HIDA LEARNING CENTER

Overview of Ambulatory Surgery Centers Legislation & Regulation

David Shapiro, M.D.
Consultant/Risk Manager,
Red Hills Surgical Center

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Major Types of ASC Classifications

- Licensure
- Certification
- Accreditation

Regulation Overview

Federal

CMS Certification

- Compliance with CMS Conditions for Coverage and
- Current “Rule “ Provisions

State

Licensure

- Compliance with State Regulations
- Local Building and Operational Requirements (usually governed by State Governments and State Healthcare Authority)

Accreditation

- Discretionary
- Deemed v. Non-Deemed
- Compliance with Standards promulgated by A.O.s

Accreditation Organizations

AAAHC - Accreditation Association for Ambulatory Health Care

ACHC - Accreditation Commission for Health Care (formally Healthcare Facilities Accreditation Program -HFAP Before the merger, HFAP and ACHC were separate accrediting organizations)

Quad A (formally American Association for Accreditation of Ambulatory Surgery Facilities - AAAASF)

The Joint Commission (TJC)

Health and Human Services (HHS)

- The Department of Health and Human Services (HHS) is the United States government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves.
- The work of HHS is conducted by the Office of the Secretary and 11 agencies.
- The offices of the Office of the Secretary provide direct support for the Secretary's initiatives.

HHS Structure: Agencies

- **Agencies**
  The agencies perform a wide variety of tasks and services, including research, public health, food and drug safety, grants and other funding, health insurance, and many others.

- OS - Office of the Secretary
  ACF - Administration for Children & Families
  AoA - Administration on Aging
  AHRQ - Agency for Healthcare Research & Quality
  ATSDR - Agency for Toxic Substances & Disease
  CDC - Centers for Disease Control & Prevention
  CMS - Centers for Medicare & Medicaid Services
  FDA - Food & Drug Administration
  HRSA - Health Resources & Services Administration
  IHS - Indian Health Service
  NIH - National Institutes of Health
  OIG - Office of Inspector General
  SAMHSA - Substance Abuse & Mental Health Services Administration

HHS Structure: Offices

- **Offices**
  The subdivisions of the Office of the Secretary provide direct support for the Secretary's initiatives.

- Immediate Office of the Secretary (IOS)
  The Immediate Office of the Secretary includes:
  - Office of the Deputy Secretary (DS)
    Directs operations of the largest civilian department in the federal government.
  - Office of the Chief of Staff (COS)
  - The Executive Secretariat (ES)
  - Office of Intergovernmental Affairs (IGA)
    Facilitates communication regarding HHS initiatives with state, local, and tribal governments.
  - Office of the Secretary's Regional Directors
    Oversees regional and state office directors.
  - Office on Disability (OD)
    Advises on HHS activities relating to persons with disabilities.

- Assistant Secretary for Administration and Management (ASAM)
  Provides leadership for HHS management, including human resource policy, grants management, acquisitions, and departmental operations

- Assistant Secretary for Resources and Technology (ASRT)
  Provides advice and guidance to the Secretary on budget, financial management, information technology, grants management, and provides for the direction and coordination of these activities throughout the Department.

- Assistant Secretary for Health (ASH)/ Office of Public Health and Science (OPHS)
  Advises the Secretary on matters involving the nation's public health, oversees the Office of Public Health and Science (OPHS) which serves as the focal point for leadership and coordination across the Department in public health and science, and leads the U.S. Public Health Service (USPHS) Commissioned Corps, providing it with strategic and policy direction.

- Assistant Secretary for Legislation (ASL)
  Serves as the primary liaison between the Department of Health & Human Services (HHS) and Congress.

- Assistant Secretary for Planning and Evaluation (ASPE)
  Directs major activities in policy coordination, legislation development, strategic planning, policy research, evaluation, and economic analysis.

- Assistant Secretary for Public Affairs(ASPA)
  Serves as the principle counsel on public affairs matters, conducts a national public affairs program, provides centralized leadership and guidance for public affairs activities, including Web and new media and broadcast communications, within HHS' staff and operating divisions and regional offices, and administers the Freedom of Information and Privacy Act.

- Assistant Secretary for Preparedness and Response (ASPR)
  Advises on matters related to bioterrorism and other public health emergencies and disasters.

- Departmental Appeals Board (DAB)
  Provides prompt, fair, and impartial dispute resolution services with parties related to HHS office issues.

- Office for Civil Rights (OCR)
  Enforces Federal laws that prohibit discrimination by health care and human services providers that receive funds from HHS.

