surgical adverse events in California: Trends in state reporting and recommendations for prevention.* Sacramento, CA: Institute for Population Health Improvement, University of California Davis Health System. (*In press*).

Of the deficiencies L&C identified in substantiated allegations (n=792, averaging about 79 per year), quality of care was the general type of allegation that surveyors cited most often. Among the potentially serious allegations were 14 general patient safety-related incidents, as well as two instances of sexual abuse, two patient falls, and one contaminated drug/device cases. Reporting practices may influence these numbers and mask their true frequency.

Data Limitations

The literature about quality of care issues in ASCs, CORFs, and ESRD facilities was relatively limited. We included sources that ranged from rigorously designed, peer-reviewed journal articles to news reports about a single patient. We felt these were illustrative of the range of quality concerns that merit consideration by policymakers. Peer-reviewed studies are valuable in understanding population-level trends, but they may aggregate or analyze data in a manner that does not recognize the rare safety hazards that regulators seek to eliminate – i.e., regardless of whether risk is significantly higher in ambulatory or hospital-based settings. Our search terms were designed to support an efficient search without excessive irrelevant hits, but they may also have missed some relevant sources.

The analysis of compliance violations in California relied upon L&C survey data. This only captures what L&C is able to detect during on-site surveys, including those that occurred as part of routine surveillance or in response to consumer complaints. It does not capture any additional issues that escaped L&C detection, non-reporting by healthcare facilities, or problems that could not be cited as deficiencies due to regulatory gaps or insufficient evidence to issue a citation. Experience in other healthcare settings suggests that under-reporting of patient safety events is widespread.[29] Given these limitations, the L&C-detected issues may not be representative of the full scope of quality concerns.

Conclusions

Overall, we found a modest body of literature describing quality of care concerns in ASCs and ESRD facilities, and very little information about quality issues in CORFs. We identified opportunities for improved clinical practice in these facilities, ranging from reducing surgical site infections in ASCs to selecting better methods of vascular access for dialysis. Serious adverse events were identified, particularly in ASCs. In ESRD facilities, safety concerns included those involving defective equipment and products. Serious safety incidents in CORFs appear to be less likely due to the nature of services provided in those settings.

[29] Institute of Medicine Committee on Quality of Health Care in America. (2000). *To err is human: Building a safer health system.* In Kohn, L. T., Corrigan, J. M. & Donaldson, M. S. (Eds.). Washington, DC: National Academies Press.

Much of the literature discussed quality issues that may be more appropriately addressed through adherence to evidence-based standards, clinical practice guidelines, and other clinical practice improvements, such as prevention of infections and complications. Some of the literature detailed serious adverse events, which merit closer scrutiny from a regulatory perspective. Because California currently requires only hospitals to report adverse events to CDPH and physician-owned ASCs to report to the Medical Board of California, ASCs, CORFs, and ESRD facilities will only report to CDPH on these adverse events if they operate under a hospital's license. News media reports about unexpected patient deaths frequently pointed to the vulnerabilities of the current regulatory structure.

The literature that most directly considered our primary question – i.e., whether existing standards used in California fully capture the quality issues that occur in these facilities – largely detailed regulators' struggles to ensure meaningful compliance with the existing minimum standards, rather than discussing whether broader standards were needed. Taken together with data from L&C that describes the universe of known compliance violations, one should be cautious about generalizing about the full spectrum of underlying quality issues. Overall, the literature offers little evidence-based guidance about the utility and likely benefit of expanded regulatory oversight of ASCs, CORFs, and ERSD facilities, and known compliance violations may represent only a portion of the problem.

V. Study Conclusions

This study sought to determine the adequacy of federal certification standards as the sole basis for state licensing of ASC, CORF, and ESRD facilities. It evaluated this question by first examining the regulatory and oversight provisions for these facilities in other states to determine whether there are examples of stronger state regulation. We found an array of additional regulations in other states, although primarily for ASC and ESRD facilities. These state-specific regulatory differences were largely semantic rather than substantive, except for matters of environmental and occupational safety in which cases CMS often defers to state requirements. We found relatively few requirements for CORFs, possibly because their scope of services does not present unique safety threats. While we found various regulatory opportunities in some state-specific requirements, no single issue emerged as a common priority among multiple states.

The noteworthy differences between licensure in California compared to other states pertain to requirements for accreditation and variations on how facilities and services are defined and regulated. These differences have consequences for various oversight provisions, such as adverse event reporting. Further details about particular topics are provided in the appendices.

State oversight for outpatient procedures performed in California is a patchwork of regulations. In the case of ASCs, for example, physician-owned facilities are regulated by a different entity than hospital-owned facilities. This has received considerable attention and is detailed elsewhere.[3] It is unclear from the evidence we examined whether the incremental benefit of expanding accreditation requirements would materially improve quality of care.

Next, we considered what quality concerns and problems have been documented in diverse information sources, ranging from peer-reviewed publications to general news media coverage. We cast a wide net, aiming to identify gaps that might signal a need for stronger regulatory oversight. We found areas for clinical practice improvement in ASC and ESRD facilities, which are often under the purview of professional guidelines rather than state regulatory requirements. It also identified an assortment of safety concerns in ASC and ESRD facilities, but these usually were attributed to non-compliance with existing standards rather than a need for expanded regulations. For example, the quality literature frequently addresses infection, but survey activity data from CDPH show that facilities are often deficient in meeting existing infection control standards.

In summary, we conclude that:

- California's use of CMS certification standards as the basis for state licensure is consistent with standard practice across the nation;
- California differs from some other states in not requiring accreditation for some ASCs (i.e., California requires accreditation only for those that provide higher levels of

sedation) or for CORFs, and in the requirements for specific types of facilities and services, such as for adverse event reporting;

- Better compliance with existing federal regulations would likely address many of the documented quality problems that CDPH has cited in these facilities; and
- Based on information reviewed, expanded state-specific regulations for ASC, CORF, and ESRD facilities would be of uncertain marginal value; and
- Future consideration of the need for expanded regulatory oversight of ASCs, CORFs and ESRD facilities should be based on a more detailed, evidence-based understanding of quality problems in these facilities and how regulations would specifically address the root causes of such problems.

Appendix A -
State Licensing Laws

Table A1. State Licensing Laws: ASCs

STATE	REGULATORY AGENCY	RULEMAKING AUTHORITY	ASC: DEFINITION & EXCLUSIONS	STATE LICENSURE REQUIRED?	ADDITIONAL STATE LICENSURE REQUIREMENTS NOT ADDRESSED IN FEDERAL STANDARDS	ADDITIONAL STATE DETAIL FOR EXISTING FEDERAL STANDARDS (RELEVANT CFR §)
Alabama	Alabama Department of Public Health, Bureau of Health Provider Standards, Division of Licensure and Certification	Legislature of Alabama, Code of Alabama, 1975, Sections 22-21-20, et seq.	A healthcare facility that primarily provides medically necessary or elective surgical care. Exclusions: private doctors and dentists, including those organized as professional corporations, professional associations, partnerships, or sole proprietorships, and facilities defined as hospitals. Abortions can only be performed at a surgical center if it is also licensed as an abortion or reproductive health center.	Yes	A food safety system must be in place. Accreditation encouraged where deep sedation/ analgesia or general anesthesia is provided. The rules require registration and reporting, in addition to standards based on level of anesthesia provided.	A copy of the governing body meeting minutes must be kept as a permanent record of the facility. (§416.41. Governing body and management) The Director of Nursing must be a licensed graduate of a professional nursing school with one or more years of experience in surgical/recovery nursing. (§416.46. Nursing services)
Alaska	Alaska Department of Health and Social Services, Division of Health Care Services, Health Facilities Licensing & Certification	AS 47.32	A facility that is not part of a hospital or general medical practice which provides surgical services to patients who do not require hospitalization.	Yes	None	None
Arizona	Arizona Department of Health Services, Division of Licensing, Bureau of Medical Facilities Licensing	9 A.A.C. 10	A facility with services for the diagnosis or treatment of patients by surgery whose recovery does not require inpatient hospital care.	Yes	None	None

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Arkansas	Arkansas Department of Health, Health Facilities Services	Ark. Code Ann.§§20-9-201 et seq., 20-7-123	Outpatient surgery center means a facility in which surgical services that require the use of general or intravenous anesthetics are offered and where, in the opinion of the attending physician, hospitalization is not necessary. Minor dental surgeries are excluded from this definition.	Yes	The supervisor of Food and Nutrition services must be at a minimum a certified dietary manager.	The extended stay area must be staffed by at least two caregivers, one of which must be an RN (§416.52. Patient admission, assessment and discharge)
California	California Department of Public Health Medical Board of California (only for *accredited* outpatient surgical settings)	CA HSC: 1200-1209 HSC 1248 SB 100	A surgical clinic is one that is not part of a hospital and provides care for patients who stay less than 24 hours.	Yes, but surgical clinics that are owned wholly or in part by physicians are regulated solely by the Medical Board of California.	If the surgical procedure requires anesthesia to be administered in doses that have the probability of placing a patient at risk for loss of the patient's life-preserving protective reflexes, then the surgery must be performed in an accredited, licensed, or certified setting. Unlicensed ASCs must be accredited only if general anesthesia is used in the clinic (California Health & Safety Code Section 1248.1), but is not needed for ASCs that operate strictly with local anesthesia or peripheral nerve blocks (Business & Professions Code Section 2216). Accreditation is not required for clinics that use strictly anxiolytics (e.g., Xanax) and analgesics when their use is within at dosage levels that do not place patients at risk for loss of protective reflexes.	None

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Colorado	Colorado Department of Public Health & Environment, Health Facilities Division	6 CCR 1011-1 Chap 02 6 CCR 1011-1 Chap 20	A facility which operates exclusively to provide surgical services to patients not requiring hospitalization and for patients who are not expected to require more than a total of 23 hours for preparation, the surgery itself, and recovery. This does not include a facility that is licensed as part of a hospital.	Yes	The license shall be for the maximum operational capacity determined by the DPH. The use of flammable anesthetics is prohibited.	None
Connecticut	Connecticut Department of Public Health	Connecticut General Assembly Statute Sec. 19a-493b	An outpatient surgical facility (OSF) provides surgical care requiring a medical environment that exceeds that normally found in a doctor's office and does not require overnight stay. Common procedures include: colonoscopy, biopsy, endoscopy, eye procedures, ear/nose/throat procedures, hernia repair, and gynecological procedures. Dental clinics are not included.	Yes	The acronym OSF is used in Connecticut law and regulation to refer to a particular type of licensed facility. The term ASC used in federal law and regulation refers to a specific type of facility that must comply with CMS rules and accreditation standards. Connecticut has many ASCs that are licensed as OSFs, but not all OSFs are ASCs. OSFs may be free-standing or hospital owned/operated. Accredited facilities are still subject to inspection.	None

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Delaware	Delaware Department of Health and Social Services, Health Facilities Licensing and Certification	Administrative Code Title 16 Del.C. §122(3)(p)	A Free Standing Surgical Center (FSSC) is a facility, other than a hospital or the office of a physician, dentist or podiatrist, or professional association, which exists to provide surgical services that do not exceed 23 hours and 59 minutes.	Yes	Separate licenses are required for FSSCs maintained in separate locations and are specific for number and class of operating rooms and recovery beds. Nutritional services must be provided as detailed in the administrative code. FSSCs may provide services through the Delaware Medical Assistance Program if the facility is certified by the Office of Health Facilities, Licensing and Certification or a comparable certifying agency in the State. The Health Resource Board requires AAAHC or accreditation by another accrediting organization within one year of licensure as a condition of approving new or converted freestanding ambulatory centers.	A governing body with full-time director must be in place (§416.41. Governing body and management)
District of Columbia	The Mayor of Washington, DC	Title 44 of the DC Official Code	An ASC is a facility other than a hospital or maternity center where outpatient surgical procedures are performed. This does not include office-based facilities.	Yes	After initial licensure, the Mayor may accept accreditation by a private accrediting body, federal certification in a health insurance or medical assistance program, or federal qualification of a health maintenance organization as in lieu of inspection.	None

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Florida	Florida Agency for Health Care Administration (AHCA)	Chapter 395, Part 1, Florida Statutes; Chapter 59A-5, Florida Administrative Code; Chapter 59A-10, Florida Administrative Code; Chapter 408, Part II, Florida Statutes; Chapter 59A-35, Florida Administrative Code	A facility with the primary purpose of providing elective surgical care, in which the patient is admitted to and discharged from such facility within the same working day and is not permitted to stay overnight, and which is not part of a hospital.	Yes	A licensed facility shall not operate a number of beds greater than the number indicated by the agency on the face of the license without approval from the agency. Internal risk management program is required. Zoning requirements apply.	A detailed emergency management plan is outlined in the administrative code (§416.41. Governing body and management) A facility must notify each patient during admission and at discharge of his or her right to receive an itemized bill upon request. (§416.50. Patient rights)
Georgia	Georgia Department of Community Health, Healthcare Facility Regulation Division, Office of Facility Licensure	O.C.G.A. §§ 31-2-4 et seq., 31-7-1 et seq. and 50-13-1 et seq.	A facility that provides surgical treatment to patients who do not require hospitalization and does not provide accommodations for treatment. They don't operate under the control of a hospital. Exceptions include federally owned facilities and private physician and dentist offices.[1] Service classifications include: general surgery; eye, ear, nose, and throat; plastic surgery; oral and maxillofacial; obstetrical-gynecological; oncological; ophthalmological; and urological.	Yes	Locations using flammable anesthetic agents shall comply with specific state regulations. All electrical work and equipment shall be designed and installed in accordance with state and local laws and ordinances. Any advertising of the services provided in or by ambulatory surgical treatment center shall include the full name of the center and its Georgia license number, as shown on the face of the permit. An applicant for an expanded ASC must meet accreditation requirements of the AAAHC or other appropriate accrediting agency within one year of obtaining a state license.	None

[1] https://dch.georgia.gov/sites/dch.georgia.gov/files/imported/vgn/images/portal/cit_1210/1/28/146709912ambulatorysurgicaltrmt_July_2012.pdf

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Hawaii	State of Hawaii, Department of Health, Office of Health Care Assurance	HRS §§321-9, 321-10, 321-11	A freestanding surgical outpatient facility is a facility developed for the purpose of performing surgical procedures which do not require hospitalization and is not an integral part of a broad service hospital or private doctor's office. Patients may not stay longer than 18 hours.	Yes	A consulting dietitian shall supervise the preparation and service of whatever special diets may be deemed necessary for the patients to meet the objectives of the facility. There shall be written policies covering whatever dietetic services are deemed necessary by the governing board.	None
Idaho	Idaho Department of Health and Welfare, Division of Licensing and Certification	No statutes apply	An ASC operates exclusively to provide surgical services to those not requiring hospitalization.	No	None	None
Illinois	Illinois Department of Public Health, Office of Health Care Regulation	210 ILCS 5	Any facility that meets the definition of ASC under CMS rules. The facility shall not provide accommodations for overnight stays. An ambulatory surgical treatment center (ASTC) includes facilities in which a procedure is used to terminate a pregnancy.	Yes	None	None
Indiana	Indiana State Department of Health, Division of Acute Care	IC 16-21-1-7; IC 16-21-1-9	An ASC specializes in surgery, pain management and certain diagnostic (e.g., colonoscopy) services in an outpatient setting. These procedures are more intensive than those done in a typical doctor's office, but not so much so that hospitalization is required.	Yes	A short stay record form must be used. The details contained in this form (identification data, medical history, etc.) mirror CFR requirements for patient record keeping, but the term "short stay record from" is unique to Indiana.	None

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Iowa	Iowa Department of Public Health, Health Facilities Division	No relevant statutes could be found	Outpatient surgical facilities are classified as institutional health facilities. Their primary function is to provide surgical procedures not ordinarily performed in a private physician's office, but not requiring 24-hour hospitalization, and which is neither a part of a hospital nor the private office of a healthcare provider who engages in the lawful practice of surgery.[2]	No	No information about state licensing requirements could be found.	No information about state licensing requirements could be found.
Kansas	Kansas Department of Health and Environment	K.S.A. 65	An ASC includes the following: (1) An organized medical staff of one or more physicians; (2) Permanent facilities that are equipped and operated primarily for the purpose of performing surgical procedures and do not provide services or other accommodations for patients to stay >24 hours; (3) Continuous physician services during surgical procedures and until the patient has recovered from the obvious effects of anesthesia, and at all other times with continuous physician services available whenever a patient is in the facility; (4) Continuous registered professional nursing services whenever a patient is in the facility.	Yes	None	None

[2] http://www.idph.state.ia.us/adper/common/pdf/cert_of_need/iowa_code_2013.pdf

Table A1. State Licensing Laws: ASCs

STATE	REGULATORY AGENCY	RULEMAKING AUTHORITY	ASC: DEFINITION & EXCLUSIONS	STATE LICENSURE REQUIRED?	ADDITIONAL STATE LICENSURE REQUIREMENTS NOT ADDRESSED IN FEDERAL STANDARDS	ADDITIONAL STATE DETAIL FOR EXISTING FEDERAL STANDARDS (RELEVANT CFR §)
Kentucky	Kentucky Cabinet for Health and Family Services, Division of Health Care	902 KAR 20:106, KRS 216B.042(1)(a) and (c)	An ASC provides outpatient surgical services. ASCs may be freestanding facilities or operated by a hospital. Services may include: general surgery, gynecology, ophthalmology, orthopedics, otolaryngology, plastic surgery, pain blocks, podiatry, and urology.	Yes	None	None

