



Report to the Ranking Member,
Subcommittee on Health, Committee
on Energy and Commerce, House of
Representatives

July 2012

PATIENT SAFETY

HHS Has Taken Steps to Address Unsafe Injection Practices, but More Action Is Needed

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Highlights of [GAO-12-712](#), a report to the Ranking Member, Subcommittee on Health, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

Recent outbreaks of blood-borne pathogens—specifically hepatitis B and C—that were linked to a specific health care facility or clinician have resulted when clinicians use unsafe injection practices. Such infections can have serious long-term consequences for patients, including cirrhosis or liver cancer. Of the known incidents of blood-borne pathogen outbreaks attributed to unsafe injection practices—which include reusing syringes for multiple patients—most have occurred in ambulatory care settings, such as ASCs and physician offices. CMS oversees injection practices by setting and enforcing health and safety standards that apply to ASCs but not physician offices. GAO was asked to examine (1) available information on the extent and cost of blood-borne pathogen outbreaks related to unsafe injection practices in ambulatory care settings, (2) the changes in federal oversight to prevent unsafe injection practices in ambulatory care settings since 2009, and (3) other federal efforts to improve injection safety practices in ambulatory care settings. GAO reviewed CDC and CMS documentation and CDC data, and interviewed officials from various HHS agencies and other stakeholders.

What GAO Recommends

GAO recommends that HHS (1) resume collecting data on unsafe injection practices that will permit continued monitoring of such practices, (2) use those data for continued monitoring of ASCs, and (3) strengthen the targeting efforts of the One and Only Campaign for health care settings not overseen by CMS. HHS agreed with GAO's recommendations.

View [GAO-12-712](#). For more information, contact Linda T. Kohn at (202) 512-7114 or kohnl@gao.gov.

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What GAO Found

Data on the extent and cost of blood-borne pathogen outbreaks related to unsafe injection practices in ambulatory care settings are limited and likely underestimate the full extent of such outbreaks. An agency within the Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC), collects data on outbreaks identified by state and local health departments. These data show that from 2001 through 2011, there were at least 18 outbreaks of viral hepatitis associated with unsafe injection practices in ambulatory settings, such as physician offices or ambulatory surgical centers (ASC). CDC officials and others believe that the known outbreaks do not represent the full extent of such outbreaks for a number of reasons, such as infections often being difficult to detect and trace to specific health care facilities. Additionally, comprehensive data on the cost of blood-borne pathogen outbreaks to the health care system do not exist, but CDC and other officials believe these costs can be substantial for those affected. For example, individuals may face treatment costs and health departments may face costs for investigating and notifying patients of potential exposure to infection.

Another HHS agency, the Centers for Medicare & Medicaid Services (CMS), has expanded its oversight of unsafe injection practices in ASCs since 2009 by requiring surveyors who inspect these facilities to use its Infection Control Surveyor Worksheet to document the extent to which ASCs are following safe injection practices and to survey more facilities to determine compliance with CMS's health and safety standards. Safe injection practices are included under several of CMS's broader health and safety standards that also address a number of other topics related to infection control and medication administration. As part of implementing the expanded oversight of ASCs, CMS collected and plans to analyze detailed information from these surveyor worksheets for fiscal years 2010 and 2011. This information will be used to assess CMS's oversight efforts to improve infection control and also allow CDC—with which CMS shared its data—to determine a baseline assessment of the extent of unsafe injection practices in ASCs nationally. However, in part because of concerns that collecting these data is a burden to surveyors, CMS officials said the agency stopped collecting data from surveyor worksheets after fiscal year 2011. Without some form of continued collection and analysis of injection safety data, CMS will lose its capacity to oversee how well surveyors monitor unsafe injection practices, and CDC will be unable to determine the extent of these practices.

To improve injection practices, various HHS agencies have taken steps to communicate information on safe injection practices to clinicians. For example, CDC has developed tools to communicate its evidence-based guidelines to clinicians in ambulatory care settings. In partnership with other health-care-related organizations, CDC also developed an educational campaign—the One and Only Campaign—that seeks to broadly educate both clinicians and patients about safe injection practices. While the campaign has targeted some types of clinicians and health care settings that have experienced a blood-borne pathogen outbreak related to unsafe injection practices, additional targeted outreach is needed for health care settings not overseen by CMS.