- Office of Global Health Affairs (OGHA)
  Represents the Department to the governments, other Federal Departments and agencies, international organizations and the private sector on international and refugee health issues.

- Office of Inspector General (OIG)
  Protects the integrity of HHS programs, as well as the health and welfare of the beneficiaries of those programs.

- Office Of Medicare Hearings and Appeals (OMHA)
  Administers nationwide hearings for the Medicare program.

- Office of the National Coordinator for Health Information Technology (ONC)
  Provides counsel to the Secretary of HHS and Departmental leadership for the development and nationwide implementation of an interoperable health information technology infrastructure.

- Office of the General Counsel (OGC)
  Represents HHS and offers legal advice on a wide range of highly visible national issues.

- Center for Faith Based and Community Initiatives (CFBCI)
  Provides information and technical assistance to help faith-based and community organizations to compete more effectively for Federal funds.

Guess Who's Coming to Dinner

...or, to an ASC...

Occupational Safety & Health Administration (OSHA)

hazards such as sharps injuries that expose healthcare workers to bloodborne pathogens

Food and Drug Administration (FDA)

primarily pertaining to the facility's response to recalls

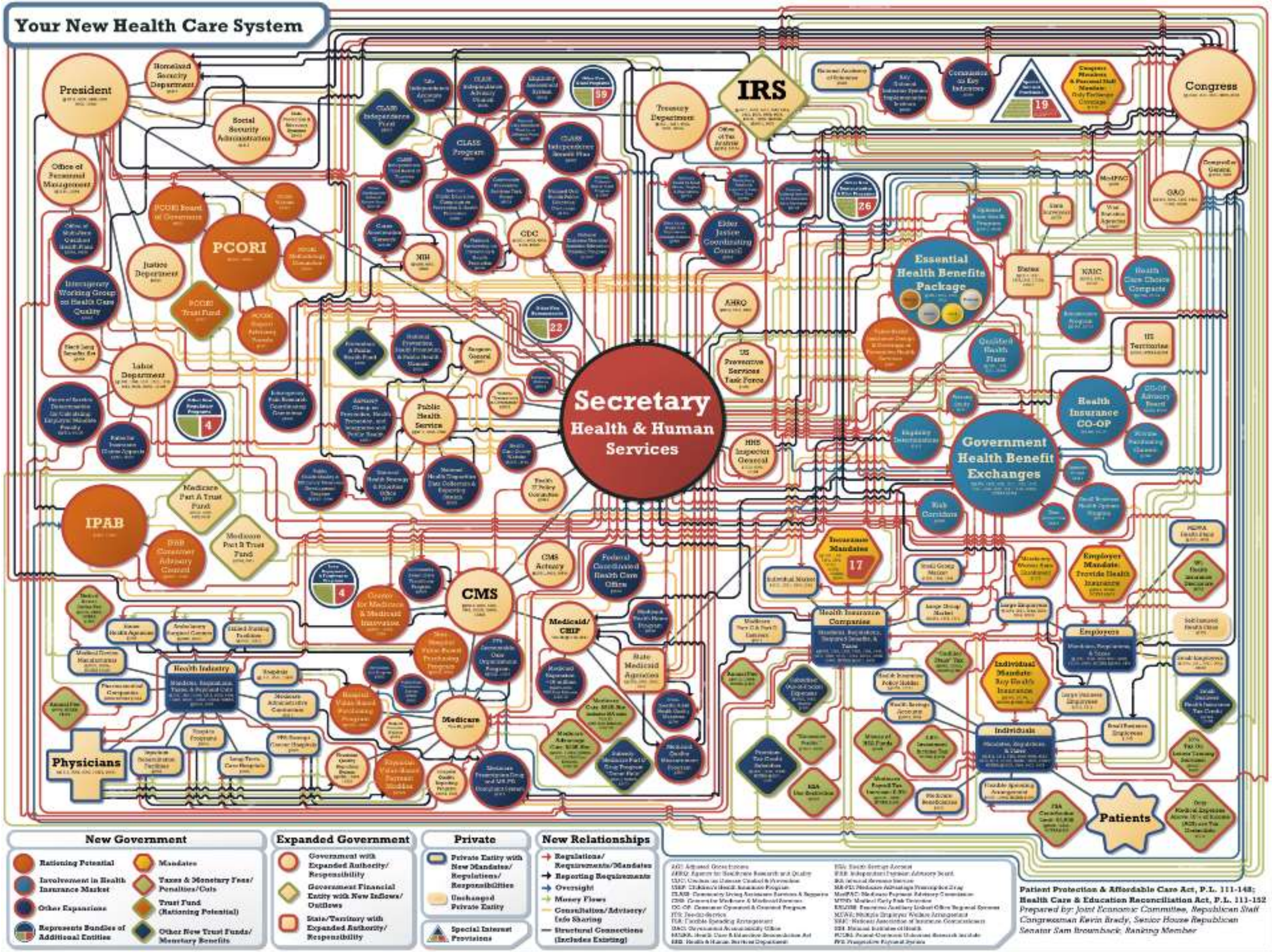
Environmental Protection Agency (EPA)