Table A1. State Licensing Laws: ASCs

STATE	REGULATORY AGENCY	RULEMAKING AUTHORITY	ASC: DEFINITION & EXCLUSIONS	STATE LICENSURE REQUIRED?	ADDITIONAL STATE LICENSURE REQUIREMENTS NOT ADDRESSED IN FEDERAL STANDARDS	ADDITIONAL STATE DETAIL FOR EXISTING FEDERAL STANDARDS (RELEVANT CFR §)
Louisiana	Louisiana Department of Health and Hospitals, Health Standards Section (HSS)	R.S. 40:2131-2143	An ASC is an establishment with an organized medical staff of physicians, with permanent facilities that are equipped and operated primarily for the purpose of performing surgical procedures, with continuous physician services and registered professional nursing services available whenever a patient is in the facility, which does not provide services or other accommodations for patients to stay overnight, and which offers the following services whenever a patient is in the center: a. Drug services as needed for medical operations and procedures performed. b. Provisions for physical and emotional well-being of patients. c. Provision of emergency services. d. Organized administrative structure. e. Administrative, statistical and medical records. Services include stereotactic radiosurgery by use of a Gamma Knife or similar neurosurgical tool.	Yes	None	None

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Maine	Maine Department of Health and Human Services, Division of Licensing and Regulatory Services	22 M.R.S.A. §1813	An ASC is a facility with the primary purpose of providing elective surgical care to a patient who is admitted to and discharged from the facility within the same day. In order to meet this primary purpose, a facility must at least administer anesthetic agents, maintain a sterile environment in a surgical suite and charge a facility fee separate from the professional fee. It does not include a facility that is part of a hospital, abortion facilities, or private physician or dentist in private practice (unless it is certified as a Medicare ASC).	Yes	Zoning requirements apply. All healthcare provider employees providing direct patient care must wear an identification badge displaying name, title, and registration/ licensure/certification initials.	None
Maryland	Maryland Department of Health and Mental Hygiene, Office of Health Care Quality, Ambulatory Care Programs Unit	Health-General Article, §19-3B-01 et seq., Annotated Code of Maryland	A facility, service, office facility, or other entity that operates primarily for the purpose of providing surgical services, such as microscopic, endoscopic, arthroscopic, or laparoscopic procedures, to patients requiring a period of postoperative observation but not requiring overnight hospitalization, and that seeks reimbursement as a freestanding ambulatory surgical facility.	Yes	CMS certification is required.	None

Table A1. State Licensing Laws: ASCs

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Massachusetts	Massachusetts Department of Public Health, Division of Health Care Facility Licensure and Certification	114.3 CMR 47.00 is adopted pursuant to M.G.L. c.118G	A distinct entity that operates exclusively for the purpose of providing surgical services that do not require the availability of hospital facilities (such as debridement, biopsy, and autograph), is licensed by the Massachusetts Department of Public Health, and meets the conditions for payment by the purchaser for facility services.	Yes	Those affiliated with the clinic must be vaccinated against the flu; clinic must have current agreement with a licensed blood bank.	None
Michigan	Michigan Department of Community Health, Bureau of Health Systems, Department of Licensing and Regulatory Affairs	Public Health Code Part 222	A distinct entity that operates exclusively for the purpose of providing surgical services, including surgical abortions and post-operative care, to patients not requiring hospitalization and has an agreement with CMS to participate in Medicare.	Yes	CMS certification is required.	None
Minnesota	Minnesota Department of Health	MS s 144.56	An outpatient surgical center is organized for the specific purpose of providing elective outpatient surgery for pre-examined, pre-diagnosed, low risk patients. Admissions are limited to procedures which use local or general anesthesia and which do not require overnight inpatient care.	Yes	None	None
Mississippi	Mississippi State Department of Health	Mississippi Code Annotated § 41-75-1 thru § 41-75-25	An institution that is primarily established for the purpose of providing elective outpatient surgical services. This does not include offices of private physicians or dentists.	Yes	Every position shall have a written description which adequately describes the duties of the position.	None

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Missouri	Missouri Department of Health and Senior Services, Health Services Regulation	197.200, RSMo	A facility operated primarily for the purpose of performing surgical procedures, childbirths, or any establishment primarily operated to perform or induce second or third-trimester abortions or five or more first-trimester abortions per month. This does not include dentist offices or services that require accommodations for patients to stay more than twenty-three hours within the establishment.	Yes	ASCs licensed as either abortion providers or birthing centers must adhere to additional state licensure standards, found at 19 CSR 30-30.050-30.070 (for abortion) and 19 CSR 30-30.090-30.110 (for birthing).	None
Montana	Montana Department of Public Health and Human Services, Quality Assurance Division	37.106.310	A healthcare facility that operates primarily for the purpose of furnishing outpatient surgical services to patients.	Yes	None	None
Nebraska	Nebraska Department of Health & Human Services, Division of Public Health Licensure Unit	Neb. Rev.Stat. §§ 71-401 to 71-462.	An ASC is a facility where surgical services which do not require hospitalization are provided. This does not include independent physician, dentist, or podiatric offices. It may also be referred to as a "health clinic."	Yes	Each health clinic must complete and maintain documentation of pre-employment criminal background and registry checks on each unlicensed direct care staff member.	None
Nevada	Nevada Department of Health and Human Services, Division of Public and Behavioral Health	NRS 449.030 to 449.2428	A facility with limited medical services available for diagnosis or treatment of patients by surgery where the patients' recovery, in the opinion of the surgeon, will not require care as a patient in the facility for more than 24 hours.	Yes	Assembly Bill 123 mandates accreditation for licensed surgical centers. Newly licensed centers must submit proof of accreditation within six months of obtaining a license.[3]	None

[3] http://www.aaahc.org/en/news/federal-and-state-regulations/state-laws-and-regulations/

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New Hampshire	New Hampshire Department of Health and Human Services; Health Services Planning & Review Board	RSA 151:2, I(d)	Any facility, exclusive of physician or dentist offices, that maintains and operates services for the performance of outpatient surgical procedures.	Yes	Application for initial license must include the credentials of the ASC administrator and proof of compliance with state fire code.	None
New Jersey	State of New Jersey, Department of Health, Division of Health Facilities Evaluation and Licensing New Jersey Board of Medical Examiners (for private physician practices with only one OR)	N.J.A.C. 8:43E-5.3 (2015)	Centers where surgical or other medical procedures can be safely performed without requiring the patient to stay in the hospital overnight. The ambulatory surgery facility may be physically connected to another licensed facility, such as a hospital, but is corporately and administratively distinct. They are also referred to as surgicenters, same day surgery centers, or outpatient surgery centers.	License required for facilities with more than one OR.	Private physician practices with only one OR are regulated by the state Board of Medical Examiners. Inspections for licensed clinics occur every three years. Requirements for counseling are outlined in the Administrative Code.	The facility shall establish and implement written policies and procedures concerning the identification of the need for counseling services and referral to counseling services. (§416.45. Medical staff)
New Mexico	New Mexico Department of Health - Health Facility Licensing & Certification Bureau (HFL&C)	7.11.2.3 NMAC - Rn, 7 NMAC 11.2.3	A facility that operates exclusively for the purpose of providing surgical services without anticipation of overnight stay of patients. This type of facility may be integrated with the surgical department of an existing hospital and its outpatient department utilizing many of their services and resources. Those facilities which are freestanding may provide some services such as specialized diagnostic and laboratory by agreement or contract with another healthcare provider.	Yes	At least one examination or treatment room meeting the requirements outlined in Sections 57 and 58 of 7.11.2 NMAC. An emergency communication connected with the surgical control station is required. Flammable anesthetics are not permitted.	None

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New York	New York State Department of Health	10 NYCRR Section 755.1	An ASC provides surgical procedures which need to be performed for safety reasons in an operating room on anesthetized patients requiring a stay of less than 24 hours' duration. These procedures include services for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition, but do not include those outpatient surgical procedures which can be performed safely in a private physician's office or an outpatient treatment room.	Yes	Physician offices that perform surgical or invasive procedures using more than mild sedation must be accredited by the AAAHC, AAAASF, or The Joint Commission within two full years of operation.[4]	None
North Carolina	North Carolina Department of Health and Human Services, Division of Health Service Regulation, Acute and Home Care Licensure and Certification Section	Pursuant to NC General Statute 131E-149, the NC Medical Care Commission has rulemaking authority. Rules in Title 10A of the NC Administrative Code (10A NCAC 13C) apply.	A facility designed for the provision of a specialty ambulatory surgical program or a multispecialty ambulatory surgical program and serves patients who require local, regional or general anesthesia and a period of post-operative observation.	Yes	Ambulatory surgery facilities are required to obtain accreditation from AAAHC or a comparable accreditation authority within two years of completion of the facility.[5] An ambulatory surgery facility accredited by The Joint Commission, AAAHC or AAAASF is deemed to meet licensure requirements.[6]	A post-anesthesia note containing the general condition of the patient and any instructions to the patient must be written prior to discharge. (§416.52. Patient admission, assessment and discharge)

4 http://www.aaahc.org/en/news/federal-and-state-regulations/state-laws-and-regulations/

5 http://www.aaahc.org/en/news/federal-and-state-regulations/state-laws-and-regulations/

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North Dakota	North Dakota Department of Health	North Dakota Century Code section 23-16-01	ASC means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission. This includes surgical and trauma centers and may be operated in connection with a hospital.	Yes	Administration of drugs and blood transfusions must be in accordance with state law.	None
Ohio	Ohio Department of Health, Division of Quality Assurance, Bureau of Information and Operational Support	Sections 3702.12 and 3702.13 of the Revised Code	A licensed ambulatory surgical facility (ASF) that provides outpatient surgery services and anesthesia in a facility that functions separately from a hospital's inpatient surgical service and private doctor's office.	Yes	Specific signage must be visible in ASCs that perform abortions.[7]	None
Oklahoma	Oklahoma State Department of Health, Medical Facilities Division	OAC 310:615 Authority: 63 O.S. 1990 Supp. §§ 2657-2665	An establishment with an organized medical staff of physicians, with permanent facilities that are equipped and operated primarily for the purpose of performing surgical procedures, with continuous physician services available on call, and registered professional nurse services on site, whenever a patient is in the facility, which provides services or other accommodations for patients to recover for a period not to exceed 23 hours after surgery.	Yes	Environmental pollution control considerations must be in place.	None

[6] http://www.jointcommission.org/state_recognition/state_recognition_details.aspx?ps=100&s=NC

[7] http://codes.ohio.gov/orc/3702.30

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Oregon	Oregon Health Authority, Oregon Public Health Division, Center for Health Protection, Health Care Regulation and Quality Improvement	OAR 333-076	A facility or portion of a facility which performs outpatient surgery not routinely or customarily performed in physician's offices or dentist's offices and for whom the expected duration of services does not exceed 24 hours following admission. This excludes private physician/dentist offices that lack distinct areas for outpatient services and portions of a licensed hospital designated for outpatient surgical treatment.	Yes	In-service training for nurses must be held each year.	None
Pennsylvania	Pennsylvania Department of Health, Division of Acute and Ambulatory Care	Chapter 8 of the act (35 P. S.§§448.801—448.820), and section 2102(a) and (g) of The Administrative Code of 1929 (71 P. S.§532(a) and (g))	A facility or portion thereof not located upon the premises of a hospital which provides specialty or multispecialty outpatient surgical treatment. This does not include individual or group practice offices of private physicians or dentists, unless the offices have a distinct part used solely for outpatient surgical treatment on a regular and organized basis.	Yes, except for Class A facilities (i.e., those limited to local or topical anesthesia)	For Class A facilities, must register and obtain accreditation from a named accreditation organization, including AAAHC.	None

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Rhode Island	Rhode Island Department of Health	R23-17-FASC	"Freestanding Ambulatory Surgical Center" is an establishment or place which may be a public or private organization equipped and operated exclusively for ambulatory patients for the purpose of performing surgical procedures which have the approval of the governing body and which in the opinion of the surgeon and anesthesiologist can be performed safely without requiring extensive anesthesia or overnight stay. Includes ambulatory podiatry services.	Yes	License issued for a specified number of rooms and recovery beds. Smoking is not permitted. Within 24 months of initial licensure, the physician ambulatory surgery center/ podiatry ambulatory surgery center must attain appropriate certification from an accreditation agency, and certification must be maintained as a condition of licensure.	None
South Carolina	South Carolina Department of Health and Environmental Control	REGULATION NO. 61-91 Statutory Authority - §44-7-260 S.C. Code Ann. (2002) SECTION 100	A distinct, freestanding, self-contained entity that is organized, administered, equipped, and operated exclusively for the purpose of performing surgical procedures or related care, treatment, procedures, and/or services, e.g., endoscopy, for which patients are scheduled to arrive, receive surgery or related care, treatment, procedures, and/or services, and be discharged on the same day.	Yes	Food served must be approved by the Division of Health Licensing. Live animals are not permitted in facilities.	None

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South Dakota	South Dakota Department of Heath Office of Health Facilities Licensure & Certification	SDCL 34-12-13	A facility which operates exclusively for the purposes of providing surgical services to patients not requiring hospitalization. Services are limited to those surgical and other medical procedures that may be safely performed in a dedicated operating room or suite and which may require a postoperative recovery room or short-term, not overnight, convalescent room. An ASC may not retain patients overnight. Surgical procedures which may not be performed in an ASC include those that: generally result in extensive blood loss, require major or prolonged invasion of body cavity, directly involved major blood vessels, are emergent or life-threatening in nature, or require admission to an inpatient hospital in order to perform procedure or recover.	Yes	None	None

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Tennessee	Tennessee Department of Health, Bureau of Health Licensure and Regulation, Board for Licensing Health Care Facilities, Division of Health Care Facilities	Rule 1200-08-10-.02	Any institution, place or building devoted primarily to the maintenance and operation of a facility for the performance of surgical procedures. Such facilities shall not provide beds or other accommodations for the stay of a patient to exceed 12 hours duration, provided that the length of stay may be extended for an additional 12 hours in the event such stay is deemed necessary by the attending physician, the facility medical director, or the anesthesiologist for observation or recovery, but in no event shall the length of stay exceed 24 hours.	Yes	"No smoking" signs must be posted at every entrance. If possible, the facility should be or agree to become accredited by any accrediting organization approved by CMS, such as The Joint Commission, AAAHC, AAAASF, or other nationally recognized accrediting organization.	None
Texas	Texas Department of State Health Services, Facility Licensing Group	Acts 1989, 71st Leg., ch. 678, Sec. 1; Title 25, Part 1, Chapter 135, Subchapter C, Rule 135.51	ASC means a facility that operates primarily to provide surgical services to patients who do not require overnight hospital care. An ASC must provide surgical services as its primary service. ASCs do not provide overnight or inpatient care. Care is provided on an outpatient basis.	Yes	None	None

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Utah	Utah Department of Health, Bureau of Health Facility Licensing, Certification, and Resident Assessment within the Division of Health Systems Improvement	R432-2-1	An ambulatory surgical facility is a freestanding facility, which provides surgical services to patients not requiring hospitalization.	Yes	The facility must obtain a food service establishment permit if required by the local health department.[8]	The physician must document the reason for admission to an extended recovery service and dietary orders. (§416.52. Patient admission, assessment and discharge)
Vermont	Vermont Department of Health, Agency of Human Services, Division of Licensing and Protection, Department of Disabilities, Aging & Independent Living	The Vermont Statutes Title 18, Chapter 221, 18 V.S.A. § 9434	A facility or portion of a facility that provides surgical care not requiring an overnight stay. The office of a dentist in which activities are limited to dentistry and oral or maxillofacial surgical procedures shall not be deemed an ambulatory surgical center.	No	No information on state standards could be found.	No information on state standards could be found.
Virginia	Virginia Department of Health, Office of Licensure and Certification	§§ 32.1-12 and 32.1-127 of the Code of Virginia	"Outpatient hospital" means institutions as defined by § 32.1-123 of the Code of Virginia that primarily provide facilities for the performance of surgical procedures on outpatients. Such patients may require treatment in a medical environment exceeding the normal capability found in a physician's office, but do not require inpatient hospitalization.	Yes	Must provide at least one physician licensed to practice in the state. Must establish protocol for organ donation.	None

[8] http://www.rules.utah.gov/publicat/code/r432/r432-500.htm#T17

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Washington	Washington State Department of Health	Chapter 70.230 RCW	A facility that operates for the primary purpose of providing specialty or multispecialty outpatient surgical services in which patients are admitted to and discharged from the facility within twenty-four hours and do not require inpatient hospitalization. "Surgical services" are defined as invasive medical procedures by a practitioner using a knife, laser, cautery, cryogenics or chemicals to remove, correct or facilitate the diagnosis or cure of a disease, process, injury or deformity.	Yes	Regulations related to construction, quality improvement, safety and emergency training are similar to those in the CFR, but no other conditions similar or beyond those in the CFR were found. After three years, a facility may meet state licensing standards by providing documentation that it has met the standards of an approved accreditation organization or federal agency.	None
West Virginia	West Virginia Department of Health & Human Resources, Office of Health Facility Licensure and Certification	West Virginia Code Chapter 16. Public Health. Article 5B	A facility which provides surgical treatment to patients not requiring hospitalization. This definition does not include the legally authorized practice of surgery by any one or more persons in the private office of any healthcare provider.	Yes	Licenses shall be issued for a particular number by type of beds and/or type of services.	None
Wisconsin	Wisconsin Department of Health Services	No statutes apply	A place that provides day surgery services to persons who need less than 24-hour nursing/medical care.	No	No information on state standards could be found.	No information on state standards could be found.
Wyoming	Wyoming Department of Health, Healthcare Licensing and Surveys	Health Facilities Licensure Act at W. S. 35-2-901 et seq. and the Wyoming Administrative Procedures Act at W. S. 16-3-101 et seq.	A facility which provides surgical treatment to patients not requiring hospitalization and is not part of a hospital or an office of private physicians, dentists or podiatrists.	Yes	Extended recovery care services shall not be provided to more than four patients anywhere in the ASC, between the hours of 10:00 p.m. and 6:00 a.m.	None