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Abbreviations

ASC	ambulatory surgical center
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
FDA	Food and Drug Administration
HAI	health-care-associated infection
HHS	Department of Health and Human Services
HICPAC	Healthcare Infection Control Practices Advisory Committee

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United States Government Accountability Office
Washington, DC 20548

July 13, 2012

The Honorable Frank Pallone, Jr.
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives

Dear Mr. Pallone:

Recent outbreaks of blood-borne pathogens—specifically hepatitis B and C—resulting from unsafe injection practices in health care settings indicate that safe care is not always provided to patients.¹ According to the Centers for Disease Control and Prevention (CDC), common unsafe injection practices that have resulted in blood-borne pathogen transmission include the reuse of a syringe for multiple patients or to access a medication vial used for multiple patients—both of which can transmit infections, even if the needle is changed. For example, in 2008 about 63,000 patients in Nevada were notified of their potential exposure to blood-borne pathogen infections, such as hepatitis B and C and HIV, because two related endoscopy clinics reused syringes and contaminated single-dose vials that were used for multiple patients, and 9 patients were found to be infected with hepatitis C. Similarly, in 2009, 4,600 patients of a hematology-oncology clinic in New Jersey were notified of their potential exposure to such infections because of the clinic's mishandling of medication vials and reusing of saline bags for multiple patients, and 29 patients were found to be infected with hepatitis B. Hepatitis B and C infections can have serious long-term consequences for patients, including causing the development of liver cirrhosis or liver cancer, and an estimated 15,000 people die each year in the United States because of these types of infections.² Blood-borne pathogen infections from health care settings are preventable if clinicians use safe injection practices,

¹The Centers for Disease Control and Prevention defines a health-care-associated blood-borne pathogen outbreak as an episode of transmission where two or more patients became infected, and where these infections could be epidemiologically linked to a specific health care facility or clinician.

²CDC, *Disease Burden from Hepatitis A, B, and C in the United States*, accessed October 28, 2011, www.cdc.gov/hepatitis/PDFs/disease_burden.pdf.

such as using a needle and syringe for only one patient and not reusing a needle or syringe to reenter a medication vial, even for the same patient.³

Of the incidents of blood-borne pathogen outbreaks attributed to unsafe injection practices, most have occurred in ambulatory care settings, such as ambulatory surgical centers (ASC) or physician offices, rather than in inpatient facilities, such as hospitals. For example, CDC data indicate that 90 percent of the blood-borne pathogen outbreaks associated with unsafe injection practices from 2001 through 2011 occurred in ambulatory care settings. Patients are increasingly receiving care in ambulatory care facilities and the procedures conducted in these settings are becoming more complex and invasive. For example, data from the National Survey of Ambulatory Surgery indicates that over 53 million procedures were performed in ambulatory care settings in 2006, which is a sharp increase from the nearly 32 million procedures performed in these settings in 1996, and exceeds the number of procedures performed in inpatient settings.⁴ Additionally, in 2006, many more invasive procedures were performed in ambulatory care facilities than in 1996, such as 273 percent more injections of the spinal canal and 200 percent more colonoscopies—an increase of nearly 1.5 million procedures and about 4 million procedures, respectively.⁵

Federal agencies within the Department of Health and Human Services (HHS)—including CDC and the Centers for Medicare & Medicaid Services (CMS)—have established standards and conducted other

³CDC estimates that in 2009 there were over 50,000 new blood-borne pathogen infections of hepatitis B and C in the United States. Health-care-related exposures, including unsafe injection practices, are not considered the primary source of hepatitis transmission. However, a recent case control study indicates that health-care-related exposures may contribute to hepatitis B and C transmission to a greater extent than previously recognized. For more information see, J. F. Perz et al., “Case-control Study of Hepatitis B and Hepatitis C in Older Adults: Do Healthcare Exposures Contribute to Burden of New Infections?” accepted article for *Hepatology*.

⁴K. A. Cullen, M. J. Hall, and A. Golosinskiy, *Ambulatory Surgery in the United States, 2006*, National Health Statistics Reports: number 11 (revised) (Hyattsville, Md.: National Center for Health Statistics, Sept. 4, 2009).

