

HEALTHCARE-ASSOCIATED INFECTIONS IN AMBULATORY SURGICAL CENTERS
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Madam Chair and Members of the Committee:

My name is Shawn Mathis, and I am a staff attorney with the Legislative Council Service, where my primary assignment is health care legislation. I am here today to discuss the issue of infection control in ambulatory surgical centers, or ASCs. I come by my interest and expertise in this area as a result of extensive study while pursuing a master's degree in health law. I was a Fellow at Loyola University Chicago's Beazley Institute of Health Law and Policy for the 2010-2011 school year. Infection control in ASCs was the topic of my master's thesis. Two articles that I authored on this topic have been accepted for publication this fall. I have practiced law for over 30 years and managed litigation for two Fortune 500 companies in the chemical and hazardous waste industries.

My remarks begin with an overview of the ASC industry and of conditions that health inspectors have found in recent inspections of ASCs. Next, I'll explain how the largest Hepatitis C outbreak in the nation led to the discovery of industrywide problems and discuss the current regulatory scheme that addresses infection control in ASCs. Third, I'll give examples of infection control problems in New Mexico ASCs taken from public health inspection reports and provide data on the frequency of those inspections. Finally, I will report on policy recommendations from public health authorities that advocate for more frequent facility inspections and for continuing education to prevent lapses in infection control.

Introduction

An ambulatory surgical center is a stand-alone facility where medical procedures or uncomplicated surgeries take place. An ASC can have many surgical suites or as few as two beds. Hospital outpatient departments and physician offices are not ambulatory surgical centers. ASCs typically specialize in ophthalmology, gastroenterology and orthopedics, but other specialties may offer medical services at an ASC. The cases handled by ASCs are elective and not emergencies. Procedures may take only minutes, and patients do not stay overnight. Nor is it typical for patients to return to the ASC after the procedure.¹ Patients tend to be private pay, with very few Medicare and even fewer Medicaid patients.²

The vast majority of ASCs are owned by physician investors. Very few ASCs are owned or operated by large national health care companies, and only a small percentage of ASCs are joint ventures between hospitals and physicians. Today, nearly 75% percent of all surgeries and procedures performed in the United States take place in ASCs.³ According to an ASC industry web site, more than 22 million surgeries and procedures are performed in over 5,300 ASCs in the United States each year.⁴

While ambulatory care settings understandably lack the infrastructure and resources of

hospitals to support infection prevention and surveillance activities, outbreaks from ambulatory clinics have frequently resulted from breakdowns in the most basic of infection prevention measures, such as adherence to Standard Precautions.⁵ A summary of the findings of state public health officials who randomly inspected 37 Illinois ASCs illustrates the problem:

- 35% either lacked an infection control program, or had an infection prevention program that was deficient;
- 27% could not document any infection prevention training of employees;
- 38% were cited for deficiencies in sterilization procedures, such as failing to sterilize equipment for the full time required according to the sterilizer manufacturer's instructions, or mixing sterile and non-sterile equipment or supplies in common areas;
- 21% were cited for unsanitary conditions, such as not having proper cleaning supplies, or having equipment in such a state of disrepair that surfaces could not be disinfected;
- 11% were cited for unsafe injection practices that could lead to transmission of infection from one patient to another;
- 8% were cited for reuse of single-use items such as surgical burrs used to cut bone;
- 38% were cited for hair, mask and apparel violations by physicians as well as nurses that could spread infection from one patient to another; and
- 11% were cited for other deficiencies, such as underreporting or failing to track surgical infection rates, not requiring pre-employment screening of clinic staff for tuberculosis, keeping a purse on a medication cart and observed failures of both physicians and nurses to change gloves or wash hands between patients.⁶

What Happened in Las Vegas, Nevada . . .

In 2008, a Las Vegas, Nevada, ASC was responsible for the largest Hepatitis C (HCV) outbreak in the country. The ASC where the outbreak originated performed colonoscopies and had *only two beds*. After an extensive investigation by the Southern Nevada Health District and the Centers for Disease Control and Prevention (CDC), 63,000 patients were notified that they had potentially been exposed to Hepatitis C.⁷ Public health officials estimated that the investigation, response and community testing associated with the outbreak cost between \$16-20 million.