Table A2. State Licensing Laws: CORFs

STATE	REGULATORY AGENCY	RULEMAKING AUTHORITY	CORF: DEFINITION & EXCLUSIONS	STATE LICENSURE REQUIRED?	ADDITIONAL STATE LICENSURE REQUIREMENTS NOT ADDRESSED IN FEDERAL STANDARDS	ADDITIONAL STATE DETAIL FOR EXISTING FEDERAL STANDARDS (RELEVANT CFR §)
Alabama	Alabama Department of Public Health, Bureau of Health Provider Standards, Division of Licensure and Certification	Chapter 420-5-11, Code of Ala. 1975, Section 22-21-20, et seq.	A rehabilitation center is a business entity offering and providing outpatient assistance in the rehabilitation of disabled persons by providing two or more services that must be performed by or under the supervision of a physical therapist, occupational therapist or speech pathologist. This term does not include a business entity that is a certified home health agency.	Yes	Requirements for communication systems and narcotic permits are outlined in the administrative code.	Extensive guidelines for the provision of an admission office, waiting room, and housekeeping set forth in the state administrative code. (§485.62. Physical environment) There shall be an adequate number of telephones to summon help in case of fire or other emergency, and these shall be located so as to be quickly accessible from all parts of the building. (§485.64 Disaster procedures)
Alaska	Alaska Department of Health and Social Services Division of Health Care Services Health Facilities Licensing and Certification (HFLC) program	No statutes apply	None provided	No	No information on state standards could be found.	No information on state standards could be found.
Arizona	Arizona Department of Health Services, Division of Licensing, Bureau of Medical Facilities Licensing	9 A.A.C. 10	Rehabilitation centers are grouped into a general outpatient treatment center section, which includes behavioral health services, dialysis services, sleep disorder services, and urgent care, among others.	Yes, with exceptions for hospitals and facilities affiliated with a licensed healthcare institution.	None	None

Table A2. State Licensing Laws: CORFs

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Arkansas	Arkansas Department of Health, Health Facilities Services	Arkansas Administrative Code (AAC) 007.05 Section 81	Definitions mirror CMS standards. Rehabilitation facilities may be organized under hospitals (organized departments of rehabilitation), outpatient clinics, rehabilitation centers, and other facilities designed to serve either single- or multiple-disability categories.	No	None	None
California	California Department of Public Health	Division 2. Licensing provisions	A clinic that, in addition to providing medical services directly, also provides physical rehabilitation services for patients who remain less than 24 hours. Rehabilitation clinics shall provide at least two of the following rehabilitation services: physical therapy, occupational therapy, social, speech pathology, and audiology services. A rehabilitation clinic does not include the offices of a private physician in individual or group practice.	Yes	None.	None
Colorado	Colorado Department of Public Health & Environment, Health Facilities Division	No relevant statutes could be found	CORFs are established and operated exclusively for the purpose of providing diagnostic, therapeutic, and restorative services for the rehabilitation of injured, disabled, or sick persons by or under the supervision of a physician.	No	No information on state standards could be found.	No information on state standards could be found.
Connecticut	Connecticut Department of Public Health	No relevant statutes could be found	None provided	No	No information on state standards could be found.	No information on state standards could be found.
Delaware	Delaware Department of Health and Social Services, Health Facilities Licensing and Certification	No relevant statutes could be found	None provided	No	No information on state standards could be found.	No information on state standards could be found.

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District of Columbia	The Mayor of Washington, DC	No relevant statutes could be found	None provided	No	No information on state standards could be found.	No information on state standards could be found.
Florida	Florida Agency for Health Care Administration	No relevant statutes could be found	A non-residential facility providing diagnostic, therapeutic, and restorative services at a single fixed location for the rehabilitation of injured, disabled, or sick persons, by or under the supervision of a physician.	No	No information on state standards could be found.	No information on state standards could be found.
Georgia	Georgia Department of Community Health, Healthcare Facility Regulation Division, Office of Facility Licensure	No statutes apply	A nonresidential facility that provides coordinated outpatient diagnostic, therapeutic and restorative services at a single fixed location to outpatients for the rehabilitation of injured, disabled or sick individuals. Physical therapy, occupational therapy and speech-language pathology services may be provided in an off-site location.	No	None	None
Hawaii	State of Hawaii, Department of Health, Office of Health Care Assurance	No statutes apply	None provided	No	None	None
Idaho	Idaho Department of Health and Welfare, Division of Licensing and Certification	No statutes apply	None provided	No	None	None
Illinois	Illinois Department of Public Health, Office of Health Care Regulation	No statutes apply	None provided	No	None	None
Indiana	Indiana State Department of Health, Division of Acute Care	No statutes apply	None provided	No	None	None

Table A2. State Licensing Laws: CORFs

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Iowa	Iowa Department of Public Health, Health Facilities Division	No relevant statutes could be found	None provided	No	None	None
Kansas	Kansas Department of Health and Environment	No statutes apply	None provided	No	None	None
Kentucky	Kentucky Cabinet for Health and Family Services, Division of Health Care	902 KAR 20:190	An organization with permanent facilities which provides services designed to upgrade the physical function of handicapped and disabled individuals. Rehabilitation agency services include long-term care facilities and facilities that provide physical therapy or speech pathology services and may also provide audiology or occupational therapy.	Yes	None	None
Louisiana	Louisiana Department of Health and Hospitals, Health Standards Section (HSS)	No statutes apply	A CORF is a nonresidential facility that is established and operated exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients.	No	CMS certification is required.	None
Maine	Maine Department of Health and Human Services, Division of Licensing and Regulatory Services	No statutes apply	None provided	No	None	None

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STATE	REGULATORY AGENCY	RULEMAKING AUTHORITY	CORF: DEFINITION & EXCLUSIONS	STATE LICENSURE REQUIRED?	ADDITIONAL STATE LICENSURE REQUIREMENTS NOT ADDRESSED IN FEDERAL STANDARDS	ADDITIONAL STATE DETAIL FOR EXISTING FEDERAL STANDARDS (RELEVANT CFR §)
Maryland	Maryland Department of Health and Mental Hygiene, Office of Health Care Quality, Ambulatory Care Programs Unit	10.07.18.04	Any person who provides or holds itself out as providing comprehensive physical rehabilitation services on an out-patient basis.	Yes	Licensees must keep records and make reports in the manner and form as the Secretary shall prescribe and be open to inspection by the Secretary; accreditation by the Commission on Accreditation of Rehabilitation Facilities is required.	Licensees must keep records and make reports in the manner and form as the Secretary shall prescribe and be open to inspection by the Secretary (§485.60. Clinical records)
Massachusetts	Massachusetts Department of Public Health, Division of Health Care Facility Licensure and Certification	No statutes apply	None provided	No	None	None
Michigan	Michigan Department of Community Health, Bureau of Health Systems, Department of Licensing and Regulatory Affairs	No relevant statutes could be found	None provided	No	No information on state standards could be found.	No information on state standards could be found.
Minnesota	Minnesota Department of Health	No relevant statutes could be found	None provided	No	No information on state standards could be found.	No information on state standards could be found.
Mississippi	Mississippi State Department of Health	No relevant statutes could be found	A facility that is established and operated at a single fixed location, exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients by or under the supervision of a physician. A CORF must provide, at minimum, physicians' services, physical therapy, and social or psychological services.	No	No information on state standards could be found.	No information on state standards could be found.

Table A2. State Licensing Laws: CORFs

STATE	REGULATORY AGENCY	RULEMAKING AUTHORITY	CORF: DEFINITION & EXCLUSIONS	STATE LICENSURE REQUIRED?	ADDITIONAL STATE LICENSURE REQUIREMENTS NOT ADDRESSED IN FEDERAL STANDARDS	ADDITIONAL STATE DETAIL FOR EXISTING FEDERAL STANDARDS (RELEVANT CFR §)
Missouri	Missouri Department of Health and Senior Services, Health Services Regulation	No relevant statutes could be found	A comprehensive outpatient rehabilitation facility (CORF) is a facility that provides a variety of services.	No	Certification required.	None
Montana	Montana Department of Public Health and Human Services, Quality Assurance Division	37.106.310	None provided.	No	None	None
Nebraska	Nebraska Department of Health & Human Services, Division of Public Health Licensure Unit	Laws 2000, LB 819, § 32; Laws 2002, LB 1062, § 41	Person or agency that provides occupational therapy services.	No	None	None
Nevada	Nevada Department of Health and Human Services, Division of Public and Behavioral Health	NRS (Nevada Revised Statutes) Chapter 449; NAC (Nevada Administrative Code) Chapter 449	A health facility that includes a public health center, hospital, facility for hospice care, facility for persons with intellectual disabilities, community mental health center, and other facility to provide rehabilitation.	No	No information on state standards could be found.	No information on state standards could be found.
New Hampshire	New Hampshire Department of Health and Human Services; Health Services Planning & Review Board	RSA 151	None provided.	No	No information on state standards could be found.	No information on state standards could be found.

Table A2. State Licensing Laws: CORFs

STATE	REGULATORY AGENCY	RULEMAKING AUTHORITY	CORF: DEFINITION & EXCLUSIONS	STATE LICENSURE REQUIRED?	ADDITIONAL STATE LICENSURE REQUIREMENTS NOT ADDRESSED IN FEDERAL STANDARDS	ADDITIONAL STATE DETAIL FOR EXISTING FEDERAL STANDARDS (RELEVANT CFR §)
New Jersey	State of New Jersey, Department of Health, Division of Health Facilities Evaluation and Licensing	N.J.A.C. 8:43A	An ambulatory care facility which provides medical, physical therapy and social or psychological services in a coordinated manner. The term applies to facilities which are certified or eligible for certification as comprehensive outpatient rehabilitation facilities in accordance with 42 CFR Part 485, Subpart B.	Yes	Must be certified or eligible for certification.	None
New Mexico	New Mexico Department of Health - Health Facility Licensing & Certification Bureau (HFL&C)	No relevant statutes could be found	None provided.	No	None	None
New York	New York State Department of Health	No relevant statutes could be found	None provided.	No	None	None
North Carolina	North Carolina Department of Health and Human Services, Division of Health Service Regulation, Acute and Home Care Licensure and Certification Section	No statutes apply	None provided.	No	No information on state standards could be found.	No information on state standards could be found.

Table A2. State Licensing Laws: CORFs

STATE	REGULATORY AGENCY	RULEMAKING AUTHORITY	CORF: DEFINITION & EXCLUSIONS	STATE LICENSURE REQUIRED?	ADDITIONAL STATE LICENSURE REQUIREMENTS NOT ADDRESSED IN FEDERAL STANDARDS	ADDITIONAL STATE DETAIL FOR EXISTING FEDERAL STANDARDS (RELEVANT CFR §)
North Dakota	North Dakota Department of Health	No relevant statutes could be found	Comprehensive Outpatient Rehabilitation Facility (CORF) is a nonresidential facility established and operated exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled or sick persons, at a single fixed location, by or under the supervision of a physician.	No	No information on state standards could be found.	No information on state standards could be found.
Ohio	Ohio Department of Health, Division of Quality Assurance, Bureau of Information and Operational Support	No statutes apply	A CORF is a functionally and operationally independent facility established and operated at a single fixed location exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients by or under the supervision of a physician. A CORF must provide, at a minimum, physicians' services, physical therapy, and social or psychological services. With the exception of physical therapy, occupational therapy, and speech pathology, all CORF services must be provided on the CORF premises.	No	None	None
Oklahoma	Oklahoma State Department of Health, Medical Facilities Division	No statutes apply	None provided	No	CMS certification is required.	None

Table A2. State Licensing Laws: CORFs

STATE	REGULATORY AGENCY	RULEMAKING AUTHORITY	CORF: DEFINITION & EXCLUSIONS	STATE LICENSURE REQUIRED?	ADDITIONAL STATE LICENSURE REQUIREMENTS NOT ADDRESSED IN FEDERAL STANDARDS	ADDITIONAL STATE DETAIL FOR EXISTING FEDERAL STANDARDS (RELEVANT CFR §)
Oregon	Oregon Health Authority, Oregon Public Health Division, Center for Health Protection, Health Care Regulation and Quality Improvement	No statutes apply	None provided	No	None	None
Pennsylvania	Pennsylvania Department of Health, Division of Acute and Ambulatory Care	No statutes apply	CORFs provide coordinated rehabilitation programs that include physician services, physical therapy services and social or psychological services. The facility is intended to provide diagnostic, therapeutic and restorative services to injured, disabled or ill individuals.	No	None	None
Rhode Island	Rhode Island Department of Health	No relevant statutes could be found	None provided	No	No information on state standards could be found.	No information on state standards could be found.
South Carolina	South Carolina Department of Health and Environmental Control	No relevant statutes could be found	None provided	No	No information on state standards could be found.	No information on state standards could be found.
South Dakota	South Dakota Department of Heath Office of Health Facilities Licensure & Certification	No statutes apply	None provided	No	None	None
Tennessee	Tennessee Department of Health Office of Health Care Facilities	No statutes apply	None provided	No	None	None

Table A2. State Licensing Laws: CORFs

STATE	REGULATORY AGENCY	RULEMAKING AUTHORITY	CORF: DEFINITION & EXCLUSIONS	STATE LICENSURE REQUIRED?	ADDITIONAL STATE LICENSURE REQUIREMENTS NOT ADDRESSED IN FEDERAL STANDARDS	ADDITIONAL STATE DETAIL FOR EXISTING FEDERAL STANDARDS (RELEVANT CFR §)
Texas	Texas Department of State Health Services' Health Facility Program	No statutes apply	A CORF is a nonresidential facility that is established and operated exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons, at a single fixed location, by or under the supervision of a physician.	No	None; facilities are not eligible for accreditation.	None
Utah	Utah Department of Health Bureau of Health Facility Licensing, Certification, and Resident Assessment within the Division of Health Systems Improvement	R432-12-12	None provided	No	Construction rules apply.	None
Vermont	Department of Health	No statutes found	None provided	No	No information on state standards could be found.	No information on state standards could be found.
Virginia	Virginia Department of Health, Office of Licensure and Certification	No relevant statutes could be found	None provided	No	No information on state standards could be found.	No information on state standards could be found.
Washington	Washington State Department of Health	No statutes apply	Rehabilitation agencies provide physical and occupational therapy, speech and language services and social or vocational adjustment services. These services are provided in an out-patient setting to disabled people with the goal of upgrading their physical functioning. Rehabilitation agencies include CORFs.	No	None	None

Table A2. State Licensing Laws: CORFs

STATE	REGULATORY AGENCY	RULEMAKING AUTHORITY	CORF: DEFINITION & EXCLUSIONS	STATE LICENSURE REQUIRED?	ADDITIONAL STATE LICENSURE REQUIREMENTS NOT ADDRESSED IN FEDERAL STANDARDS	ADDITIONAL STATE DETAIL FOR EXISTING FEDERAL STANDARDS (RELEVANT CFR §)
West Virginia	West Virginia Department of Health & Human Resources, Office of Health Facility Licensure and Certification	No statutes apply	None	No	None	None
Wisconsin	Wisconsin Department of Health Services	No statutes apply	A facility providing rehabilitation services on an outpatient basis.	No	None	None
Wyoming	Wyoming Department of Health, Office of Healthcare Licensing and Surveys	W.S. 35-2-901 et seq. and W.S. 16-3-101 et seq.	An outpatient facility operated for the primary purpose of assisting the rehabilitation of disabled persons including persons with acquired brain injury by providing comprehensive medical evaluations and services, psychological and social services, or vocational evaluations and training in which the major portion of the services is furnished within the facility.	Yes	Rehabilitation facilities providing services to adults with developmental disabilities must maintain CORF accreditation.	None

Table A3. State Licensing Laws: ESRD Facilities

STATE	REGULATORY AGENCY	RULEMAKING AUTHORITY	ESRD FACILITY: DEFINITION & EXCLUSIONS	STATE LICENSURE REQUIRED?	ADDITIONAL STATE LICENSURE REQUIREMENTS NOT ADDRESSED IN FEDERAL STANDARDS	ADDITIONAL STATE DETAIL FOR EXISTING FEDERAL STANDARDS (RELEVANT CFR §)
Alabama	Alabama Department of Public Health, Bureau of Health Provider Standards, Division of Licensure and Certification	Code of Alabama 420-5-5-.01	A non-hospital-based facility which furnishes end-stage renal dialysis treatment to non-hospitalized patients but does not provide a full spectrum of diagnostic, therapeutic and rehabilitative services.	Yes	None	None
Alaska	Alaska Department of Health and Social Services Division of Health Care Services Health Facilities Licensing and Certification (HFLC) program	No statutes apply	None provided	No	No information on state standards could be found.	No information on state standards could be found.
Arizona	Arizona Department of Health Services, Division of Licensing, Bureau of Medical Facilities Licensing	9 A.A.C. 10	None provided	Yes	None	None
Arkansas	Arkansas Department of Health, Health Facilities Services	No relevant statutes could be found	None provided	No	No information on state standards could be found.	No information on state standards could be found.
California	California Department of Public Health	DIVISION 2. LICENSING PROVISIONS	A “free-standing specialty clinic, which provides less than 24-hour care for the treatment of patients with End-Stage Renal Disease.”	Yes	None	None