⁵An invasive medical procedure is one that enters the body, usually by cutting or puncturing the skin or by inserting instruments into the body. An endoscopy is a procedure that enables a clinician to look inside an organ in the patient’s body by using a scope that has a small camera attached to a long thin tube. There are many different types of endoscopy, such as a colonoscopy, which uses a scope to see inside the large intestine.

activities aimed at controlling and preventing health-care-associated infections (HAI), including blood-borne pathogen infections, in ambulatory care settings.⁶ CDC has established evidence-based guidelines that provide clinicians with CDC's recommended practices for infection prevention, including safe injection practices. CMS has developed health and safety standards—including those related to infection control—that ASCs must comply with in order to participate in the Medicare program. As part of CMS's oversight of these facilities, state survey agencies and CMS-approved accrediting organizations survey ASCs to assess their compliance with CMS's health and safety standards. In 2009, CMS expanded the scope of its ASC surveys with respect to infection control.

Starting in 2008, GAO released a series of reports examining efforts to prevent HAIs in hospitals and ASCs in the United States.⁷ Given your continuing interest in this area and the concerns you raised about the incidents of blood-borne pathogen outbreaks related to unsafe injection practices, we examined

1. available information on the extent and cost of blood-borne pathogen outbreaks in ambulatory care settings related to unsafe injection practices,
2. changes since 2009 in federal oversight to prevent unsafe injection practices that may lead to blood-borne pathogen outbreaks in selected types of ambulatory care settings, and
3. other federal efforts or plans to improve current injection safety practices in order to prevent blood-borne pathogen outbreaks.

To examine available information on the extent and cost of blood-borne pathogen outbreaks in ambulatory care settings related to unsafe

⁶HAIs are infections that patients may acquire in a health care setting while receiving treatment for other conditions. HAIs are distinct from community-acquired infections, which are infections that were transmitted to patients outside of any health care facility.

⁷See, GAO, *Health-Care-Associated Infections in Hospitals: Leadership Needed from HHS to Prioritize Prevention Practices and Improve Data on These Infections*, [GAO-08-283](#) (Washington, D.C.: Mar. 31, 2008); *Health-Care-Associated Infections in Hospitals: An Overview of State Reporting Programs and Individual Hospital Initiatives to Reduce Certain Infections*, [GAO-08-808](#) (Washington, D.C.: Sept. 5, 2008); and *Health-Care-Associated Infections: HHS Action Needed to Obtain Nationally Representative Data on Risks in Ambulatory Surgical Centers*, [GAO-09-213](#) (Washington, D.C.: Feb. 25, 2009).

injection practices, we interviewed officials from several HHS agencies, including CDC, CMS, the Agency for Healthcare Research and Quality, and the Food and Drug Administration (FDA), as well as officials from relevant associations and other organizations, such as those focused on patient safety and device manufacturers. Additionally, we conducted Internet searches and reviewed documentation provided by the officials and organizations we interviewed to further identify available information on the extent and cost of such outbreaks. Regarding costs, our work focused on available estimates of direct financial costs that the organizations whose representatives we interviewed or other organizations quantified. Lastly, we reviewed CDC data on blood-borne pathogen outbreaks resulting from unsafe injection practices in ambulatory care settings from 2001 through 2011.⁸ To assess the reliability of the CDC data on blood-borne pathogen outbreaks related to unsafe injection practices, we discussed the data with responsible agency officials, reviewed related documentation, and examined the data for consistency. We determined that the CDC data were sufficiently reliable for our purposes in this report.

To examine the changes in federal oversight to prevent unsafe injection practices in selected types of ambulatory care settings since 2009—when our last report on HAIs was released—we reviewed CMS’s policies and procedures, as well as documentation from accrediting organizations that survey facilities, to ensure that they meet CMS’s health and safety standards.⁹ We examined federal oversight of injection safety in terms of the scope and content of CMS’s health and safety standards and the processes that CMS uses to ensure compliance among the facilities to which those standards apply. Our review included those types of ambulatory care settings in which CDC has identified one or more blood-borne pathogen outbreaks from 2001 through 2011, specifically ASCs and physician offices.¹⁰ We also interviewed CMS officials about related

⁸While our review focused on hepatitis and HIV infections, patients may also contract other HAIs related to unsafe injection practices. For example, from 2001 through 2011, over 260 patients developed bacterial infections from unsafe injection practices with the majority having required hospitalization.