hazardous and pharmaceutical waste disposal

Drug Enforcement Agency (DEA)

handling and disposal of controlled substances by ASCs

Centers for Medicare & Medicaid Services (CMS)



Patient Protection & Affordable Care Act, P.L. 111-148;
Health Care & Education Reconciliation Act, P.L. 111-152
Prepared by: Joint Economic Committee, Republican Staff
Congressman Kevin Brady, Senior House Republican
Senator Sam Brownback, Ranking Member

CMS

A division of the

U.S. Department of Health & Human Services (HHS)

Centers for Medicare and Medicaid Services

Why do we care?

Certify ASCs' Participation in Federal Programs

- Conditions for Coverage
  - Infection Control Checklist

Determine Payment Policies

- Allowable Procedures
- Applicable Rates
- Annual Updates

Administer Quality Reporting Programs

ASC Payment System

Medicare payment for outpatient services provided in hospitals is based on set rates under Medicare Part B.

The system for payment, known as the Outpatient Prospective Payment System (OPPS) is used when paying for services such as X rays, emergency department visits, and partial hospitalization services in hospital outpatient departments.

Payment for ambulatory surgical center (ASC) services is also based on rates set under Medicare Part B.

This system for payment is called the **ASC Payment System** and is used when paying for covered surgical procedures, including ASC facility services that are furnished in connection with the covered surgical procedure.

CMS updates the OPPS/ASC regulations together in one rule annually, with comment periods open prior to implementation of the final rule.

Because a significant amount of surgical care takes place in hospital outpatient departments and ASCs, the ACS has a strong interest in CMS' OPPS and ASC Payment System and the quality improvement efforts addressed in the OPPS/ASC rule.

CMS
Conditions for Coverage

www.ascassociation.org/conditionsofcoverage.pdf

Effective May 18, 2009

- CMS Conditions for Coverage expanded from a 9 page document to approximately 149 pages of Standards and Interpretive Guidelines, ***plus***
- A 16 page of Infection Control Surveyor Worksheet

ASC Definition

Prior-

"means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization"

Effective May 18, 2009 -

"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."

CMS Conditions for Coverage Revisions

416.50 Patients Rights (2011)
416.44 (c) Emergency Equipment (2012)
416.44 (a) Physical Environment
(Temperature & Humidity) (2013)
416.50 (c) Advance Directives (2013)
416.49 (b) Radiologic Services (2014)

§ 416.65 Covered surgical procedures

b) *Excluded services.* Facility services do not include items and services for which payment may be made under other provisions of part 405 of this chapter, such as physicians' services, laboratory, X-ray or diagnostic procedures (other than those directly related to performance of the surgical procedure), prosthetic devices (except IOLs), ambulance services, leg, arm, back and neck braces, artificial limbs, and durable medical equipment for use in the patient's home. In addition, they do not include anesthetist services furnished on or after January 1, 1989.

(a) ***General standards***. Covered surgical procedures are those surgical and other medical procedures that—

(1) Are commonly performed on an inpatient basis in hospitals, but may be safely performed in an ASC;

(2) Are not of a type that are commonly performed, or that may be safely performed, in physicians' offices;

(3) Are limited to those requiring a dedicated operating room (or suite), and generally requiring a postoperative recovery room or short-term (not overnight) convalescent room; and

(4) Are not otherwise excluded under § 411.15 of this chapter.

(b) ***Specific standards***.

(1) Covered surgical procedures are limited to those that do not generally exceed—

(i) A total of 90 minutes operating time; and

(ii) A total of 4 hours recovery or convalescent time.

(2) If the covered surgical procedures require anesthesia, the anesthesia must be—

(i) Local or regional anesthesia; or

(ii) General anesthesia of 90 minutes or less duration.