Table A3. State Licensing Laws: ESRD Facilities

STATE	REGULATORY AGENCY	RULEMAKING AUTHORITY	ESRD FACILITY: DEFINITION & EXCLUSIONS	STATE LICENSURE REQUIRED?	ADDITIONAL STATE LICENSURE REQUIREMENTS NOT ADDRESSED IN FEDERAL STANDARDS	ADDITIONAL STATE DETAIL FOR EXISTING FEDERAL STANDARDS (RELEVANT CFR §)
Colorado	Colorado Department of Public Health & Environment, Health Facilities Division	6 CCR 1011-1 Chap 10	A dialysis treatment clinic is a health facility or a department or unit of a licensed hospital that is planned, organized, operated, and maintained to provide outpatient hemodialysis treatment or hemodialysis training for home use of hemodialysis equipment.	Yes	Outpatient hemodialysis treatment to a non-ESRD patient without a referral for treatment from a board-certified or board-eligible nephrologist licensed as a physician in Colorado is not permitted.	None
Connecticut	Connecticut Department of Public Health	Connecticut General Statutes, Section 19a-491	An out-of-hospital out-patient dialysis unit that is a licensed facility which provides services on an out-patient basis to persons requiring dialysis on a short-term basis or for a chronic condition or training for home dialysis	Yes[1]	No information on state standards could be found.	No information on state standards could be found.
Delaware	Delaware Department of Health and Social Services, Health Facilities Licensing and Certification	No statutes apply	None provided	No	None	None
District of Columbia	The Mayor of Washington, DC	Title 44 of the DC Official Code	Any place, other than a hospital or the patient's home, that provides therapeutic care for persons with acute or chronic renal failure through the use of hemodialysis, peritoneal dialysis, or any other therapy that clears the blood of substances normally excreted by the kidneys.	Yes	State standards and procedures cannot be less stringent than the guidelines in the Association for Advancement of Medical Instrumentation Recommended Practice or Centers for Disease Control and Prevention Recommendations.	Reuse of tubing or transducer protectors and reuse of hemodialyzer or dialyzer caps without expressed written consent are not permitted. (§494.50. Reuse of hemodialyzers and bloodlines)

[1] http://www.ct.gov/dph/lib/dph/public_health_code/sections/19-13-d55a_dialysis_units.pdf

Table A3. State Licensing Laws: ESRD Facilities

STATE	REGULATORY AGENCY	RULEMAKING AUTHORITY	ESRD FACILITY: DEFINITION & EXCLUSIONS	STATE LICENSURE REQUIRED?	ADDITIONAL STATE LICENSURE REQUIREMENTS NOT ADDRESSED IN FEDERAL STANDARDS	ADDITIONAL STATE DETAIL FOR EXISTING FEDERAL STANDARDS (RELEVANT CFR §)
Florida	Florida Agency for Health Care Administration (AHCA)	No statutes apply	None provided	No	None	None
Georgia	Georgia Department of Community Health, Healthcare Facility Regulation Division, Office of Facility Licensure	Authority O.C.G.A §31-2-11.	A renal dialysis facility is a unit that is approved to furnish dialysis service(s) directly to ESRD patients.	Yes	None	None
Hawaii	State of Hawaii, Department of Health, Office of Health Care Assurance	No statutes apply	None provided	No	None	None
Idaho	Idaho Department of Health and Welfare, Division of Licensing and Certification	No statutes apply	None provided	No	None	None
Illinois	Illinois Department of Public Health, Office of Health Care Regulation	(210 ILCS 62/) End Stage Renal Disease Facility Act	A facility that provides dialysis treatment or dialysis training to individuals with end-stage renal disease.	Yes	None	None
Indiana	Indiana State Department of Health, Division of Acute Care	No statutes apply	None provided	No	None	None
Iowa	Iowa Department of Public Health, Health Facilities Division	No relevant statutes could be found	A unit which is approved to furnish dialysis services to ESRD patients. Renal dialysis facilities may be hospital- or non-hospital-based.[2]	No	No information on state standards could be found.	No information on state standards could be found.

[2] https://www.legis.iowa.gov/docs/ACO/rule/1-25-2012.641.203.7.pdf

Table A3. State Licensing Laws: ESRD Facilities

STATE	REGULATORY AGENCY	RULEMAKING AUTHORITY	ESRD FACILITY: DEFINITION & EXCLUSIONS	STATE LICENSURE REQUIRED?	ADDITIONAL STATE LICENSURE REQUIREMENTS NOT ADDRESSED IN FEDERAL STANDARDS	ADDITIONAL STATE DETAIL FOR EXISTING FEDERAL STANDARDS (RELEVANT CFR §)
Kansas	Kansas Department of Health and Environment	No relevant statutes could be found	None provided	No	No information on state standards could be found.	No information on state standards could be found.
Kentucky	Kentucky Cabinet for Health and Family Services, Division of Health Care	902 KAR 20:018	"Renal dialysis center" means a hospital unit approved to furnish the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients, including inpatient dialysis furnished directly or under arrangement and excluding renal transportation.	Yes	None	None
Louisiana	Louisiana Department of Health and Hospitals, Health Standards Section (HSS)	Louisiana RS 40:2117.1.	An ESRD facility provides dialysis treatment or dialysis training to individuals diagnosed with ESRD. It does not include the following: a facility which provides only transplantation services, or ESRD facilities maintained by the state at any of its penal and correctional institutions, provided that nothing herein contained shall prevent a penal or correctional institution from applying for licensure of its ESRD facilities.	Yes	None	None
Maine	Maine Department of Health and Human Services, Division of Licensing and Regulatory Services	22 MRSA c. 412 §§2041-2042	A unit that is approved to furnish dialysis services directly to ESRD patients. “Renal dialysis facility” includes a self-dialysis unit or a special-purpose renal dialysis facility.	Yes	None	None

Table A3. State Licensing Laws: ESRD Facilities

STATE	REGULATORY AGENCY	RULEMAKING AUTHORITY	ESRD FACILITY: DEFINITION & EXCLUSIONS	STATE LICENSURE REQUIRED?	ADDITIONAL STATE LICENSURE REQUIREMENTS NOT ADDRESSED IN FEDERAL STANDARDS	ADDITIONAL STATE DETAIL FOR EXISTING FEDERAL STANDARDS (RELEVANT CFR §)
Maryland	Maryland Department of Health and Mental Hygiene, Office of Health Care Quality, Ambulatory Care Programs Unit	10.05.04	A dialysis unit capable of providing staff-assisted dialysis, which is not located in an acute hospital setting.	Yes	Medicare certification required.	None
Massachusetts	Massachusetts Department of Public Health, Division of Health Care Facility Licensure and Certification	105 CMR 145.000: M.G.L. c. 111, § 3, 51A, 53.	Out-of-hospital dialysis unit is one maintained separate from a licensed or approved hospital and provides chronic maintenance dialysis to persons suffering from chronic renal disease.	Yes	None	The unit shall obtain blood from a blood bank immediately prior to its administration. All blood so obtained shall be identified, stored, handled and administered in accordance with 105 CMR 135.000: Use of Blood, Blood Components and Derivatives for the Purpose of Transfusion. (§494.30. Infection control) A minimum of 110 sq. ft. of floor space per station is required. (§494.60. Physical environment)
Michigan	Michigan Department of Community Health, Bureau of Health Systems, Department of Licensing and Regulatory Affairs	No relevant statutes could be found	None provided	No	No information on state standards could be found.	No information on state standards could be found.

Table A3. State Licensing Laws: ESRD Facilities

STATE	REGULATORY AGENCY	RULEMAKING AUTHORITY	ESRD FACILITY: DEFINITION & EXCLUSIONS	STATE LICENSURE REQUIRED?	ADDITIONAL STATE LICENSURE REQUIREMENTS NOT ADDRESSED IN FEDERAL STANDARDS	ADDITIONAL STATE DETAIL FOR EXISTING FEDERAL STANDARDS (RELEVANT CFR §)
Minnesota	Minnesota Department of Health	No relevant statutes could be found	None provided	No[3]	No information on state standards could be found.	No information on state standards could be found.
Mississippi	Mississippi State Department of Health	No relevant statutes could be found	A facility that provides either or both hemodialysis or peritoneal dialysis to patients with irreversible and permanent kidney impairment. An ESRD facility may also provide self-care dialysis and/or self-care dialysis training.	No	No information on state standards could be found.	No information on state standards could be found.
Missouri	Missouri Department of Health and Senior Services, Health Services Regulation	No statutes apply	None provided	No	None	None
Montana	Montana Department of Public Health and Human Services, Quality Assurance Division	No relevant statutes could be found	A facility that specializes in the treatment of kidney diseases and includes freestanding hemodialysis units.[4]	No	No information on state standards could be found.	No information on state standards could be found.
Nebraska	Nebraska Department of Health & Human Services, Division of Public Health Licensure Unit	Neb. Rev.Stat. §§ 71-401 to 71-462.	A health clinic providing hemodialysis and not licensed as another type of healthcare facility	Yes	None	None

[3] https://www.revisor.mn.gov/statutes/?id=144.122

[4] http://leg.mt.gov/bills/BillHtml/SB0116.htm

Table A3. State Licensing Laws: ESRD Facilities

STATE	REGULATORY AGENCY	RULEMAKING AUTHORITY	ESRD FACILITY: DEFINITION & EXCLUSIONS	STATE LICENSURE REQUIRED?	ADDITIONAL STATE LICENSURE REQUIREMENTS NOT ADDRESSED IN FEDERAL STANDARDS	ADDITIONAL STATE DETAIL FOR EXISTING FEDERAL STANDARDS (RELEVANT CFR §)
Nevada	Nevada Department of Health and Human Services, Division of Public and Behavioral Health	Nevada Administrative Codes (NAC) chapter 449	A facility for the treatment of irreversible renal disease.	Yes	None	None
New Hampshire	New Hampshire Department of Health and Human Services; Health Services Planning & Review Board	RSA 151:9	A facility which provides hemodialysis or peritoneal dialysis on an outpatient basis and any other acute or chronic dialysis related procedures as approved by their governing body.	Yes	None	None
New Jersey	State of New Jersey, Department of Health, Division of Health Facilities Evaluation and Licensing	N.J.A.C. 8:43A-1 through 11 and 13 through 19, and subchapter 24	"Ambulatory dialysis" means maintenance dialysis therapy provided to an individual on an outpatient basis.	Yes	Facilities must have transfer agreements with at least one CMS-certified hospital to provide inpatient dialysis and one Department-licensed renal transplantation program. Policies related to criteria for handling aggressive patients and orientation of new patients are required. Food is prohibited.	Facilities must provide at least six stations and an emergency generator and water supply. (§494.60. Physical environment)
New Mexico	New Mexico Department of Health - Health Facility Licensing & Certification Bureau (HFL&C)	7.36.2 NMAC	A unit which is located in a building other than a hospital which is approved and licensed to furnish dialysis services directly to ESRD patients.	Yes	None	None
New York	New York State Department of Health	No relevant statutes could be found	None provided.	No	No information on state standards could be found.	No information on state standards could be found.

Table A3. State Licensing Laws: ESRD Facilities

STATE	REGULATORY AGENCY	RULEMAKING AUTHORITY	ESRD FACILITY: DEFINITION & EXCLUSIONS	STATE LICENSURE REQUIRED?	ADDITIONAL STATE LICENSURE REQUIREMENTS NOT ADDRESSED IN FEDERAL STANDARDS	ADDITIONAL STATE DETAIL FOR EXISTING FEDERAL STANDARDS (RELEVANT CFR §)
North Carolina	North Carolina Department of Health and Human Services, Division of Health Service Regulation, Acute and Home Care Licensure and Certification Section	No statutes apply	None provided.	No	No information on state standards could be found.	No information on state standards could be found.
North Dakota	North Dakota Department of Health	No relevant statutes could be found	Kidney dialysis units provide renal dialysis services necessary for residents of the state with kidney impairment to live normal lives.	No	No information on state standards could be found.	No information on state standards could be found.
Ohio	Ohio Department of Health, Division of Quality Assurance, Bureau of Information and Operational Support	Ohio Revised Code, section 3702.141	A freestanding dialysis center is a facility that provides chronic maintenance dialysis to end-stage renal disease patients on an outpatient basis, including dialysis services in the patient's place of residence. A certified end-stage renal disease facility is a facility that provides outpatient maintenance dialysis services, or home dialysis training and support services, or both. A dialysis center may be independent or hospital-based unit.	Yes	None	None
Oklahoma	Oklahoma State Department of Health, Medical Facilities Division	No statutes apply	None provided	No	CMS certification is required.	

Table A3. State Licensing Laws: ESRD Facilities

STATE	REGULATORY AGENCY	RULEMAKING AUTHORITY	ESRD FACILITY: DEFINITION & EXCLUSIONS	STATE LICENSURE REQUIRED?	ADDITIONAL STATE LICENSURE REQUIREMENTS NOT ADDRESSED IN FEDERAL STANDARDS	ADDITIONAL STATE DETAIL FOR EXISTING FEDERAL STANDARDS (RELEVANT CFR §)
Oregon	Oregon Health Authority, Oregon Public Health Division, Center for Health Protection, Health Care Regulation and Quality Improvement	OAR 333-700: Outpatient Renal Dialysis Facility Rules	An outpatient renal dialysis facility.	Yes	None	None
Pennsylvania	Pennsylvania Department of Health, Division of Acute and Ambulatory Care	No statutes apply	Kidney Dialysis Centers provide services including support from physicians, nurses, nutritionists, and social workers to individuals with chronic kidney failure by offering dialysis treatment or education on how to perform dialysis at home.	No	None	None
Rhode Island	Rhode Island Department of Health	R23-17-DIAL	A "free-standing (non-hospital) dialysis facility for renal disease" which may be a public or private organization or sub-unit of such an agency or organization providing chronic maintenance dialysis to ambulatory patients on the premises of the facility or in the patient's place of residence.	Yes	None	None
South Carolina	South Carolina Department of Health and Environmental Control	Regulation 61-97 - Standards For Licensing	An outpatient facility which offers staff assisted dialysis or training and support services for self-dialysis to end-stage renal disease patients. A facility may be composed of one or more fixed buildings, mobile units, or a combination.	Yes	None	None
South Dakota	South Dakota Department of Heath Office of Health Facilities Licensure & Certification	No statutes apply	None provided	No	None	None

Table A3. State Licensing Laws: ESRD Facilities

STATE	REGULATORY AGENCY	RULEMAKING AUTHORITY	ESRD FACILITY: DEFINITION & EXCLUSIONS	STATE LICENSURE REQUIRED?	ADDITIONAL STATE LICENSURE REQUIREMENTS NOT ADDRESSED IN FEDERAL STANDARDS	ADDITIONAL STATE DETAIL FOR EXISTING FEDERAL STANDARDS (RELEVANT CFR §)
Tennessee	Tennessee Department of Health, Bureau of Health Licensure and Regulation, Board for Licensing Health Care Facilities, Division of Health Care Facilities	CHAPTER 1200-08-32	Any institution, facility, place or building devoted to the provision of renal dialysis on an outpatient basis to persons diagnosed with end-stage renal disease.	Yes	None	None
Texas	Texas Department of State Health Services, Facility Licensing Group	25 TAC § 117	A facility that provides dialysis treatment or dialysis training and support to individuals with end-stage renal disease.	Yes	None	None
Utah	Utah Department of Health Bureau of Health Facility Licensing, Certification, and Resident Assessment within the Division of Health Systems Improvement	R432-650-1	Approved dialysis facility means any free-standing State-licensed facility providing dialysis services, and certified to participate in the Medicare program.	Yes	CMS certification is required.	Facilities must establish a written health surveillance and evaluation program for facility personnel (according to the Communicable Disease Rule, R386-702, Tuberculosis Control Rule, R388-804, and OSHA guidelines for Blood borne Pathogens) that includes a health status exam. (§494.30. Infection control)
Vermont	Vermont Agency of Human Services, Division of Licensing and Protection, Department of Disabilities, Aging & Independent Living	No statutes apply	None provided	No	None	None

Table A3. State Licensing Laws: ESRD Facilities

STATE	REGULATORY AGENCY	RULEMAKING AUTHORITY	ESRD FACILITY: DEFINITION & EXCLUSIONS	STATE LICENSURE REQUIRED?	ADDITIONAL STATE LICENSURE REQUIREMENTS NOT ADDRESSED IN FEDERAL STANDARDS	ADDITIONAL STATE DETAIL FOR EXISTING FEDERAL STANDARDS (RELEVANT CFR §)
Virginia	Virginia Department of Health, Office of Licensure and Certification	No relevant statutes could be found	None provided	No	No information on state standards could be found.	No information on state standards could be found.
Washington	Washington State Department of Health	No statutes apply	Kidney centers, also known as ESRD facilities, provide services to individuals with chronic kidney failure by offering dialysis treatment or education on how to perform dialysis at home.	No	None	None
West Virginia	West Virginia Department of Health & Human Resources, Office of Health Facility Licensure and Certification	No statutes apply	A facility that provides a regular course of dialysis or kidney transplant to maintain life.	No	None	None
Wisconsin	Wisconsin Department of Health Services	No statutes apply	An entity that provides treatment two or three times a week that removes wastes from the blood that the kidneys are unable to remove.	No	None	None
Wyoming	Wyoming Department of Health, Healthcare Licensing and Surveys	W. S. 35-2-901 et seq. and W. S. 16-3-101 et seq.	A freestanding facility for the treatment of kidney diseases.	Yes	None	None

Appendix B -
Quality Issues from the Literature

Table B1. Literature Review: ASCs

QUALITY ISSUE	TITLE (First author, Year)	SOURCE: DESIGN/AIM	KEY CONCLUSIONS	KEY SUPPORTING DATA
Quality domain: Safety				
Post-operative: Infection	Surgical site infections (SSIs) following ambulatory surgery procedures (Owens, 2014)	Journal: Retrospective analysis of 2010 Healthcare Cost and Utilization Project State Ambulatory Surgery and State Inpatient Databases for 8 states [including CA (n=284,098)] to determine the incidence of clinically significant (CS) SSIs following low to moderate risk ambulatory surgery in patients with low risk for complications	Rates of postsurgical visits for CS-SSIs were low relative to all cause, but they may represent a substantial number of adverse outcomes in the aggregate.	• Postsurgical acute care visits for CS-SSIs occurred in 3.09 per 1000 surgical procedures at 14 days and 4.84 per 1000 surgical procedures at 30 days. • All-cause inpatient or outpatient postsurgical visits, including those for CS-SSIs, following surgery occurred in 19.99% per 1000 procedures at 14 days and 33.62 per 1000 at 30 days.
Post-operative: Infection	Proactive risk assessment of surgical site infections in ASCs (Steighner, 2012)	Report: Development of a risk assessment tool and recommendations for preventing SSIs in the ambulatory surgery setting	The risk assessment tool developed in the study provided a foundation for future infection prevention efforts, though it may need to be adapted to be more accessible. The Agency for Healthcare Research and Quality (AHRQ) should support implementation of the recommended interventions.	Overall, infection control and communication between healthcare providers were key areas for intervention. Specific areas in need of improvement included practices to address skin preparation, antibiotic administration, infection control, glove punctures, and removal of watches, jewelry, and fake nails.
Post-operative: Infection	Healthcare-acquired infections 2009-2013 Oregon report (Oregon Health Authority, 2014)	Report: Summary of infection reporting mandates, vaccination implementation strategies, and vaccination rates in Oregon	The decline in healthcare-acquired infections in Oregon was likely due to staff education efforts, implementation of process improvement programs, and prevention collaboratives.	Healthcare worker influenza vaccination rates increased 8% for all facilities. Central line associated bloodstream infection standardized infection ratio (SIR) in neonatal ICUs and SSI SIR decreased.
Post-operative: Infection	OSHA most frequently cites ASCs for blood borne pathogen violations (Infection Control Today, 2011)	News: Infection-related issues at ASCs	An increasing number of ASCs and physician offices are being cited by OSHA for blood borne pathogen standard violations.	The most frequent causes of blood borne pathogen violations were outdated or nonexistent exposure control plans, poor documentation, failure to use safety devices, and lack of free training during work hours.
Post-operative: Infection	Non-compliance with identifying infection risks still an issue in ambulatory care (Infection Control Today, 2010)	News: Infection-related issues at ASCs	ASCs are still struggling with certain requirements relating to infection prevention and control.	Accredited and certified ASCs most frequently identified as non-compliant in infection control and prevention areas.