⁹See [GAO-09-213](#).

¹⁰Additional types of ambulatory care settings for which CMS conducts oversight, but which were not included in our review, include end-stage renal disease facilities, rural health clinics, and federally qualified health centers.

oversight policies and procedures and officials from two main accrediting organizations to identify their processes for preventing unsafe injection practices in selected ambulatory care settings.¹¹ Throughout these interviews we also gathered information on how CMS works with state survey agencies and accrediting organizations to implement the agency's policies to ensure that facilities meet CMS's health and safety standards, including those related to infection control.

To examine other federal efforts under way or planned to improve current injection safety practices in ambulatory care settings since 2009, we interviewed officials from several HHS agencies, including CDC, CMS, and FDA, as well as relevant associations and organizations. We also reviewed documentation describing federal efforts to improve current injection safety practices and identified funding for these efforts. We identified these efforts through multiple sources, including interviews with federal agencies and other organizations and Internet searches. The information we provide may not represent all federal efforts to improve current injection safety practices in ambulatory care settings.

We conducted this performance audit from December 2011 to July 2012 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

CDC issues recommendations for clinicians to follow in order to prevent and control HAIs. CDC issues these recommendations in the form of evidence-based guidelines and other informal communications, such as clinical reminders, which are generally recognized as authoritative interpretations of the current scientific knowledge base regarding the prevention of HAIs. CDC develops these guidelines in collaboration with the Healthcare Infection Control Practices Advisory Committee (HICPAC)—a federal advisory committee that provides recommendations

¹¹Specifically, we interviewed officials from two of the four CMS-approved accrediting organizations for ASCs—the Accreditation Association for Ambulatory Health Care and The Joint Commission. The American Association for Accreditation of Ambulatory Surgical Facilities, Inc. and the American Osteopathic Association also accredit ASCs.

to the Secretary of HHS and to CDC and includes members from outside the federal government selected for their expertise on infection control.¹² In 2007, CDC issued its most recent infection control guideline outlining Standard Precautions, which serves as the foundation for preventing transmission of infections during patient care in all health care settings, and includes recommendations for safe injection practices.¹³ Examples of safe injection practices include administering medication from one syringe to only one patient, administering medications from single-dose vials to only one patient, and using bags or bottles of intravenous solution for only one patient.¹⁴ Additionally, CDC also helps to provide assistance to state and local health departments in their investigations of possible blood-borne pathogen outbreaks resulting from unsafe injection practices, and maintains information on blood-borne pathogen outbreaks.

In addition, CMS—consistent with statute—has established and oversees compliance with health and safety standards for ASCs as a condition of their participation in Medicare.¹⁵ An ASC must be certified or deemed through accreditation as meeting these standards in order to participate in

¹²Representatives from the following government agencies are nonvoting members of HICPAC: CMS, the Agency for Healthcare Research and Quality, FDA, the National Institutes of Health, the Health Resources and Services Administration, and the Department of Veterans Affairs.

¹³See J. D. Siegel, E. Rhinehart, M. Jackson, L. Chiarello, and HICPAC, *2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings*, accessed October 26, 2011, <http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>.

¹⁴In May 2012, CDC released a paper restating its position on the appropriate use of single-dose and single-use vials. CDC recommends that clinicians limit the sharing of medications whenever possible. In times of critical need, qualified health care personnel may repack unopened single-dose or single-use vials for multiple patients when performed in accordance with standards in the United States Pharmacopeia on sterile preparations for pharmaceutical compounding, as well as the manufacturer's recommendations for safe storage. See, CDC, *Single-dose/Single-use Vial Position and Messages* (May 2, 2012), accessed May 24, 2012, <http://www.cdc.gov/injectionsafety/CDCposition-SingleUseVial.html>.