§ 416.65 Covered surgical procedures

3) Covered surgical procedures may not be of a type that—

(i) Generally result in extensive blood loss;

(ii) Require major or prolonged invasion of body cavities;

(iii) Directly involve major blood vessels; or

(iv) Are generally emergency or life-threatening in nature.

(c) *Publication of covered procedures.* CMS will publish in the FEDERAL REGISTER a list of covered surgical procedures and revisions as appropriate.

Outpatient Surgery Quality and Access Act of 2023

ASCs save Medicare approximately $7 billion a year. Future savings, however, are threatened by problematic Medicare policies that result in continually declining reimbursement and other factors that limit Medicare beneficiaries' access to outpatient surgical care.

By enacting the *Outpatient Surgery Quality and Access Act of 2023* (H.R. 972/S. 312), Congress will ensure Medicare beneficiaries' continued access to high-quality outpatient surgery.

Align the Reimbursement Update Factor for Identical Outpatient Procedures

Issue: Medicare and its beneficiaries generally pay twice as much for procedures performed in hospital outpatient departments (HOPD) instead of ASCs.

This disparity exists, in part, because ASC payment rates were updated annually using the Consumer Price Index for All Urban Consumers (CPI-U), while HOPD payments were updated with the hospital market basket.

In 2019, the Centers for Medicare & Medicaid Services (CMS) agreed to align the update factors and use the hospital market basket to update payments in ASCs for a five-year trial period.

Solution: This provision of the bill makes permanent the alignment of update factors, helping to move to a more complete alignment of the ASC and HOPD payment systems.

Provide Beneficiaries with Outpatient Surgery Quality Information

Issue: While price comparisons for ASCs and HOPDs are readily available to the public, quality data is not available in a consumer-friendly format.

Solution: This provision of the bill directs the US Department of Health & Human Services (HHS) to publish a comparison of quality measures that apply to both ASCs and HOPDs.

Add an ASC Representative to the Advisory Panel on Hospital Outpatient Payment

Issue: The Advisory Panel on Hospital Outpatient Payment makes recommendations to the HHS secretary on issues impacting the HOPD and ASC payment systems, but membership is comprised solely of hospital and health system representatives.

Solution: This provision of the bill designates one seat on the panel for a representative from the ASC community.

Create a Review Process for Potential Outpatient Procedures

Issue: There is no formal process for stakeholders to request that codes be added to the ASC Covered Procedures List (ASC-CPL), and CMS is not required to be transparent as to its rationale for keeping a procedure off the ASC-CPL.

Solution: This provision of the bill directs CMS to publish its rationale for declining to add any codes to the ASC-CPL that were formally requested by industry stakeholders.

Eliminate the Copay Penalty for Part B Services

Issue: A beneficiary typically has a coinsurance responsibility of 20 percent of the procedure's cost when that procedure is performed in an ASC. When a beneficiary receives the same procedure in an HOPD, the copay is capped at the inpatient deductible amount, which is $1,600 for 2023, and the hospital is made whole by the Medicare program. This copay penalty limits patients' access to care in ASCs and ultimately increases costs to Medicare, its beneficiaries and taxpayers.

This issue primarily impacts those without supplemental coverage—an area where a racial disparity in access has been observed, with only 40 percent of black beneficiaries being covered by supplemental insurance in contrast to 72 percent of white beneficiaries.

Solution: This provision of the bill applies the same framework that applies to HOPD services, capping a beneficiary's copay and making the facility whole for the difference.

Allow ASC Services to Grow Naturally

Issue: The HOPD relative payment weights are scaled for budget neutrality. Then, CMS applies a second, ASC-specific weight scalar to maintain budget neutrality within the ASC payment system. While the legislation directing HHS to implement a revised ASC payment system required CMS to use this second weight scalar in the *first year of implementation*, the agency has continued to apply this calculation to ASC payment weights annually. The secondary weight scalar penalizes ASCs for shifting Medicare services from higher-cost settings, and in doing so, artificially limits what otherwise would be the natural migration to the lower-cost ASC setting.

Solution: This provision of the legislation prohibits the agency from conducting the secondary scaling calculation. Instead, the legislation directs the agency to combine ASC and HOPD volume and calculate one outpatient weight scalar, making this provision budget neutral.

Selected State Legislative Issues

CON

Length of Stay: 23-hour, 72-hour (e.g., recovery care)

Scope of Practice: RNs, STs, CRNAs

“Transparency” (OON, Line-Item Billing)

Workman’s Comp

Smoke Evacuation

Facility Fees

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