Table B1. Literature Review: ASCs

QUALITY ISSUE	TITLE (First author, Year)	SOURCE: DESIGN/AIM	KEY CONCLUSIONS	KEY SUPPORTING DATA
Post-operative: Infection	Compliance with infection control conditions for coverage in ASCs (Pyrek, 2014)	News: Infection-related issues at ASCs	Breaches in safe practice are due to both knowledge gaps and implementation gaps.	Challenges for infection control: patients remain in common areas for prolonged periods; surgical prep, recovery rooms and ORs turned around quickly; risk of infection at the surgical site.
Peri-operative Adverse Events	The Wrong Site Surgery Project (Joint Commission Center for Transforming Healthcare, 2011)	Report: Description of a Robust Process Improvement project to address wrong site surgery and prevent wrong site, wrong side, and wrong patient surgical procedures	Wrong site surgeries are frequently the result of a cascade of small errors that are able to penetrate organizational defenses.	Participating organizations reduced risks associated with wrong site surgery: in surgical booking from 39% to 21%; in pre-op from 52% to 19%; in OR from 59% to 29% and decreased incidence of cases containing one or more risks by 57% in surgical booking; by 72% in pre-op/holding; and 76% in OR.
Peri- and Post-operative: Adverse Events	Preventing errors in the outpatient setting: A tale of three states (Lapentina, 2015)	Journal: Review of the need for attention to error in the outpatient setting, focusing on outpatient surgery	Current regulatory system for outpatient facilities was badly fragmented across three different accreditation agencies. Guidelines may exist, but oversight and enforcement are inadequate.	Death rate from office-based lipoplasty was higher than from motor vehicle crashes or homicides. The greatest risks are facilities unable to perform the procedure, unable to deal with emergency, with outdated or inadequately maintained equipment, or with practitioners operating without peer review or with insufficient training.
Peri- and Post-operative: Adverse Events	CMS pulls Medicare coverage at Yorkville Endoscopy (Burger, 2015)	News: Clinic where Joan Rivers went into cardiac arrest cited for numerous failures.	CMS terminated its Medicare agreement with the ASC where Joan Rivers went into cardiac arrest, citing several deficiencies.	Yorkville Endoscopy failed to complete post-anesthesia evaluations before discharge; develop and implement a quality-improvement program; maintain and appropriately operate equipment; post written notice of patient rights; adequately address patient grievances; protect patient confidentiality; inadequate fire protection; and improper oxygen storage.
Peri- and Post-operative: Adverse Events	You won't believe these Indiana medical errors (Rudavsky, 2014)	News: Highlights from the Indiana State Health Report	A significant number of medical errors occurred at ASCs in Indiana	In 2013, 111 medical errors occurred at 293 facilities. One hospital had 10 reported events. Twice, a foreign object was left in a patient after surgery and 8 patients developed serious bedsores.

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QUALITY ISSUE	TITLE (First author, Year)	SOURCE: DESIGN/AIM	KEY CONCLUSIONS	KEY SUPPORTING DATA
Peri- and Post-operative: Adverse Events	Indiana Medical Error Reporting System (Indiana State Department of Health, 2014)	Report: Summary of reportable events occurring in Indiana healthcare facilities in 2013	Medical errors are generally the result of systems and processes failure. The requirement to report events identifies persistent problems, encourages increased awareness of patient safety issues, and assists in the development of evidence-based initiatives to improve patient safety.	The most frequently reported event was stage 3 or 4 pressure ulcers, followed by retention of a foreign object after surgery, followed by surgery performed on the wrong body part.
Peri- and Post-operative: Adverse Events	Joan Rivers' death spurs new look at outpatient centers (Boodman, 2014)	News: Death of Joan Rivers leads to questions about safety in ASCs	Rivers' death raises important safety concerns	Numerous violations were found at the clinic where Rivers lost consciousness, including failure to weigh and performance of a procedure without patient's written consent.
Peri- and Post-operative: Adverse Events	Lap-band patient's death blamed on "suboptimal anesthesia care" (Tsikitas, 2011)	News: Woman who suffered from sleep apnea died after post-op respiratory failure and cardiac arrest in surgery center.	Woman died after lap-band surgery due to suboptimal anesthesia care.	Patient suffered from morbid obesity and sleep apnea when she presented for a hiatal hernia repair and weight-loss surgery at the Beverly Hills Surgery Center. The operation was performed under general anesthesia with excessive delays in treatment. The anesthesiologist on duty left the patient unattended for 80 minutes post-surgery.
Peri- and Post-operative: Adverse Events	Mortality in Outpatient Surgery (Keyes, 2008)	Journal: Review of data from 2001-2006 of the AAAASF Internet-Based Quality Assurance and Peer Review Reporting System	The safety record was strong in surgeries performed by board-certified surgeons. The overall risk of death was comparable whether the procedure was performed in an AAAASF-accredited ASC or a hospital.	There were 23 deaths in 1,141,418 outpatient procedures performed. Pulmonary embolism caused 13 of the 23 deaths; these are most common after abdominoplasty. Only one death was intraoperative.
Pre-operative: infection control; Peri-operative: adverse events, burns; Post-operative: hospital transfer/ admission	ASC quality measures implementation guide version 2.1 (ASC Quality Collaboration, 2014)	Report: Recommendations to guide ASC implementation and data collection for the six quality measures endorsed by the National Quality Forum.	Specific recommendations about hair removal, reducing patient burn risk and falls, administration of prophylactic antibiotics, and wrong site/side/patient/procedure surgeries were made.	Guidelines cited include The Joint Commission's Universal Protocol, American National Standards Institute, American Society of Anesthesiologist Practice Advisory Committee for the Prevention and Management of Operating Room Fires, ECRI Institute, and Agency for Healthcare Research and Quality's Prevention of Falls in Acute Care

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Pre-operative: patient evaluation	Ambulatory surgery centers can be risky for older patients (Rice, 2014)	News: Elderly safety in ASCs	Surgery carries more risks for older adults because they tend to have multiple health conditions which affect how their bodies respond to surgical stress. The key to safety is thorough patient assessment and presence of proper clinical staff during procedures.	ASCs are not often staffed to manage emergencies, and an elderly patient's condition can rapidly deteriorate while awaiting 911 dispatch and hospital transfer. Approximately 1 out of 31 patients are admitted to a hospital or receive emergency follow-up after ASC discharge.
General	Patient safety in outpatient surgery: The viewpoint of the healthcare providers (Carayon, 2006)	Journal: Survey to understand the viewpoint of healthcare providers with regard to patient safety in outpatient surgery settings	Gathering input from the healthcare providers regarding the quality and safety of care rather than relying only on traditional measures about patient outcomes was important.	• Few physicians and staff indicated that their surgery center had patient safety problems. • Primary quality and safety of care issues concerned communication to patients, coordination of reports/forms, patient/staff time pressures and standards of care.
General	Walk inside, have surgery - but is it safe? (Brooks, 2005)	News: Concerns that doctors are not using the appropriate procedures in NJ ASCs	Procedures that were more invasive than regulations permitted were being conducted in ASCs, as well as procedures exceeding the regulated four-hour time limit.	20% of centers are not fully accredited.
General	State probes weight-loss deaths at NYU (Goldstein, 2010)	News: A probe into the safety of the New York University bariatric program began following patient complaints	Lawyers claim that surgeries are being performed on patients who do not have severe weight problems.	The doctors in charge of the NYU unit who pioneered the lap band surgery have several malpractice claims and lawsuits filed against them and are accused of hiding the weight of a patient, who later died, to qualify her for surgery.
General	Clinic errors alarming (Layton, 2011)	News: Quality of care issues in ASCs in New Jersey	Inspectors found more problems in unlicensed ASCs than in licensed ASCs.	• 8 licensed and 17 unlicensed ASCs inspected in 2009 and 2010 had "immediate jeopardy" violations. • More than half of the ASCs inspected failed to meet federal safety standards. • More than one-quarter were cited for violations that can cause serious injury to patients. • Inspectors found equipment was not sterilized properly and employees did not wash hands between procedures.
General	The spotlight grows on outpatient surgery; Popularity carries risks, some say (Marcus, 2007)	News: Risks of surgery	Patients should be aware of the risks and drawbacks of non-hospital-based surgery.	Free-standing ASCs do not have an emergency room, and cannot care for patients appropriately in an emergency.

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QUALITY ISSUE	TITLE (First author, Year)	SOURCE: DESIGN/AIM	KEY CONCLUSIONS	KEY SUPPORTING DATA
General	Lap-Band clinic is directed to improve (Pfeifer, 2011)	News: Unannounced inspection of the New Life Surgery Center revealed several issues that could result in loss of accreditation	Beverly Hills Lap-Band Surgery Center has been advised to make improvements or risk losing its Joint Commission accreditation	The Joint Commission found deficiencies in the following areas: environment of care, infection control, leadership, and medication management.
General	Litigation develops over weight loss surgery (Stephenson, 2012)	News: Allegations that "1-800-GET-THIN" is engaging in misleading advertising to attract consumers and then performing surgeries without meeting adequate standards of care	The advertisements fail to adequately state the risks of Lap-Band surgery.	The enterprise consisting of doctors, surgery centers and a marketing company has several suits pending against them, including wrongful death cases, a number of medical malpractice claims and a class action alleging false advertising based on the billboards and television ads.
Policy	Ambulatory surgical facility licensing and patient safety (Leslie, 2008)	Policy: Description of Washington State effort to move toward licensing surgical facilities, focusing on patient safety through requirements for emergency preparedness and quality review	The new statutes are a good start at protecting patients from substandard practices at ASCs, but don't go far enough in regulating the administration of general anesthesia and physicians without privileges to practice in a hospital.	• Many facilities employ certified registered nurse anesthetists instead of anesthesiologists. • Hospitals, but not ASCs in WA require physicians with privileges to carry professional liability insurance. • Other states and Medicare limit ASF surgeries to 90 minutes and allow a recovery period of 4 hours or less.
Policy	Health information and the law (RWJF, 2012)	Policy: Description of patient safety laws and regulations in Oregon	Oregon has a number of laws to oversee patient safety in the state; the Oregon Patient Safety Commission provides general oversight.	Oregon state laws require collection of healthcare-acquired infections data and reporting of adverse events and patient abuse. It also covers the collection, use, and disclosure of patient safety data and patient abuse records.
Pre-operative: Patient selection	Patient selection for day case-eligible surgery identifying those at high risk for major complications (Mathis, 2013)	Journal: Review of the American College of Surgeons' National Surgical Quality Improvement Program database from 2005 to 2010 to identify specific risk factors that increase the likelihood of day case-eligible surgical morbidity or mortality in order to advance patient-selection processes for outpatient surgery	The demonstrated low rate of peri-operative morbidity and mortality confirms the safety of current day case-eligible surgeries.	• 232 (0.1%) of 244,397 surgeries studied experienced perioperative morbidity/ mortality. • Risk factors were overweight or obese body mass index, chronic obstructive pulmonary disease, history of transient ischemic attack/stroke, hypertension, previous cardiac surgical intervention, and prolonged operative time.

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QUALITY ISSUE	TITLE (First author, Year)	SOURCE: DESIGN/AIM	KEY CONCLUSIONS	KEY SUPPORTING DATA
Quality domain: Effectiveness				
Post-operative hospital transfer/ admission	Predictors of readmission after outpatient plastic surgery (Miotin, 2014)	Journal: Retrospective analysis of the 2011 National Surgical Quality Improvement Program database to determine hospital readmission rates and predictors of readmission following outpatient plastic surgery	Unplanned readmission after outpatient plastic surgery was infrequent and compared favorably to rates of readmission among other specialties.	• Outpatient plastic surgery had a low associated readmission rate (1.94% of 7005 outpatient surgery procedures) compared with other specialties. • Obesity, wound infection within 30 days of the index operation, and American Society of Anesthesiologists class 3 or 4 physical status are independent predictors of readmission.
Post-operative hospital transfer/ admission	Hospital admission following ambulatory surgery (Greenburg, 1996)	Journal: Review of unplanned admissions following ambulatory surgery	Unanticipated hospital admission following outpatient surgery, though rare, may be an indicator of overall system and facility quality issues.	• Unplanned admission rate = 0.85% (129/15,132). General surgery, ophthalmology and orthopedic procedures comprised 86.8% of admissions. • 24.8% of unplanned admissions due to need for pain medication, 21% due to cardiopulmonary problems, 14.7% due to coagulation/bleeding/wound issues, 11.6% due to nausea and vomiting related to anesthesia or analgesia.
Post-operative hospital transfer/ admission	What happens after discharge? return hospital visits after ambulatory surgery (Twersky,1997)	Journal: Retrospective review to examine the frequency of return hospital visits after ambulatory surgery discharge and to identify any predictor variables for its occurrence	Ambulatory surgical patients were instructed to go to the emergency department if they experience problems, placing a burden on emergency rooms. Interventions to improve post-operative patient outcomes are needed, as is better patient education about bleeding risk and alternatives to emergency room care for non-emergencies.	• 15% of total hospital revisits were due to readmission from surgical complications •Bleeding was most common reason for returns (41.5%). 76.5% of patients were treated and discharged through the emergency department.
Post-operative pain	Pain management after ambulatory surgery (Schug, 2009)	Journal: Literature review to examine the current situation and recent advances in post-operative pain management	Poor multimodal analgesia use, reliance on opioids, and lack of analgesic continuation post-operatively result in poor post-operative pain management. Multimodal analgesia and local anesthetic techniques may improve the quality of analgesia post-surgery.	• Literature supports the use of multimodal analgesia with an emphasis on the use of appropriate non-opioids such as nonsteroidal anti-inflammatory drugs or cyclo-oxygenase-2 inhibitors. • Local anesthetics are shown to be safe and effective.

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QUALITY ISSUE	TITLE (First author, Year)	SOURCE: DESIGN/AIM	KEY CONCLUSIONS	KEY SUPPORTING DATA
Post-operative pain	Nausea and vomiting after office-based anesthesia (Kolodzie, 2002)	Journal: Review of incidence and risk factors for post-discharge nausea and vomiting (PDNV)	Valid data for incidence and optimal treatment of PDNV are rare. A PDNV prediction model will help clinicians better identify patients at risk for developing symptoms.	• Patients with PDNV experience a longer recovery time and delayed discharge. • PDNV was a leading cause of unexpected hospital admission after planned outpatient surgery.
Post-operative pain	Systematic review and analysis of post-discharge symptoms after outpatient surgery (Wu, 2002)	Journal: Systematic review and analysis to evaluate the incidence of patient-reported symptoms after outpatient surgery	The economic burden placed on patients, caregivers, and society due to post-discharge symptoms was unclear, but may represent considerable resource use issues.	The incidence of post-discharge symptoms in patients undergoing outpatient surgery was approximately: 45% for pain, 17% for nausea, 8% for vomiting, 17% for non-specific headaches, 9% for post-dural puncture headaches, 42% for drowsiness, 18% for dizziness, and 21% for fatigue.
Peri-operative care, post-operative nausea, adverse events	Ambulatory surgery: an overview (Troy, 2002)	Journal: Review of recent studies about day case anesthesia	Careful patient selection can minimize peri-operative events.	Anesthetic management measures such as mortality, morbidity, postoperative stay and patient satisfaction ensure peri-operative care and treatment are optimized.
Post-operative pain, post-operative nausea and vomiting, pre-operative anxiety	Which clinical anesthesia outcomes are both common and important to avoid? The perspective of a panel of expert anesthesiologists (Macario, 1999)	Journal: Poll of 56 expert anesthesiologists to determine which clinical anesthesia outcomes associated with routine outpatient surgery were perceived to occur frequently and to be important to avoid	The anesthesia outcomes ranked by respondents as most important to avoid should be prioritized in quality improvement efforts.	The five items with the highest combined score (e.g., most important to avoid) were (in order): incisional pain, nausea, vomiting, pre- operative anxiety, and discomfort from IV insertion.
Quality domain: Patient-centeredness				
Patient satisfaction	Patient anxiety and patient satisfaction in hospital-based and freestanding ASCs (Gardner, 2005)	Journal: Survey to study differences in patient anxiety and patient satisfaction between patients who underwent surgery at a hospital-based ASC versus freestanding ASC	The site where the surgery was performed was not linked to patient anxiety or satisfaction levels. Nurses in ASCs should continue to take measures to decrease patient preoperative anxiety and facilitate patient satisfaction.	Mean outcome scores for patient anxiety and satisfaction did not significantly differ between hospital-based and freestanding group.
Quality domain: Timeliness				
No literature meeting search criteria was found about this domain.				