¹⁵See 42 U.S.C. § 1395k(a)(2)(F)(i). For ASCs, CMS calls its health and safety standards “conditions for coverage.” 42 C.F.R. Part 416, Subpart C (2011). For other types of ambulatory care facilities, such as end-stage renal disease facilities, rural health clinics, and federally qualified health centers, CMS has established different standards for participation in Medicare. See 42 C.F.R. Part 405, Subpart U (for end-stage renal disease facilities) and 42 C.F.R. Part 491, Subpart A (for rural health clinics and federally qualified health centers).

Medicare and qualify for Medicare facility payments.¹⁶ As part of the agency's certification process, CMS contracts with state survey agencies to conduct on-site surveys of facilities subject to CMS's standards. These surveys include on-site inspections by a survey team, generally of two or more surveyors, who review documents, interview staff and patients, observe practices, and examine medical records to ensure compliance with CMS's standards. When surveyors find that a facility's practices do not meet CMS's health and safety standards, these discrepancies are cited as deficiencies and reported to CMS.¹⁷ Additionally, ASCs may choose to instead undergo accreditation by CMS-approved accrediting organizations that CMS has determined meet or exceed its standards.¹⁸ Facilities that are deemed as meeting CMS's standards through this means are also eligible to participate in Medicare and receive facility payments. As part of this accreditation process, accrediting organizations conduct periodic on-site surveys to ensure that facilities meet their standards, including those related to infection control.

Not all ambulatory care settings are subject to CMS's health and safety standards.¹⁹ For example, patients may receive a wide array of services similar to those provided at ASCs, such as endoscopy and pain management services, in facilities designated as physician offices, which

¹⁶CMS defines an ASC as a distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization in which the expected duration of services would not exceed 24 hours following an admission, including pre- and postoperation care. 42 C.F.R. § 416.2. Various ambulatory care facilities may meet CMS's definition of an ASC, including pain management clinics and endoscopy clinics. For fiscal year 2011, 5,356 ambulatory care facilities enrolled in Medicare as ASCs and were thus eligible for facility payments.

¹⁷Depending upon the severity of the deficiency, state surveyors issue standard- or condition-level deficiencies. CMS requires an ASC to respond to standard-level deficiencies with an acceptable plan for correction, while for condition-level deficiencies—used for substantial levels of noncompliance—an ASC must generally undergo a second on-site inspection to demonstrate that it has corrected the deficient practice or else the Medicare agreement for these facilities would be terminated. The deficiencies are recorded in a national database that supports CMS's survey and certification operations.

¹⁸See 42 C.F.R. § 416.26(a). According to CMS, approximately 25 percent of ASCs that participate in Medicare—and are thus eligible for facility payment under Medicare—are inspected by accrediting organizations to determine compliance with CMS's health and safety standards. The remaining 75 percent of Medicare-participating ASCs are inspected through state survey agencies.

¹⁹With respect to ambulatory care settings not subject to CMS's oversight, states may provide some degree of oversight of injection practices.

may range in scale from a small office facility with a single physician to a large clinic with multiple physicians and extensive medical or surgical capabilities. However, physician offices are not subject to CMS oversight, and thus these facilities do not undergo on-site surveys. In addition, even ambulatory care facilities that could potentially meet CMS's definition of an ASC may choose not to participate in Medicare as an ASC. Consequently, these facilities would not undergo the Medicare certification or deeming processes and not receive ASC Medicare facility payments.²⁰

These efforts by CDC and CMS to prevent unsafe injection practices represent efforts to change clinical practices, which research shows can be challenging. Making clinicians aware of the scientific basis for specific practices to achieve patient safety plays a role in changing their behavior, but on its own tends to bring about only modest improvement. Researchers point to other barriers that need to be overcome, including the challenge of integrating the new practice into established work flow patterns, organizational cultures in many health care settings that can be resistant to change, and the challenge of establishing open communication and accountability across distinct professional groups with differing hierarchical status, such as nurses and physicians.²¹ Ongoing efforts to ensure that every clinician performs hand washing or other hand hygiene prior to contact with each patient is an example of the difficulty of achieving consistent compliance with even the most basic and noncontroversial patient safety measures.²²

²⁰Medicare generally pays physicians separately for their services whether the treatment takes place in ASCs, for which CMS has established health and safety standards, or in other facilities that are not subject to CMS's health and safety standards, such as physician offices.