The reason a two-bed ASC was able to potentially infect so many patients is due in part to the ASC business model. ASCs have been called "focused factories" that are models of highly specialized and efficient delivery of health care.⁸ Tight scheduling is not the exception, it is the

rule for this industry. One ASC industry web site recently saluted 30 ASCs that each performed more than 10,000 procedures annually.⁹ The Nevada ASC responsible for the outbreak had two surgical suites, with patients double-booked and scheduled at 15-minute intervals. The clinic would perform from 50 to 60 procedures a day.¹⁰

As this committee well knows, HCV is a serious disease that can cause liver damage, liver cancer and even death if untreated.¹¹ It is the single leading cause of liver transplantation in the United States.¹² There is no vaccine to prevent HCV, and treatment is expensive.¹³ It is a national epidemic, and it is the most common blood-borne viral infection in the nation.¹⁴ Of interest to this committee, New Mexico has the highest rate of deaths due to chronic liver disease and cirrhosis in the nation.¹⁵ In New Mexico, HCV is 10 times more prevalent than HIV.¹⁶ A 2002 UNM study of emergency room admissions found that 17% of patients were infected with HCV.¹⁷

Another factor that contributed to the magnitude of the Nevada outbreak is the nature of the Hepatitis C virus itself. The virus is spread through blood-to-blood contact and not through household or casual contact.¹⁸ At room temperature, the virus can survive on surfaces from 16 to 96 hours.¹⁹ Fewer than 10% of those infected with HCV develop acute disease characterized by the sudden onset of symptoms — and those who do become symptomatic may only do so from two weeks to six months after infection.²⁰

HCV is such a serious public health concern that it is tracked in national case surveillance.²¹ As a result of this public health reporting requirement, three HCV cases came to the attention of Nevada public health authorities, with the Las Vegas ASC determined to be the common denominator. Unfortunately, the delay of onset of HCV symptoms also delayed identification of the ASC as the source of the infections, during which time the ASC continued to operate unsafely and place patients at risk. In the end, Nevada authorities determined that the unsafe practices leading to the outbreak had been going on for several years.²² Following the outbreak, Nevada health authorities inspected every ASC in the state; almost half had infection control deficiencies.²³

... Can Happen Anywhere

While there has been great attention paid to the issue of healthcare-associated infections (HAIs) in hospitals, little attention has been paid to HAIs originating in ASCs. This is due to the lack of regulatory oversight of ASCs when compared to the regulation of hospitals. Under the Social Security Act, the United States Department of Health and Human Services is responsible for promulgating and enforcing regulations to protect the health and safety of ASC patients.²⁴ Facility inspections were, and remain, the only method used to determine an ASC's compliance with federal regulations. The Centers for Medicare and Medicaid Services (CMS) contracts with state departments of health to survey, or inspect, ASCs that are not voluntarily accredited but that seek to participate in federal health care programs. In addition to their role as inspectors for CMS, state health agencies are also responsible for oversight and enforcement of state certification or accreditation for ASCs operating within their jurisdiction.

Due to the explosive growth of ASCs from the mid-1970s, surveys of unaccredited ASCs

have been infrequent, and until very recently, surveyors did not formally assess infection control as part of the process.²⁵ As a result, the nation's ASCs were not inspected more often than every five to 10 years. The Nevada ASC responsible for the Hepatitis C outbreak had not been fully inspected by state surveyors in seven years. Nor were ASCs required to report data to federal or state regulators that could signal industrywide deficiencies. Further, CDC experts studying hepatitis outbreaks in non-hospital settings have concluded that many outbreaks go undetected — and that those that are discovered represent the "tip of the iceberg".²⁶

And as it turns out, infection control is a problem for the ASC industry as a whole. Following the Nevada Hepatitis C outbreak, CMS and the CDC conducted a pilot study to generate nationally representative data on infection control in ASCs. The results of the study were not comforting; overall, 67% of the ASCs surveyed had at least one lapse in infection control.²⁷