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QUALITY ISSUE	TITLE (First author, Year)	SOURCE: DESIGN/AIM	KEY CONCLUSIONS	KEY SUPPORTING DATA
Quality domain: Efficiency				
Pre-operative evaluation	Preoperative laboratory testing in patients undergoing elective, low-risk ambulatory surgery (Benarroch-Gampel, 2012)	Journal: Statistical analysis to evaluate the use of pre-operative laboratory testing	Preoperative testing was overused in patients undergoing low-risk, ambulatory surgery. The high testing rates in healthy patients suggest physician/ facility preference dictate use.	• 54% of patients (n=25,149) with no National Surgical Quality Improvement Program comorbidities and no clear indication for testing received at least one test. • Testing was associated with older age, American Society of Anesthesiologists class >1, hypertension, ascites, bleeding disorders, systemic steroids, and laparoscopies. • Neither testing nor abnormal results were associated with postoperative complications.
Pre-operative evaluation	Unnecessary preoperative investigations: evaluation and cost analysis (Allison, 1996)	Journal: Statistical analysis of the necessity for pre-operative testing in ambulatory surgery and associated cost	Preoperative testing was over-used and often inappropriate. Unnecessary costs and patient discomfort are incurred.	• 2/3 of investigations are done unnecessarily or inappropriately according to revised Veterans Affairs policy. • Unnecessary testing caused patient inconvenience and dissatisfaction. • No adverse events occurred in patients who did not undergo testing and no comorbidities or other conditions were found in tests of patients with no clinical indication.
Pre-operative evaluation	Nurse-led versus doctor-led preoperative assessment for elective surgical patients requiring regional or general anesthesia (Nicholson, 2013)	Journal: Literature review to examine whether a nurse-led service rather than a doctor-led service affects the quality and outcome of preoperative assessment for elective surgeries requiring regional or general anesthesia	No trials have assessed the impact of nurse-led pre-operative assessment strategy on patient outcomes, and it was not clear if randomized control trials were feasible.	Cancellations after admission for hip and knee surgery less common when pre-operative assessment was done by nurse (3.1% vs. 7.4%) and length of stay was reduced from 20 to 13 days; however, the details of the assessment for the control group are not clear.
Pre-operative evaluation	Ambulatory surgery: how much testing do we need? (Richman, 2010)	Journal: Review of evidence on the appropriateness of pre-operative testing for ambulatory surgery patients	Pre-operative testing lacks utility when there are no specific indications. The pre-operative history and physical is a more valuable assessment tool. When testing is necessary, orders should be carried out by anesthesiologists, who do so more appropriately and with cost reduction.	• A study by Kaplan et al. found that 60% of tests were no indicated. Only 0.22% of the abnormal results lead to management change. • Obesity and age are not risk factors for adverse outcomes in ambulatory surgical settings.

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Pre-operative anxiety	Premedication for anxiety in adult day surgery (Walker, 2009)	Journal: Literature review to assess the effect of anxiolytic premedication on time to discharge in adult patients undergoing day case surgery under general anesthesia.	There was little evidence to support the idea that pre-operative anxiolytic medication delays discharge.	The diversity of drugs, doses, and contexts makes comparing studies difficult and meta-analysis inappropriate.
Post-operative hospital transfer/ admission, organizational structure	Strategy, structure, and patient quality outcomes in ambulatory surgery centers (1997-2004) (Chukmaitov, 2011)	Journal: Statistical analysis of large, all-payer claims data for 1997-2004 to examine potential associations among ASCs' organizational strategy, structure, and quality performance.	Higher levels of specialization and volume of procedures may be associated with an increase in quality outcomes.	• Positive association between the rate of specialization in ASCs and patient quality outcomes in ASCs; the effect declined as specialization increased. • Increases in ASC procedure volumes are weakly associated with better quality outcomes.
Quality domain: Equity				
No literature meeting search criteria was found about this domain.				
Quality Domain: General				
Policy	Quality oversight of ambulatory surgical centers: A system in neglect (DHHS Office of Inspector General, 2002)	Report: Assessment of how state agencies and accreditors oversee ASCs and how CMS holds them accountable	Recommendations for CMS: determine the minimum survey cycle for ASCs certified by the state, update Conditions of Coverage to include patient rights and continuous quality improvement, ensure certification and accreditation agencies strike balance between compliance and quality improvement, and hold agencies accountable to Medicare and the public.	Medicare systems of quality oversight have not kept up with ASC growth, and they do little to hold the certification and accreditation agencies accountable to Medicare and the public.
Policy	Quality oversight of ambulatory surgical centers: The role of certification and accreditation, Supplemental report 1 (DHHS Office of Inspector General, 2002)	Report: Assessment of ASC oversight	The limited role of the surveyor does little to move the ASC beyond Medicare's minimum requirements and toward improving the quality of care.	• Certification agencies: Nearly 1/3 of ASCs certified by state agencies have gone 5+ years without a recertification survey. The average time between recertification was 4.4 years. •Accreditation agencies: accreditors have policies to survey every 3 years; standards are adjusted regularly to match the risk and complexity of surgeries performed; surveys are educational in nature and less attention was paid to compliance.

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QUALITY ISSUE	TITLE (First author, Year)	SOURCE: DESIGN/AIM	KEY CONCLUSIONS	KEY SUPPORTING DATA
Policy	Quality oversight of ambulatory surgical centers holding state agencies and accreditors accountable, Supplemental report 2 (DHHS Office of Inspector General, 2002)	Report: Assessment of ASC oversight by state agencies and accreditors	CMS does little to hold state and accreditation agencies accountable to the Medicare program or to the public. Changes are needed to ensure this occurs.	• Electronic data reporting was not used, survey results are not published on Medicare website, formal evaluations or complaint summaries to allow for cross-agency comparisons are not available, no clear instructions for complaining about poor care received.
Policy	New Jersey ambulatory surgery center and surgical practice transparency report (New Jersey Health Care Quality Institute, 2011)	Report: Summary of observations by inspectors to assist healthcare consumers who are considering or are scheduled for treatment at an outpatient surgery center.	Unlicensed facilities pose greater risk to consumers than licensed ASCs.	• 49 of the 91 facilities did not meet standards to participate in Medicare, and more than 25% of the facilities were cited for “Immediate Jeopardy.” • 43% (17/40) of unlicensed ASCs reviewed were non-compliant and 15% (8/51) of licensed ASCs were non-compliant.
Policy	Consumers Union urges California to adopt Medical Board reforms to improve oversight of centers and problem physicians (McCauley, 2013)	News: Recommendations to state lawmakers of provisions to strengthen oversight of ambulatory surgery centers and problem physicians	Provisions include: public disclosure of accreditation history, adverse event reporting, notice of complaint procedures, uniform standards for substance abusing physicians, statute of limitations for filing complaints, improved disclosure of malpractice settlements, and physician disclosure of disciplinary orders to patients.	• Unclear how adverse event reports are collected, assessed for fines, and disclosed. • Medical Board has not implemented the standards set forth by SB1441 regarding physician substance abuse. • Currently no requirement to notify patients of physicians who are being/have been disciplined
Policy	Concerns rise as N.J. inspections find high number of violations among same-day surgery centers (Livio, 2011)	News: Facility concerns in New Jersey ASCs	A number of New Jersey ASCs placed patients at alarming health risk.	The inspection team found 17 centers posed an "immediate jeopardy" to patient health and safety and temporarily shut seven of them until they corrected their problems, according to inspection reports. The state also inspected 51 licensed centers, found eight posing "immediate jeopardy" and closed two down temporarily.
Policy	PA steps up surgical-licensing campaign; The death of a young woman who underwent liposuction in May has officials notifying doctors of two-year-old changes. (Fitzgerald, 2001)	News: Licensing issues for ASC physicians in Pennsylvania	Few doctors across state have applied for a license. The lack of response did not prompt a reaction from regulators at the Health Department.	Efforts to notify doctors about updated regulations did not begin until patient died 2 days after undergoing liposuction in the office of a plastic surgeon who did not have a license to operate the facility.

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QUALITY ISSUE	TITLE (First author, Year)	SOURCE: DESIGN/AIM	KEY CONCLUSIONS	KEY SUPPORTING DATA
Policy	113 surgical sites may lack licenses; A liposuction death in 2001 has Pa. looking at offices where doctors operate (Fitzgerald, 2002)	News: Licensing issues for ASCs in Pennsylvania	Until the death of a teen undergoing elective liposuction, licensure rules went largely unnoticed and unenforced.	The state will send additional letters to more than 2,000 doctors.

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Table B2. Literature Review: CORFs

QUALITY ISSUE	TITLE (First author, Year)	SOURCE: DESIGN/AIM	KEY CONCLUSIONS	KEY SUPPORTING DATA
Quality domain: Safety				
No literature meeting search criteria was found about this domain.				
Quality domain: Effectiveness				
Clinical education	Cancer rehabilitation education during physical medicine and rehabilitation residency: preliminary data regarding the quality and quantity of experiences (Raj, 2014)	Journal: Survey to understand the education and experiences of resident physicians in oncology rehabilitation	More cancer-specific rehabilitation training for resident physicians is needed, and the current quantity and quality of such training is insufficient.	• The majority of respondents felt cancer rehabilitation should be important part of curriculum, but current training is inadequate. • 32% of programs did not have a dedicated faculty for cancer rehabilitation; 26% had outpatient clinics focused specifically on rehab needs for oncology patients.
Policy	State regulation and the delivery of physical therapy services (Resnik, 2006)	Journal: Statistical analysis to examine the relationship between state regulations of physical therapists (PT) and physical therapist assistant (PTA) utilization, number of visits, and patient self-reported functional health status (FHS) at discharge	The substitution PTs with PT assistants and therapy aids is likely to result in less efficient and lower quality care.	• High PTA utilization and regulations requiring fulltime onsite supervision were associated with more visits. • High PTA utilization and use of therapy aides were associated with more visits per episode and lower discharge FHS.
General	State-of-the-science on post-acute rehabilitation: setting a research agenda and developing an evidence base for practice and public policy (Heinemann, 2007)	Report: Summary of a two-day symposium to describe current knowledge, identify challenges to research, foster idea exchange, and identify critical issues	Little is about which aspect of the rehabilitation process produce the best outcomes. Strong research is needed to develop better measures for case-mix adjustment and outcomes.	Critical research needs include: • Development of clinical measures that are precise and sensitive to change across a wide range of patients, are retrievable in electronic medical records, and assess clinically relevant outcomes • The relationship between access and family dynamics, social support, and culture • Treatments or services that are most effective across the continuum of care

Table B2. Literature Review: CORFs

QUALITY ISSUE	TITLE (First author, Year)	SOURCE: DESIGN/AIM	KEY CONCLUSIONS	KEY SUPPORTING DATA
Quality domain: Patient-centeredness				
Access to care	Perceptions of care access: the experience of rural and urban women following brain injury (Sample, 1998)	Journal: Qualitative, phenomenological study to examine care access among women with brain injuries	Cost, efficiency, and logistics were difficult to overcome, but other barriers can be changed through education, training and policy making.	All the women experienced barriers to accessing care, including problems with service providers and service systems, financial challenges, traveling for services, lack of information or services in their area, lack of care coordination, and funneling.
Quality domain: Timeliness				
Access to care	Outpatient rehabilitation among stroke survivors - 21 states and District of Columbia, 2005 (Centers for Disease Control & Prevention, 2007)	Report: Assessment of data from the 2005 BRFSS survey to examine care access among women with brain injuries	Timely and intensive rehabilitation can substantially improve patients' functional outcomes and quality of life after acute stroke.	The prevalence of stroke survivors receiving outpatient stroke rehabilitation services was lower than would be expected if clinical practice guideline recommendations for all stroke patients had been followed.
Quality domain: Efficiency				
No literature meeting search criteria was found about this domain.				
Quality domain: Equity				
Access to care	Racial-ethnic disparities in stroke care: The American experience. A statement for healthcare professionals from the American Heart Association/American Stroke Association (Cruz-Flores, 2011)	Journal: Review of the effect of race and ethnicity on stroke epidemiology, personal beliefs, access to care, response to treatment, and participation in clinical research; and of factors that may explain disparities in care.	Racial and ethnic disparities in stroke were prevalent and included differences in the biological determinants of disease and disparities throughout the continuum of care, including access to and quality of care.	• African Americans had higher outpatient rehabilitation use than whites (adjusted OR 1.49, 95% CI 1.1 to 2.0). • Access to and participation in research is limited among minority groups.

Table B2. Literature Review: CORFs

QUALITY ISSUE	TITLE (First author, Year)	SOURCE: DESIGN/AIM	KEY CONCLUSIONS	KEY SUPPORTING DATA
Quality domain: General				
Quality measures	Integrating stakeholder perspectives in outcome measurement (Magasi, 2009)	Journal: Review of key issues shaping the field of rehabilitation outcome measurement	Lack of consistency in instruments and measures makes it difficult to compare outcomes across post-acute care settings and the process of measuring outcomes in neuro-rehabilitation is challenged further by issues of natural recovery, timing, and case mix.	Challenges to developing outcome measures include: the need to be responsive to multiple stakeholders with vested interests in the rehabilitation process; lack of consensus over what constitutes a good outcome; and differing priorities based on one's position within the rehabilitation process.

Table B2 References

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Table B3. Literature Review: ESRD Facilities

QUALITY ISSUE	TITLE (First author, Year)	SOURCE: DESIGN/AIM	KEY CONCLUSIONS	KEY SUPPORTING DATA
Quality domain: Safety				
Adverse event	Why dialysis patient bled to death a mystery (Olsen, 2008)	News: An unusual patient death in a dialysis clinic	Employee error or defective equipment likely contributed to patient's death.	Resources to regularly inspect dialysis centers or perform timely follow up to ensure correction of deficiencies may be unavailable.
Adverse event	Warning on equipment is issued after 5 dialysis patient deaths (Stolberg, 2002)	News: Warning about unsafe dialysis equipment	It is unclear whether faulty equipment is to blame in the deaths of 5 dialysis patients.	Preliminary investigation found that four of the five patients who died were treated with the combination of blood tubing and dialysis machines.
Adverse event	Dialysis patients face high risk of death at some San Gabriel Valley clinics (Vaelasco, 2012)	News: Issues found during inspections	Widespread quality care issues were found in several San Gabriel Valley dialysis clinics.	A number of clinics had mortality rates 87-190% worse than would be expected for clinics with similar patient demographics.
Adverse event	Dialysis product may pose fatal risk (Washburn, 2012)	News: A product that may increase patient's risk of heart attacks and sudden cardiac death	The use of GranuFlo will likely cause serious adverse health events.	Despite being recalled, GranuFlo, an ingredient in dialysis solution, is still being used in clinics because of a short supply of alternative products and may have contributed to over 900 cardiac deaths in Fresenius-owned clinics.
Infection, vascular access	Epidemiology of hemodialysis vascular access infections from longitudinal infection surveillance data: Predicting the impact of NKF-DOQI clinical practice guidelines for vascular access (Stevenson, 2002)	Journal: Prospective analysis of vascular access-related infections at six ESRD facilities in southern Idaho and eastern Oregon	National Kidney Foundation-Dialysis Outcomes Quality Initiative (NKF-DOQI) Vascular Access Guidelines 29 and 30 were based on opinion, rather than published evidence. The impact of these guidelines on reducing vascular access infection rates is unknown. Data support the role of several other NKF-DOQI guidelines in preventing infectious complications attributed to vascular access.	A major risk for vascular access infections is the type of access used (temporary catheters > tunneled catheters > AV grafts > AV fistulae).
Infection	Healthcare-associated infections in Colorado - January 2015 (Hoxworth, 2015)	Report: A summary of infection reporting mandates and infection rates in CO	Access-related bloodstream (ARB) infection rates were similar to national rates.	Ten centers reported zero ARB infections, compared to six last year. Six centers had ARB rates worse than the national average and one had a better rate.