²¹See, for example, John Øvretveit, *Economics and Effectiveness of Interventions for Improving Quality and Safety of Health Care - A Review of Research* (Stockholm: Medical Management Centre, Karolinska Institute, 2007).

²²See Richard Grol and Jeremy Grimshaw, "From Best Evidence to Best Practice: Effective Implementation of Change in Patients' Care," *The Lancet*, vol. 362 (2003): 1225-1230.

Limited Data Are Available on the Extent and Cost of Blood-borne Pathogen Outbreaks Resulting from Unsafe Injection Practices in Ambulatory Care Settings

Data on the extent of blood-borne pathogen outbreaks related to unsafe injection practices in ambulatory care settings are limited and likely underestimate the full extent of such outbreaks. Additionally, comprehensive data on the cost of blood-borne pathogen outbreaks to the health care system do not exist, but CDC and other officials believe these costs can be substantial for those affected by such outbreaks, including individuals, state and local health departments, and clinicians and health care facilities.

Available Data Are Limited and Likely Underestimate the Full Extent of Blood-borne Pathogen Outbreaks in Ambulatory Care Settings

According to CDC officials and others we interviewed, there are relatively few sources of information available on the extent of blood-borne pathogen outbreaks resulting from unsafe injection practices in ambulatory care settings, and these data likely underestimate the full extent of such outbreaks. Specifically, CDC tracks and keeps records of reported blood-borne pathogen outbreaks related to unsafe injection practices in the United States, which it identifies through state and local health departments seeking investigative assistance for potential outbreaks. According to CDC records, from 2001 through 2011, there were 18 known outbreaks—episodes of infection transmission where 2 or more patients became infected—of viral hepatitis associated with unsafe injection practices at ASCs and other ambulatory care settings in the United States. In these known outbreaks in ambulatory care settings, nearly 100,000 individuals were notified to seek testing for possible exposure to viral hepatitis and HIV, and 358 of them were infected with viral hepatitis.²³ (See app. I for more comprehensive information on the 18 blood-borne pathogen outbreaks related to unsafe injection practices in ambulatory care settings.) In addition, over 17,000 other patients were also notified of possible exposure to blood-borne pathogens because of

²³For these 18 outbreaks CDC had sufficient evidence to epidemiologically link the new cases of blood-borne pathogen infections with a health care facility. According to CDC officials, evidence to link an infection to unsafe injection practices is obtained by methods that may include interviewing patients with new infections, testing potentially exposed patients for the presence of infection, using molecular epidemiology to determine if the infections are related, and investigating health care facilities to review medical records and observe or otherwise assess clinicians' injection safety practices.

unsafe injection practices in ambulatory care settings outside of these 18 recognized outbreaks. These notification events were not identified as outbreaks because they did not meet CDC's definition of a blood-borne pathogen outbreak, which is an episode of transmission where two or more patients became infected and where these infections could be epidemiologically linked to a specific health care facility or clinician.²⁴

Our analysis of CDC's data on the 18 known blood-borne pathogen outbreaks in ambulatory care settings indicates that these incidents were associated with one or more types of unsafe injection practices and most were related to improper use of syringes that led to contaminated medication vials or saline bags that were then reused for multiple patients (see table 1). These outbreaks were in a number of different ambulatory care facility types across multiple states. Specifically, of the 18 outbreaks, 5 occurred in pain management clinics, 5 occurred in endoscopy clinics, 3 occurred in alternative medicine clinics, and 2 occurred in hematology-oncology clinics. Additionally, two of the facilities that had outbreaks were participating in Medicare as ASCs, according to CDC officials. With the exception of these two facilities, the facilities that have experienced outbreaks were not subject to CMS's health and safety standards, which require facilities to take steps to prevent unsafe injection practices from occurring, because they are considered physician offices. Finally, while some states may appear to have more outbreaks than others, CDC officials noted that some states are more advanced in identifying, investigating, and reporting blood-borne pathogen outbreaks than others, which may make them appear to have more outbreaks.