Infection control lapses of greatest concern related to medication handling and equipment reprocessing. Nearly a third of ASCs used single-dose vials of medication for multiple patients. Apparently to reduce costs, many of the ASCs surveyed had purchased single-dose medications in large-quantity vials and then used the contents for multiple patients.²⁸

Six percent of the ASCs in the pilot study were reprocessing and reusing items that were packaged and labeled as single-use devices.²⁹ Devices such as bite blocks and syringes used to flush the endoscope during endoscopy procedures fall into this category.³⁰ Reprocessing of single-use devices is regulated by the Food and Drug Administration (FDA) and may only be performed by third-party or hospital reprocessors who are approved and registered with the FDA.³¹ None of the pilot study ASCs cited for reprocessing single-use devices used third-party reprocessors, preferring to do it themselves.³²

Finally, 21% of the ASCs in the pilot study that performed blood glucose testing were using single-use lancing penlets for multiple patients. Even if the lancet is changed after each use, the barrel of the device can expose subsequent patients to blood-borne pathogens.³³ One-third of the facilities performing blood glucose testing failed to clean and disinfect the blood glucose meter after each use; facility personnel explained that they only cleaned it if it was visibly soiled.³⁴ Both of these types of lapses in infection control have been linked to viral hepatitis transmission in other health care settings.³⁵

Current Regulations Addressing Infection Control in ASCs

In 2009, CMS revised its Conditions for Coverage to specifically address the need for infection control and prevention programs in ASCs. Currently, a Medicare-certified ASC is required to maintain an infection control and prevention program based on nationally recognized guidelines. This program must be under the direction of a designated health care professional with training in infection control and prevention. The program must be integrated into the ASC's Quality Assessment and Performance Improvement Program. ASCs are not required to report this information; they are required to produce this information as part of any inspection to verify compliance with Conditions for Coverage.³⁶ Finally, the ASC is expected to prevent, identify and manage healthcare-associated infections through its infection control and prevention program.³⁷

New Mexico has 18 ASCs ("deemed" and "non-deemed") that are certified to participate in federal health care programs.³⁸

As a condition of initial licensure and renewal of licensure, the New Mexico Department of Health (DOH) may enter and inspect any ASC, unannounced.³⁹ Over the last four years, 14 out of 26 New Mexico ASCs have been inspected by DOH.⁴⁰ In 2010, CMS used American Recovery and Reinvestment Act (ARRA) funds to pay for a one-time survey of one-third of each state's non-accredited ASCs.⁴¹ New Mexico received an additional \$30,000 to survey six ASCs (one licensed-only and five non-deemed) in 2010.⁴² Using these figures, it appears that the average cost of each inspection is \$5,000.

New Mexico requires ASCs to report any serious incident or unusual occurrence that has, or could, threaten the health, safety or welfare of patients or staff, including any serious outbreak of contagious diseases dangerous to the public health, or any serious human error by a staff member of the facility "which has resulted in the death, serious illness, or physical impairment of a patient".⁴³ Since 2008, the Division of Health Improvement of the DOH has not received any reports of any infection or blood-borne disease associated with, or suspected of being associated with, a New Mexico ASC.⁴⁴

New Mexico requires each licensed ASC to have an ongoing comprehensive self-assessment of the services provided by the facility.⁴⁵ Each ASC is also expected to have written policies and procedures on 1) aseptic techniques and scrub procedures; 2) cleaning of operating rooms after each use; 3) sterilization and disinfection; 4) operating room attire; and 5) special provisions for infected or contaminated patients.⁴⁶

Results of New Mexico Inspections

While several New Mexico ASCs have passed inspection, others have been cited for deficiencies bearing on infection control. Observed problems documented in publicly available surveys for New Mexico's ambulatory facilities include:

- A 2008 survey of a Taos dialysis clinic found 10 treatment chairs with dried blood residue, and that the condition of several other treatment chairs prevented effective cleaning. (New Mexico has 40 dialysis clinics.)
- In 2011, a Las Cruces endoscopy center was cited for failure to ensure that all surgical procedures were performed in a safe manner "since the physicians and clinical staff did not follow acceptable standards of practices in meeting aseptic and sterile technique in performing procedures . . . [placing] all patients at higher risk of infection". The surveyor reported observing two procedures for which: inadequate case cleaning was done in the procedure rooms; not all staff were scrubbing prior to the case; the physician was observed going from the computer keyboard to put on a pair of disposable gloves, and then putting on a second set of gloves without scrubbing; and staff were not leaving disinfectant on surfaces in the procedure room long enough to achieve disinfection. The same center was cited for having [dirty]

scopes hanging from a rack in the procedure room with the tips touching the floor, and for having cleaned scopes stored in a storage unit open to air from an exhaust fan pulling air from a non-sterile corridor.

- In 2010, a Santa Fe surgery center was cited for inadequate cleaning between cases when an OR nurse was observed mopping the OR floor with a cleaning solution that was not left on the surface for the time necessary to kill infectious organisms as directed by the solution's manufacturer. In addition, overhead surgical lights that had been used during the previous surgery were not wiped down between cases.
- In 2010, an Albuquerque ASC was not collecting Quality Assurance data on any indicators on a regular basis, no data were being analyzed, no actions were being taken as a result of the QA program and no data or reports were being reported to the ASC's governing body.

Lessons Learned from the Nevada Outbreak

While progress has recently been made toward improving regulatory oversight of ASCs, CMS places ultimate accountability for HAI prevention and safe care on the ASC itself.⁴⁷ CMS reports that, based upon the number of citations issued by state inspectors since the implementation of the Conditions for Coverage targeted at infection prevention, "clearly there are educational needs that are not being met".⁴⁸

Following the Nevada outbreak, Nevada health officials determined that a system failure had allowed dangerous industry practices to continue in the absence of swift corrective action and decided to adopt a systems approach to analyzing the problem.⁴⁹ As a result, Nevada's Health Division developed an action plan to identify areas where policy could facilitate measures to protect the public.⁵⁰ Among the areas identified were:

1. State legislation or regulation specifically designating how often to survey ASCs. If a state does not have such laws, the default is the timetable established by CMS. Accredited ASCs are generally inspected each three years; CMS's stated goal for non-accredited ASCs is to conduct surveys once every four years.⁵¹ Nevada's Health Division suggests surveying all state licensed facilities every 18 months.

New Mexico follows CMS's timetable for inspecting ASCs and End Stage Renal Disease clinics, which appears to be once every three to four years.

2. State legislation or regulation mandating periodic infection control training for certain health care professionals. Nevada's Health Division strongly advises that physicians and other health care providers undergo periodic mandated education in proper infection control procedures by requiring certain health care professionals to certify to knowledge of, and compliance with, CDC infection prevention guidelines.⁵² According to the CDC, many outbreaks occur when health care

workers "[do] not adhere to fundamental principals related to safe injection practices, suggesting that they [fail] to understand the potential of their actions to lead to disease transmission".⁵³ To prevent the transmission of blood-borne viruses, the CDC recommends certification and training in infection control principles and practices, including aseptic techniques and safe injection practices. In addition, it recommends frequent in-service education and oversight by management to detect and correct breaches in infection control practices.⁵⁴ In 2011, Nevada enacted legislation that conditions the granting or renewal of licenses for certain health care professionals upon certification that the licensee has knowledge of and complies with CDC guidelines concerning the transmission of infectious agents through safe and appropriate injection practices. Further, physicians must attest that any person who is under the control or supervision of the physician and who is not licensed and whose duties involve injection practices has knowledge of and is in compliance with the CDC guidelines.⁵⁵

New Mexico does not currently require any continuing medical education or training in infection control and prevention as a condition of a professional licensure or renewal.

3. Development of an internet-based standard infection control curriculum based on CDC guidelines for health care personnel.⁵⁶
4. Transparency of survey and complaint investigation results.⁵⁷

Survey reports for New Mexico ASCs may be accessed online at <https://dhi.health.state.nm.us/providersearch>.