Table B3. Literature Review: ESRD Facilities

QUALITY ISSUE	TITLE (First author, Year)	SOURCE: DESIGN/AIM	KEY CONCLUSIONS	KEY SUPPORTING DATA
Infection	Tackling the high risk of infection in dialysis patients (Williamson, 2015)	News: Hygiene tips for personnel in dialysis clinics	The primary physician should model sound hygiene practice and be held accountable for any failure to comply with hygiene guidelines.	Infection is the most frequent reason for hospitalization in ESRD patients and is the second leading cause of death. Repeated opportunities exist for person-to-person transmission of infectious agents.
Vascular access	Hemodialysis vascular access morbidity (Feldman, 1996)	Journal: Summary of data on the magnitude and growth of vascular access-related hospitalization in the United States, review of literature on the morbidity associated with specific vascular access types	Identification of the fundamental mechanisms of vascular access dysfunction will allow for the development and implementation of specific therapies and preventative strategies.	Growth in vascular access morbidity may be a result of the rising age of the ESRD population, worsening severity of illness, increasing demands on vascular accesses to tolerate greater blood flow rates, construction of synthetic polytetrafluoroethylene dialysis vascular access grafts, and increasing diagnostic activities focused on detecting occult access dysfunction.
Organizational structure	Sale of EMMC dialysis clinics stirs concerns about patient safety (Farwell, 2012)	News: Proposed sale of a dialysis clinic to a for-profit corporation	There is concern that a for-profit corporation will prioritize profits over patient health and take control over doctors' decisions about patient care. There is also fear that patients could be discharged against their will for complaining about substandard care and left with no other treatment options.	• DaVita recently settled a whistle-blower lawsuit. • Former DaVita patient was informed that the facility would no longer treat him because he had placed "extensive limitations" on the clinic's staff.
Dialysis care	Dialysis facilities: problems remain in ensuring compliance with Medicare quality standards (GAO, 2003)	Report: Review of quality of care problems, effectiveness of state survey agencies, and CMS oversight and recommendations for executive action	A number of facilities go many years between inspections. There is little incentive for deficient facilities to take corrective action, and terminating the facility from Medicare is rare.	• 15% of surveys conducted between 1998 and 2002 revealed serious quality problems that would warrant termination from the Medicare program. • Infrequent, inadequate, and poorly targeted state inspections allow quality issues to go undetected or remain uncorrected. In 2002, 5.4% of facilities went 9+ years without inspection, compared to 1.6% in 1998.
Quality domain: Effectiveness				
Quality measures	Hemodialysis facility–based quality-of-care indicators and facility-specific patient outcomes (Lacson, 2004)	Journal: Prospective observational study of whether incremental achievement of eight facility quality goals was associated with improvement in facility-specific mortality and hospitalization rates	Achieving more facility quality goals was significantly associated with better facility-based measurements of patient outcomes. Findings support continued monitoring of facility performance.	• Facilities achieving more than five quality goals averaged 3.5 fewer hospital days/patient-year and 20% lower standardized mortality ratios. • Catheter and albumin level goals were achieved by the fewer facilities.

Table B3. Literature Review: ESRD Facilities

QUALITY ISSUE	TITLE (First author, Year)	SOURCE: DESIGN/AIM	KEY CONCLUSIONS	KEY SUPPORTING DATA
Quality measures	Attainment of clinical performance targets and improvement in clinical outcomes and resource use in hemodialysis care: A prospective cohort study (Plantinga, 2007)	Journal: Longitudinal, prospective, cohort study to assess whether meeting multiple clinical performance targets was associated with better patient outcomes	Facilities should aim to achieve high performance on multiple performance targets, in order to maximize patient outcomes and minimize waste.	Achieving more performance targets was associated with decreased mortality, fewer hospital admissions and days, and lower costs. These trends remained statistically significant for all outcomes after adjustment, except cost, which was marginally significant.
Quality measures	Cycler adequacy and prescription data in a national cohort sample: The 1997 core indicators report (Rocco, 1999)	Journal: Cohort study and data analysis to assess whether a random sample of adult U.S. peritoneal dialysis patients met the guidelines for cycler dialysis adequacy	Practitioners need to be more aggressive in increasing dwell volumes, adding daytime dwells, and adjusting nighttime dwell times in order to compensate for the loss of residual renal function over time. Dialysis doses should follow the National Kidney Foundation-Dialysis Outcomes Quality Initiative guidelines.	• 36% of patients met National Kidney Foundation-Dialysis Outcomes Quality Initiative guidelines for weekly Kt/V urea, 33% met guidelines for weekly creatinine clearance, and 24% met guidelines for both urea and creatinine clearances • Only 60% of patients were prescribed at least one daytime dwell.
Quality measures	Relationship between clinical performance measures and outcomes among patients receiving long-term hemodialysis (Rocco, 2006)	Journal: Cohort study to determine whether attaining clinical performance measures for hemodialysis care is associated with favorable 12- month mortality and hospitalization rates	The risks for death and hospitalization increased for each guideline indicator that did not meet clinical target. Comorbid conditions, socioeconomic barriers, non-adherence, transportation issues, and cost make it more difficult to achieve intermediate outcomes.	• Six percent of patients did not meet any clinical measure targets, 24% met 1 target, 39% met 2 targets, 24% met 3 targets, and 7% met all 4 targets. Mortality and 12-month hospitalization rates were linked to the number of targets that were met.
Quality measures	Monitoring quality of care at dialysis facilities: A case for regulatory parsimony and beyond (Stivelman, 2012)	Journal: Editorial assessing the effectiveness of current quality improvement tools	Streamlining present quality improvement instruments and the replacing some traditional quality improvement tools with those that address specific health threats may produce more compelling measurements.	Quality measures do not consider important issues such as the facility's affiliation with a larger group, or hemodialysis adequacy in home and peritoneal settings.
Quality measures	Associations between CMS's Clinical Performance Measures (CPM) project benchmarks, profit structure, and mortality in dialysis units (Szczech, 2006)	Journal: Statistical analysis of datasets from the US Renal Data System and CMS' ESRD Clinical Performance Measures from 1995–2000 to examine the association between profit status and mortality while achieving benchmarks	Survival among patients in for-profit units was similar to not-for-profit units, suggesting that for-profit status does not impair the ability to deliver performance benchmarks and does not affect survival.	19.4% of patients in for-profit facilities and 18.6% in not-for-profit facilities died.

Table B3. Literature Review: ESRD Facilities

QUALITY ISSUE	TITLE (First author, Year)	SOURCE: DESIGN/AIM	KEY CONCLUSIONS	KEY SUPPORTING DATA
Quality measures	Which targets in clinical practice guidelines are associated with improved survival in a large dialysis organization? (Tentori, 2007)	Journal: Retrospective analysis to assess whether meeting all clinical guideline targets outlined by the Kidney Disease Outcomes Quality Improvement is associated with improved mortality	Meeting all guidelines, except for blood pressure, were associated with decrease in mortality. Meeting the blood pressure target was associated with increase in mortality, suggesting that the ideal target may vary due to differences in arterial and cardiac structure and function in hemodialysis patients.	Values within guidelines for single-pool Kt/V, hematocrit, serum albumin, calcium, phosphorus, and parathyroid hormone were associated with an 89% reduction in mortality. The largest survival benefit was found for serum albumin.
Quality measures	Clinical and data technical expert panel meetings synthesis report (Arbor Research Collaborative for Health and University of Michigan Kidney Epidemiology and Cost Center, 2010)	Report: Review of evidence and recommendations for the development of measurements that can be used to provide quality care to Medicare beneficiaries	Recommendations were made for six measurement areas: anemia management/iron targets, mineral and bone disorder, hemodialysis vascular access related infections, pediatric hemodialysis adequacy, pediatric anemia, and fluid weight management.	Clinical Technical Expert Panels provided guidance in the development of new quality measures in specific clinical areas, as well as in defining target values for specific current measures. The report did not summarize the current levels of performance for these measures.
Quality measures	2005 Annual Report, ESRD Clinical Performance Measures (CPM) Project (CMS, 2005)	Report: Description of the clinical performance measures and other findings for patient samples and clinical parameters of care for pediatric dialysis patients	There is opportunity for improvement in all CPM areas.	Opportunities for improvement exist in the areas of adequacy, vascular access, anemia management, and serum albumin.
Quality measures	2007 Annual Report, ESRD Clinical Performance Measures (CPM) Project (CMS, 2007)	Report: Description of the clinical performance measures and other findings for patient samples and clinical parameters of care for pediatric dialysis patients	There is opportunity for improvement in all CPM areas.	Opportunities for improvement exist in the areas of adequacy, vascular access, anemia management, and serum albumin.
Quality measures	2008 Annual Report, ESRD Clinical Performance Measures (CPM) Project (CMS, 2008)	Report: Description of the clinical performance measures and other findings for patient samples and clinical parameters of care for pediatric dialysis patients	There is opportunity for improvement in all CPM areas.	Opportunities for improvement exist in the areas of adequacy, vascular access, anemia management, and serum albumin.
Organizational structure	Comparison of mortality between private for-profit and private not-for-profit hemodialysis centers: A systematic review and meta-analysis (Devereaux, 2002)	Journal: Systematic review to determine if there is a difference in adjusted mortality rates between patients receiving care in private for-profit vs. private not-for- profit dialysis centers.	There is statistically significant increased risk of death in private for-profit facilities versus private not-for-profit facilities.	Six of the eight studies reviewed showed statistically significant increases in mortality in for-profit facilities, and one study showed a non-significant trend.

Table B3. Literature Review: ESRD Facilities

QUALITY ISSUE	TITLE (First author, Year)	SOURCE: DESIGN/AIM	KEY CONCLUSIONS	KEY SUPPORTING DATA
Organizational structure	Effect of the ownership of dialysis facilities on patients' survival and referral for transplantation (Garg, 1999)	Journal: Longitudinal cohort study using national data to examine the effect of for-profit ownership of dialysis facilities on patients' survival and referral for possible transplantation	For-profit ownership of dialysis facilities, as compared with not-for- profit ownership, is associated with increased mortality and decreased rates of placement on the waiting list for a renal transplant.	• Treatment in a for-profit facility was associated with higher mortality than treatment in a not-for-profit facility, even after adjusting for risk factors. • Treatment in a for-profit facility was associated with a 1/3 reduction of in the rate of transplant waiting list placement in unadjusted models and 1/4 reduction in fully adjusted multivariate models.
Organizational structure	Quality of care differences by ownership in United States renal dialysis facilities (Irvin, 2000)	Journal: Statistical analysis of the relationship between mortality and facility ownership types	Patients in for-profit renal dialysis facilities had slightly higher mortality during the study period than patients in not-for-profit facilities, after controlling for patient case mix and market type.	For–profit patients had a 1-2% higher risk of dying during the year of study.
Dialyzer reuse	Dialysis unit and patient characteristics associated with reuse practices and mortality: 1989-1993 (Collins, 1998)	Journal: A multivariate data analysis to evaluate the risk of reuse compared with no-reuse, adjusting for comorbidity, unit characteristics, and profit status	Mortality is not consistently associated with reuse or no-reuse practices. Factors such as dialysis therapy, nutrition, and anemia correction may better explain mortality.	Data suggest that no-reuse and reuse outcomes do not differ.
Dialyzer reuse	Mortality risk by hemodialyzer reuse practice and dialyzer membrane characteristics: Results from the USRDS dialysis morbidity and mortality study (Port, 2001)	Journal: Analysis of United States Renal Data System Dialysis Mortality and Morbidity Study data to evaluate whether the reuse of dialyzers, reuse agent, or dialyzer membrane type had an effect on morbidity and mortality	There was no overall difference in mortality risk when comparing reuse to no-reuse. Differences may exist regarding reuse agent. High-flux synthetic membrane dialyzers were associated with lower mortality risk, especially when exposed to bleach.	Dialyzers were reused for 83% of patients. Concerns with reuse include pyrogenic reactions, infections, toxicity from disinfecting agent, and decreased dialyzer performance for clearance and ultrafiltration.
Vascular access	Hemodialysis vascular access monitoring: Current concepts (Allon, 2009)	Journal: Summary of the literature on clinical monitoring and surveillance in the detection of graft and fistula stenosis before thrombosis	The success of clinical monitoring in detecting graft stenosis is highly dependent on the proficiency of the dialysis staff and the consistency with which they monitor the graft.	• Clinical monitoring has a relatively high (69%–93%) positive predictive value for angiographically confirmed stenosis. • The majority (80%) of grafts fails due to irreversible thrombosis; improving graft longevity requires interventions to prevent or delay thrombosis.
Vascular access	Type of vascular access and mortality in U.S. hemodialysis patients (Dhingra, 2001)	Journal: Case-mix adjusted analysis to test the hypothesis that the type of vascular access in use is correlated with overall mortality and cause-specific mortality	Central venous catheter (CVC) and arteriovenous graft (AVG) were correlated with increased mortality risk when compared with AVF, both overall and by major causes of death.	Higher associated mortality in patients with AVG and CVC as compared with arteriovenous fistula (AVF); higher infection-related deaths for CVC and AVG compared with AVF. Deaths caused by cardiac causes were higher in CVC than AVF.

Table B3. Literature Review: ESRD Facilities

QUALITY ISSUE	TITLE (First author, Year)	SOURCE: DESIGN/AIM	KEY CONCLUSIONS	KEY SUPPORTING DATA
Vascular access	Hemodialysis access failure: A call to action – revisited (Hakim, 2009)	Journal: Review to examine causes of, and propose solutions to, the ongoing multi-factorial problem of catheter based vascular access	Late referral patients may benefit from use of forearm graft or peritoneal dialysis rather than catheters.	Catheter-related bacteremia occurs at a frequency of 1.5 to 5.5 episodes per 1000-catheter days. Earlier use of catheters is associated with a 60–70% higher risk of subsequent fistula failure.
Vascular access	Association of clinic vascular access monitoring practices with clinical outcomes in hemodialysis patients (Plantinga, 2006)	Journal: National prospective cohort study to examine whether patient outcomes were associated with vascular access monitoring practices in an incident dialysis cohort	Frequent monitoring of dialysis access may initially increase the number of interventions, but is beneficial to longer-term outcomes, including septicemia-related and all-cause hospitalization.	• Patients who received monitoring weekly or more often were more likely to have an access intervention than those who received monitoring less frequently. • Patients treated at clinics that reported performing regular access monitoring were less likely to be hospitalized.
Pre-dialysis care	Hemodialysis treatment center early mortality rates for incident hemodialysis patients are associated with the quality of care prior to starting but not following onset of dialysis (Kanda, 2011)	Journal: Statistical analysis to examine the independent contribution of pre-ESRD care and care post-hemodialysis with facility-specific mortality	Pre-ESRD and post-hemodialysis care were both strongly associated with individual patient mortality. In contrast, only pre-ESRD care is associated with facility mortality, suggesting that early mortality reflects differences in pre-ESRD care at the facility level.	• Individual patient mortality was associated with both pre-ESRD and post-hemodialysis care scores. Better care score is linked to a reduction in mortality. • There is substantial variation between treatment centers in case-mix-adjusted standardized mortality ratio, pre-ESRD, and post-hemodialysis care.
Pre-dialysis care	Pre-dialysis nephrologic care and a functioning arteriovenous fistula at entry are associated with better survival in incident hemodialysis patients (Lorenzo, 2004)	Journal: Prospective, observational, cohort study to evaluate the influence of two variables on mortality: presentation mode (planned versus unplanned) and type of access (arteriovenous fistula versus temporary catheter) at entry	Unplanned dialysis and catheter initiation were independently associated with greater mortality rates. The combined influence of both variables was associated with greater morbidity and mortality than either variable alone.	At 12 months, the number of deaths was three times higher in both the unplanned vs. planned groups and catheter vs. arteriovenous fistula groups. The joint effect of unplanned dialysis initiation and catheter use had an additive impact on mortality.
Dialysis care	Mortality in end-stage renal disease is associated with facility-to-facility differences in adequacy of hemodialysis (McClellan, 1998)	Journal: Survey and data analysis of 213 hemodialysis treatment facilities in North Carolina, South Carolina, and Georgia to examine the association between facility-to-facility differences in delivered hemodialysis dose and facility specific mortality rates	Lower average levels of dialysis adequacy in treatment centers were associated with higher rates of death; the association persists after controlling for facility-to-facility differences in patient and non-patient characteristics.	• Strong, inverse association between increasing treatment center urea reduction ratio and adjusted mortality. • Other characteristics associated with increased mortality: free standing status and decreasing frequency of reported physician supervision of care.

Table B3. Literature Review: ESRD Facilities

QUALITY ISSUE	TITLE (First author, Year)	SOURCE: DESIGN/AIM	KEY CONCLUSIONS	KEY SUPPORTING DATA
Quality domain: Patient-centeredness				
Patient Satisfaction	Patient assessment of quality of care in a chronic peritoneal dialysis (CPD) facility (Wuerth, 2000)	Journal: Cohort study and literature review to examine patients' perceptions of the organization and structure of the peritoneal dialysis facility and their interactions with the facility, focusing attention on areas of patient satisfaction and dissatisfaction with the facility	A taxonomy tool that directly reflects the patients' perception can be used to compare the organization, structure, and care provided by different CPD facilities and identifies domains that provide the best patient satisfaction.	Patients were most satisfied with the amount of information and instruction provided by the staff, personal atmosphere of the facility, efficiency of delivery of the dialysis supplies, and availability of the primary nurse. They were most dissatisfied by the dialysis regimen itself.
Quality domain: Timeliness				
No literature meeting search criteria was found about this domain.				
Quality domain: Efficiency				
Organizational structure	Relationships between registered nurse staffing, processes of nursing care, and nurse-reported patient outcomes in chronic hemodialysis units (Thomas-Hawkins, 2008)	Journal: Cross-sectional, correlational study to examine the effects of patient-to-RN ratios and necessary tasks left undone by RNs on the likelihood of nurse-reported frequent occurrences of adverse patient events in chronic hemodialysis units	RN staffing levels have a significant impact on patient outcomes.	High patient-to-RN ratios and increased numbers of tasks left undone by RNs were associated with an increase in dialysis hypotension, skipped/shortened treatments, and an increase in patient complaints.
Organizational structure	Adequacy of dialysis clinic staffing and quality of care: A review of evidence and areas of needed research (Wolfe, 2011)	Journal: Review of evidence related to inadequacies in clinic staffing and how they may be contributing to suboptimal care and outcomes	Staffing is an important consideration for improvement and is a structural measure of quality.	• There is an association between high patient to nurse ratios and several adverse outcomes. • Inconsistencies in technician education and training put patients at risk of adverse events and outcomes. • Dieticians help to mitigate malnutrition; social workers can mitigate other problems that affect clinical outcomes.