²⁴Additionally, CDC data indicate that there have been numerous outbreaks related to unsafe practices associated with assisted blood glucose monitoring, which refers to monitoring of blood glucose—usually through the use of a glucose meter and finger-stick device—that is performed for one or more persons by either a health care clinician or a caregiver. Specifically, from 2001 through 2011, at least 22 hepatitis B outbreaks related to unsafe practices during the assisted monitoring of blood glucose occurred in U.S. health care settings, mainly in assisted-living facilities. In these outbreaks, more than 1,850 people were screened for possible infections and more than 160 patients were infected with hepatitis B.

Table 1: Unsafe Injection Practices That Led to the Known Blood-borne Pathogen Outbreaks in Ambulatory Care Settings, 2001 through 2011

Infection control lapse that led to outbreak	Number of outbreaks	Settings	States	Years of outbreaks	Type of infection
Syringe reuse or suspected reuse that contaminated medication vials or saline bags, and syringe reuse from one patient to another or from clinician to patient	16	Alternative medicine clinic, cardiology clinic, endoscopy clinic, hematology-oncology clinic, hospital-based outpatient radiology clinic, hospital-outpatient pain management clinic, outpatient surgery clinic, pain management clinic, physician office	CA, FL, NE, NV, NY, NC, OK	2001, 2002, 2003, 2005, 2006, 2007, 2008, 2009, 2010, 2011	Hepatitis C, hepatitis B, or both
Medication reuse, such as the use of saline bags or single-dose vials for more than one patient, or multi-dose vials used for multiple patients without appropriate infection control practices	12	Alternative medicine clinic, cardiology clinic, endoscopy clinic, hematology-oncology clinic, outpatient surgery clinic, pain management clinic, physician office	CA, FL, NE, NV, NJ, NY, NC	2002, 2005, 2006, 2007, 2008, 2009, 2010, 2011	Hepatitis C, hepatitis B, or both
Other infection control lapses, such as mishandling of medication vials or medication preparation, such as preparing medication in contaminated environment or failure to store or prepare medication in aseptic conditions	9	Alternative medicine clinic, hematology-oncology clinic, pain management clinic, physician office	CA, FL, NJ, NY	2001, 2005, 2009, 2010	Hepatitis C, hepatitis B, or both

Source: GAO analysis of CDC data.

Notes: The total number of outbreaks does not add up to 18 because for some outbreaks there was more than one infection control lapse that contributed to the outbreak. Moreover, because of variation in the way the investigations are conducted by health departments that typically lead outbreak investigations, additional lapses may have occurred that were not observed or recorded.

According to CDC officials, there were no known HIV infections linked to unsafe injection practices from 2001 through 2011.

For a number of reasons, CDC officials and others we interviewed believe that the known outbreaks do not represent the full extent of blood-borne pathogen outbreaks related to unsafe injection practices in ambulatory care settings. First, blood-borne pathogen infections, regardless of how they are contracted, can be difficult to detect. According to CDC officials and others we interviewed, as well as published literature we reviewed, blood-borne pathogen infections may go undetected because most people infected with viral hepatitis either do not have symptoms for years or have only mild nonspecific symptoms. For example, a 2010 study by

the Institute of Medicine reports that about 65 to 75 percent of individuals infected with hepatitis are unaware that they are infected.²⁵ Many people infected with hepatitis are not aware that they have been infected until they have symptoms of cirrhosis or liver cancer many years later. Second, when symptoms do occur, it may be too late to determine the exact incident that caused the infection. Clinicians are generally required to report cases of acute hepatitis B and C infections to their state or local health department, though this varies by state. However, according to health department officials we interviewed, tracking an infection to a specific health care facility can be difficult because treatment in a health care facility is not generally considered to be an important risk factor for these types of infections. Third, CDC officials said that while state and local health departments and even medical staff often may choose to notify CDC about potential blood-borne pathogen outbreaks, including those possibly related to unsafe injection practices, there is no requirement for such reporting.²⁶ CDC officials said that the agency generally identifies that potential blood-borne pathogen outbreaks related to unsafe injection practices have occurred when state or local health departments seek CDC assistance during their investigations of potential outbreaks. However, CDC officials said that because of the variability in states' surveillance and investigation capacity, many outbreaks may not come to the attention of the health department or CDC. Lastly, available evidence indicates that the unsafe injection practices that can cause blood-borne pathogen outbreaks may be prevalent in ASCs, which increases the likelihood that other such outbreaks are occurring undetected in addition to those that have been identified. Specifically, CDC researchers found in a 2008 survey of a randomly selected sample of 68 ASCs in three states that about 28 percent of ASCs were cited for deficiencies related to injection practices or medication handling—primarily for the use of single-dose vials for more than one patient—and

²⁵Institute of Medicine of the National Academies, *Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C* (Washington, D.C.: the National Academies Press, 2010).