STANDARD PRECAUTIONS

Standard precautions are minimum infection-prevention practices that apply to all patient care, regardless of suspected or confirmed infection status of the patient, in any setting in which health care is delivered. These practices are designed both to protect health care personnel and prevent health care personnel from spreading infections among patients.

Standard precautions include: 1) hand hygiene; 2) use of personal protective equipment (e.g., gloves, gowns, masks, etc.); 3) safe injection practices; 4) safe handling of potentially contaminated equipment or surfaces in the patient environment; and 5) respiratory hygiene/cough etiquette.

Source: Centers for Disease Control and Prevention, *Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care*, <http://www.cdc.gov/HAI/pdfs/guidelines/standards-of-ambulatory-care-7-2011.pdf>, p. 8.

SAFE INJECTION PRACTICES

- Needles are used for only one patient.
- Syringes are used for only one patient.
- Medication vials are always entered with a new needle and syringe.
- Single-use vials are used on only one patient.
- Manufacturer pre-filled syringes are used on only one patient.
- Bags of IV solution are used on only one patient.
- Medication tubing and connectors are used on only one patient.
- If a product is labeled "single use", it cannot be used again.

"A Persistent Misconception and Dangerous Practice"

- The lack of a needle does NOT make a syringe reusable. A syringe should be used only once.
- A syringe is never protected against contamination by changing the needle or by using needleless systems.

Source: The Association for Professionals in Infection Control & Epidemiology, *Infection Prevention for Ambulatory Surgery Centers: Meeting CMS Conditions for Coverage* (2011).

1. Patients "present to the ASC for the procedure itself but typically do not return for routine post-operative care, or if there are complications with the procedures. Instead, they present to an area hospital or their personal physician for evaluation and treatment. These visits are not necessarily reported back to the ASC". U.S. Department of Health & Human Services, *National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination*, p. 3, http://www.hhs.gov/ash/initiatives/hai/ambulatory_surgical_centers.html.
2. MedPac, *Report to Congress — Medicare Payment Policy*, 98 (Mar. 2010).
3. Centers for Disease Control and Prevention, *Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care*, last accessed February 11, 2012 at <http://www.cdc.gov/HAI/pdfs/guidelines/standards-of-ambulatory-care-7-2011.pdf>, p. 3.
4. Ambulatory Surgery Center Advocacy Committee, *ASC Policy Focus*, last accessed August 6, 2012 at <http://advancingsurgicalcare.com/asc-policy/>.
5. Centers for Disease Control and Prevention, *Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care*, last accessed February 11, 2012 at <http://www.cdc.gov/HAI/pdfs/guidelines/standards-of-ambulatory-care-7-2011.pdf>, p. 3. Standard Precautions are "minimum infection prevention practices that apply to all patient care, regardless of suspected or confirmed infection status of the patient, in any setting in which healthcare is delivered. These practices are designed to both protect [healthcare personnel] and prevent [healthcare personnel] from spreading infections among patients. Standard Precautions include: 1) hand hygiene, 2) use of personal protective equipment (e.g., gloves, gowns, masks), 3) safe injection practices, 4) safe handling of potentially contaminated equipment or surfaces in the patient environment, and 5) respiratory hygiene/cough etiquette." *Id.*, p. 8.
6. Surveys were conducted by state surveyors between January 1, 2010 and October 15, 2011, and copies are on file with the author.
7. *Southern Nevada Health District Outbreak Investigation Report* (December 2009) ("SNHD Outbreak Investigation Report").
8. John Bian & Michael A. Morrissey, *Free-Standing Ambulatory Surgery Centers and Hospital Surgery Volume*, 44 INQUIRY- J. HEALTH CARE 200 (2007).
9. Abby Callard, *30 ASCs Performing More Than 10,000 Procedures A Year*, (February 1, 2012) last accessed at <http://www.backersasc.com/lists/30-asc-performing-more-than-10000-procedures-a-year/print.html>. To put this into perspective, the average hospital performs 5,600 outpatient procedures annually.
10. *SNHD Outbreak Investigation Report*, *supra* note 7, at 12.
11. New Mexico Department of Health, *Hepatitis C Fact Sheet* (March 12, 2008).
12. *Id.*
13. *Id.*
14. *Id.*
15. *Id.*