Table B3. Literature Review: ESRD Facilities

QUALITY ISSUE	TITLE (First author, Year)	SOURCE: DESIGN/AIM	KEY CONCLUSIONS	KEY SUPPORTING DATA
Organizational structure	Patient care staffing levels and facility characteristics in U.S. hemodialysis facilities (Yoder, 2013)	Journal: Cross-sectional study using Poisson regression to examine variation and associations of patient care staffing levels and hemodialysis facility characteristics	There is significant variation in patient-care staffing levels and its associations with facility characteristics.	• Ratios of RNs and LPNs to patients were 35% and 42% lower, but the PCT-to-patient ratio was 16% higher in for-profit facilities than in nonprofit facilities • Regionally, compared to the Northeast, the adjusted RN-to-patient ratio was 14% lower in the Midwest, 25% lower in the South, and 18% lower in the West.
Quality measures	Changes in Medicare reimbursement and patient-nephrologist visits, quality of care, and health-related quality of life (Mentari, 2005)	Journal: Statistical analysis to determine the impact of Medicare's reimbursement change on patient-nephrologist visits, quality of care, and health-related quality of life	Despite a marked increase in visits between patients and nephrologists, there was no clinically important impact on parameters related to quality of care or health-related quality of life.	• The number of visits per patient-month increased from 1.52 to 3.14. • There were no clinically important changes in Kt/V, albumin level, hemoglobin level, phosphorus level, calcium level, hemodialysis catheter use, ultrafiltration volume, shortened or skipped treatments, hospital admissions, hospitalization days, or health-related quality of life, including patient satisfaction.
Quality domain: Equity				
Access to care	Variation in access to kidney transplantation across dialysis facilities: Using process of care measures for quality improvement (Alexander, 2002)	Journal: Cohort study examining steps in the transplantation process (medical suitability, interest in transplantation, pre-transplantation workup, and waiting list), in order to guide efforts to improve the equity and efficiency of transplantation	There is substantial variation across dialysis facilities in access to kidney transplantation, even after adjustment for patient characteristics. Identifying steps with less than expected completion rates may help facilities target such efforts as treatment of medical conditions, patient education, and early referral for pre-transplantation workup and waiting list placement.	• No significant relationship between facility characteristics and overall transplantation rate or completion of specific steps in the transplantation. • Markedly greater transplantation rate and completion of more steps in the transplantation process at combined dialysis and transplantation centers. These centers better educate patients about the benefits of transplantation and address concerns about adverse effects or costs of transplantation.
Access to care	Variation in nephrologist visits to patients on hemodialysis across dialysis facilities and geographic locations (Erickson, 2013)	Journal: Statistical analysis of variation in the frequency of physician visits to patients receiving hemodialysis, adjusting for provider practice patterns and patient health	Visit frequency depends more on geography and facility location and characteristics than patients' health status or acuity of illness.	Patient characteristics accounted for 0.9% of the total visit frequency variation. Accounting for case-mix differences, facility characteristics explained about 24.9% of variation. More recent dialysis initiation and recent hospitalization were associated with decreased visit frequency.

Table B3. Literature Review: ESRD Facilities

QUALITY ISSUE	TITLE (First author, Year)	SOURCE: DESIGN/AIM	KEY CONCLUSIONS	KEY SUPPORTING DATA
Access to care	National profile of practice patterns for hemodialysis vascular access in the United States (Reddan, 2002)	Journal: Statistical analyses of associations of access type with demographic, laboratory, and geographic variables	Despite translation of practice guidelines for hemodialysis vascular access into national Clinical Performance Measures, there is substantial geographic variability and gender and racial disparity in angio-access allocation in the United States.	• Independent predictors of having a catheter for hemodialysis were female gender, white race, and lower hemoglobin and serum albumin. • Catheter use is less frequent in the Northeastern U.S. region.
Access to care	Who will protect the "disruptive" dialysis patient? (Smetanka, 2006)	Journal: Case study examining past cases of disruptive patient dismissal and discuss possible solutions to ensure continued treatment of difficult patients	The “no duty to treat” principle perpetuates the problem of disruptive patient discharge into a healthcare landscape without options. Presumptions traditionally lie in favor of the healthcare provider unless the patient can prove discrimination. Patients may be asked to sign an agreement that they refrain from disruptive behavior.	• Difficult patients can drive staff away and create an uncomfortable environment in a facility. • A disruptive patient whose behavior is perceived as dangerous faces the possibility of being denied access to other facilities.
Quality measures	Variation in dialysis quality measures by facility, neighborhood and region (Saunders, 2013)	Journal: Statistical analysis to examine whether dialysis facility characteristics, neighborhood demographics, and region were associated with CMS dialysis quality measures in order to determine the most important areas for intervention	The proportion of African-Americans in a dialysis facility neighborhood is strongly and consistently associated with lower facility quality.	Facilities with the highest proportion of African-Americans in the neighborhood had worse patient survival, were less likely to have adequate dialysis, and achieve targeted hemoglobin compared to those with the lowest proportion. No other predictor (facility, neighborhood, or region) was consistently associated with dialysis facility quality.
Quality domain: General				
No additional literature found.				

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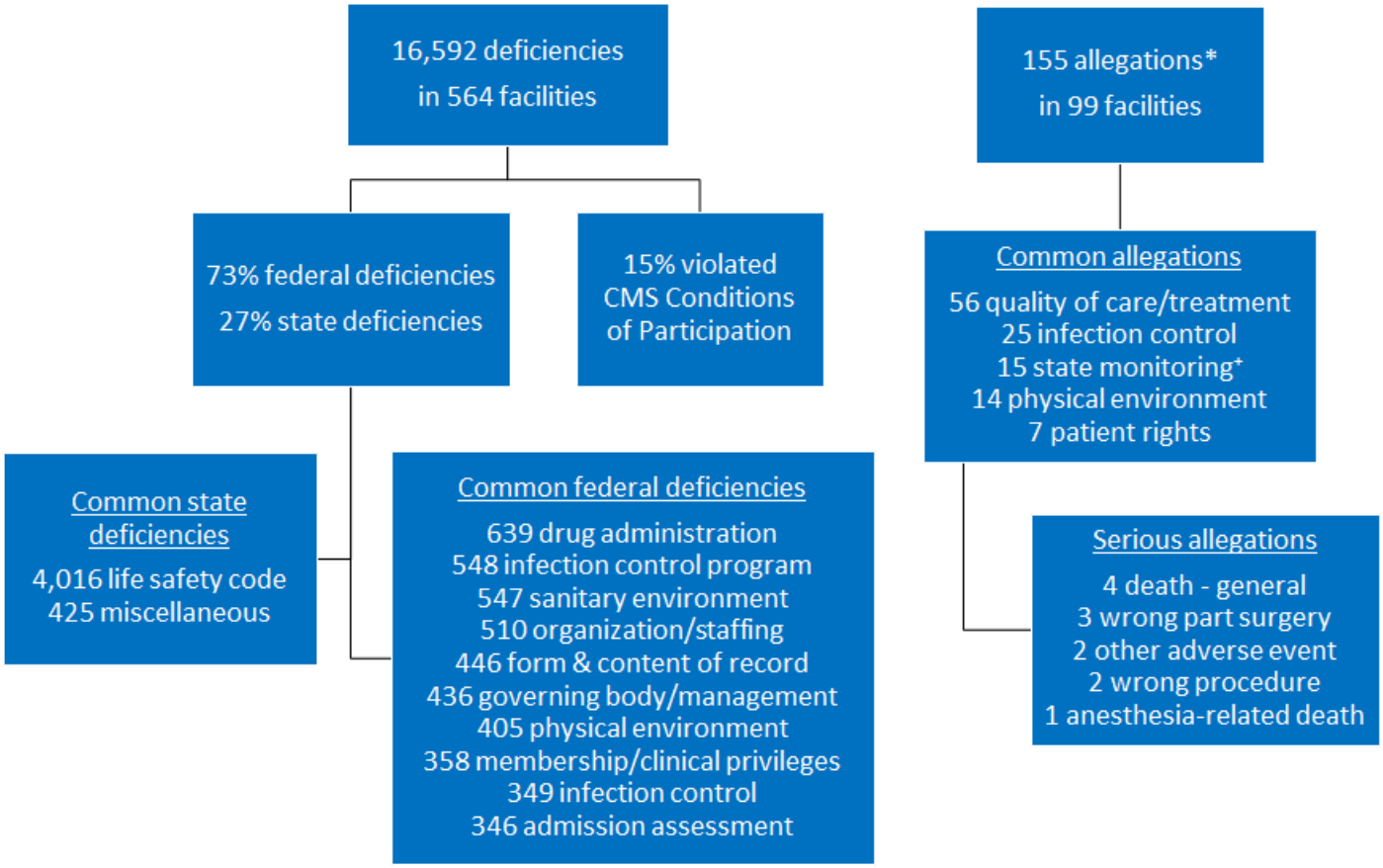
Appendix C -
Quality Issues in California:
L&C Survey Findings

Figure C1. Compliance Violations in California ASCs

September 2005-September 2015

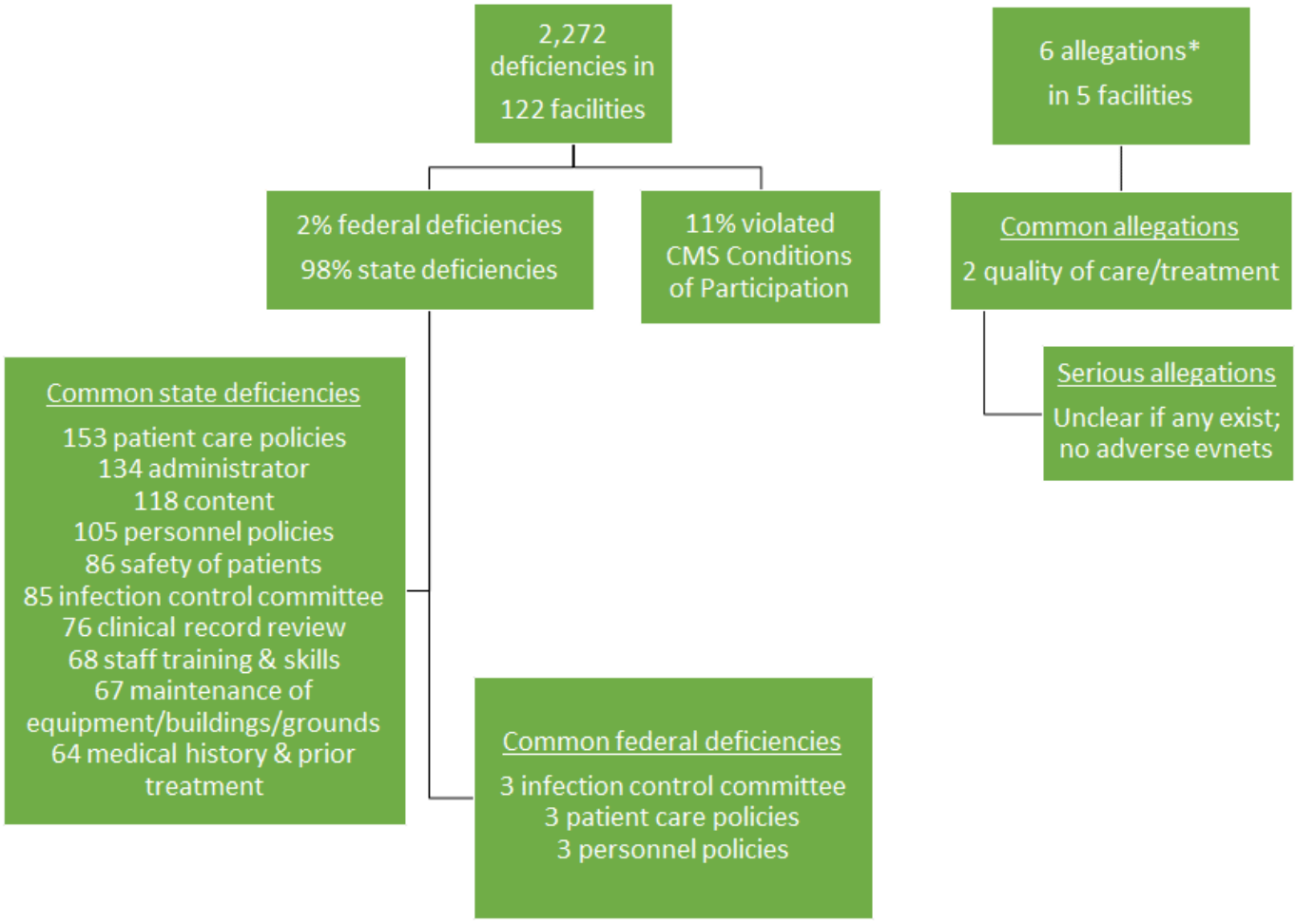


* For cases that were determined by L&C surveyors to be substantiated, with deficiencies .

+ Includes breach of information, adverse event, product/device events - selected examples are detailed under serious allegations.

Figure C2. Compliance Violations in California CORFs

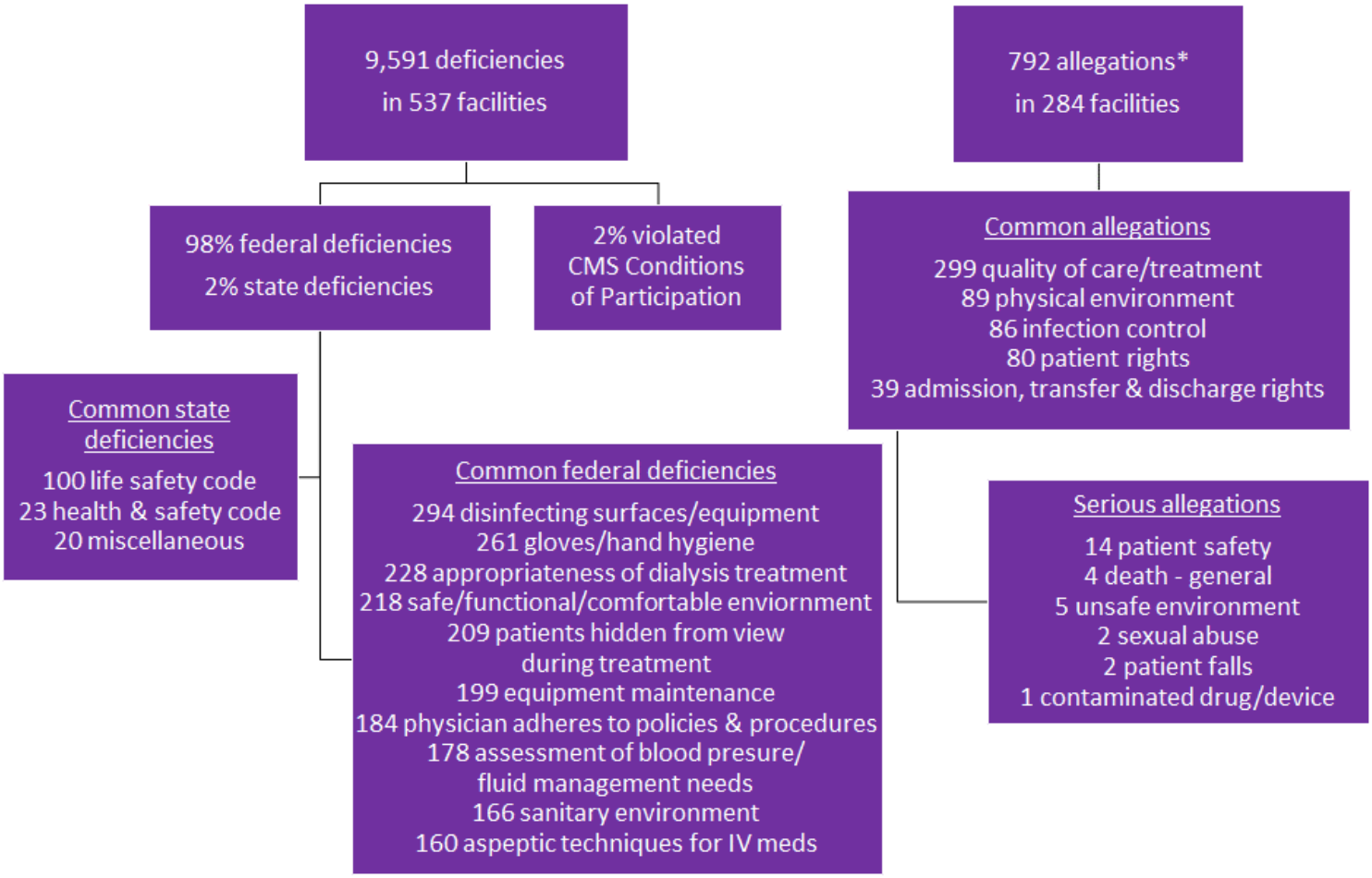
September 2005-September 2015



* For cases that were determined by L&C surveyors to be substantiated, with deficiencies.

Figure C3. Compliance Violations in California ESRD Facilities

September 2005-September 2015



* For cases that were determined by L&C surveyors to be substantiated, with deficiencies.

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