16. *Id.*
17. *Id.*
18. SNHD Outbreak Investigation Report, *supra* note 7, at 6.
19. *Id.*
20. *Id.* at 7.
21. *Id.*
22. *Id.* at 35.
23. Nevada Department of Health and Human Services, Health Division, *2008 Ambulatory Surgical Centers Annual Report*, p. 4. At the time, Nevada had 51 licensed ASCs, nearly twice as many as New Mexico has in 2012.
24. Medicare and Medicaid Programs; *Ambulatory Surgical Centers, Conditions For Coverage*, 72 Fed. Reg. 50, 469-470 (August 2007) (to be codified at 42 C.F.R. pt. 416).
25. U.S. Government Accountability Office, GAO-09-213, *Health-Care-Associated Infections: HHS Action Needed to Obtain Nationally Representative Data on Risks in Ambulatory Surgical Centers*, 2 (Feb. 2009).
26. Nicola D. Thompson, et al., *Non-hospital Health Care Associated Hepatitis B and C Virus Transmission: United States, 1998-2008*, 150 *Annals Internal Med.* 33, 137-38 (2009).
27. Melissa K. Shafer, et al., *Infection Control Assessment of Ambulatory Surgical Centers*, 303 *JAMA* at 2273-74 (2010).
28. *Id.* at 2276.
29. *Id.*
30. *Id.*
31. *Id.*
32. *Id.*
33. *Id.* at 2276-278.
34. *Id.* at 2278.
35. *Id.*
36. August 8, 2012 Letter from Judy Parks, Acting Director, Division of Health Improvement, New Mexico Department of Health, to Shawn Mathis.
37. U.S. Department of Health & Human Services, *National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination*, p. 2, *supra* note 1.

38. August 8, 2012 Letter from Judy Parks, *supra* note 36.
39. NMAC 7.11.2.21; *see also*, August 8, 2012 Letter from Judy Parks, *supra* note 36.
40. See Chart, Inspections of New Mexico ASCs 2009-2012.
41. U.S. Department of Health & Human Services, *National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination*, *supra* note 1.
42. U.S. Department of Health & Human Services, Center for Medicaid and State Operations/Survey Certification Group, *Memorandum Regarding American Recovery and Reinvestment Act of 2009 (Recovery Act) Ambulatory Surgical Center Healthcare-Associated Infection (ASC-HAI) Prevention Initiative* (June 12, 2009), p. 4; *see also*, August 8, 2012 Letter from Judy Parks, *supra* note 36.
43. NMAC 7.11.2.22.
44. August 8, 2012 Letter from Judy Parks, *supra* note 36.
45. NMAC 7.11.2.23.
46. NMAC 7.11.2.28 (B).
47. U.S. Department of Health & Human Services, *National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination*, p. 3, *supra* note 1.
48. *Id.*
49. State of Nevada, Department of Health and Human Services, Health Division, *2008 Ambulatory Surgical Centers Annual Report*, (March 2009), p. 10.
50. *Id.*
51. U.S. Department of Health & Human Services, *National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination*, *supra* note 1.
52. Nevada State Health Division Technical Bulletin, *Hepatitis C Investigation Section/Program: Bulletin Number: Epi February 2008* (adapted from CDC, *Transmission of Hepatitis B and C Viruses in Outpatient Settings — New York, Oklahoma, and Nebraska, 2000-2002*; MMWR 52(38): 901-906 (September 26, 2003)).
53. CDC, *Transmission of Hepatitis B and C Viruses in Outpatient Settings — New York, Oklahoma, and Nebraska, 2000-2002*; MMWR 52 (38): 901-906 (September 26, 2003).
54. *Id.*
55. 2011 Nevada Laws Ch. 362 (SB 419), enacted June 13, 2011.
56. State of Nevada, Department of Health and Human Services, Health Division, *2008 Ambulatory Surgical Centers Annual Report*, *supra* note 49.
57. *Id.* at 22.