²⁶In 2011, the National Quality Forum updated its list of serious reportable events or “never” events to include blood-borne pathogen infections related to unsafe injection practices. See, National Quality Forum, *Serious Reportable Events in Healthcare – 2011 Update: A Consensus Report* (Washington D.C.: 2011).

about 68 percent were cited for at least one lapse in basic infection control.²⁷

Comprehensive Data on the Costs to the U.S. Health Care System of Blood-borne Pathogen Outbreaks from Unsafe Injection Practices Are Not Available

According to CDC officials and others we contacted, while the financial costs to the health care system of blood-borne pathogen outbreaks related to unsafe injection practices can be substantial, there are no comprehensive data on the total costs attributed to such outbreaks. CDC officials said that assessing such costs is difficult because the costs are borne by different groups—for example, individuals, state and local health departments, and clinicians and health care facilities—and the costs are often intermingled with other health care costs. However, various parties have developed estimates of some of the potential and actual costs associated with such outbreaks for each of these three groups.

- *Individuals.* For individuals who are notified that they are at risk of a blood-borne pathogen infection, costs may be incurred for testing. For example, in response to a large hepatitis C outbreak in Nevada—which required notification of more than 60,000 patients to seek blood-borne pathogen testing—the Southern Nevada Health Department estimated that the laboratory costs for testing all of the potentially exposed patients would be \$13.8 million. Additionally, for individuals who are infected, costs include those for short- and long-term treatment. For example, the Southern Nevada Health Department estimated that the cost of treatment for an infected patient would be about \$30,000, including the direct costs for professional services, laboratory testing, and medication, but excluding the costs of annual monitoring and possible complications related to cirrhosis or liver transplants.
- *State and local health departments.* State and local health care departments may incur costs for investigating and responding to potential outbreaks, including the costs of notifying and potentially providing blood-borne pathogen testing for patients who may have

²⁷This study was conducted in collaboration with CMS. For more information see, M. Schaefer et al., “Infection Control Assessment of Ambulatory Surgical Centers,” *Journal of the American Medical Association*, vol. 303, no. 22 (2010): 2273-2279. Similarly, a survey conducted by the Premier Safety Institute also showed that clinicians use unsafe injection practices to some extent. See G. Pugliese et al., “Injection Practices Among Clinicians in United States Health Care Settings,” *American Journal of Infection Control*, vol. 38, no. 10 (2010): 789-798.

been exposed to unsafe injection practices. Generally, according to health department officials we interviewed, state and local health departments do not track such costs because investigating and responding to such outbreaks is considered part of their normal duties. One exception is the case of the Nevada outbreak, where officials said such costs were calculated because of the magnitude of the outbreak. Specifically, the Southern Nevada Health Department estimated that from January 2008 through May 2009, the outbreak investigation and response cost the health department about \$830,000, including \$255,605 in staff time by health department employees.

- *Clinicians and health care facilities.* Clinicians and health care facilities that are directly involved in outbreaks may incur costs associated with lawsuits and settlements. For example, following the Nebraska outbreak in 2002, the Nebraska Excess Liability Fund—a fund administered by the Nebraska Department of Insurance for medical professional liability coverage—paid nearly \$9 million in indemnity costs to settle 83 cases as of December 2010.²⁸ In addition, clinicians who cause blood-borne pathogen outbreaks through their use of unsafe injection practices may be at risk of losing their medical licenses or facing felony charges related to the outbreak. For example, the physician and two nurse anesthetists involved in the Nevada outbreak currently face state criminal charges tied to the outbreak.²⁹

²⁸See Nebraska Department of Insurance, *Nebraska Hospital-Medical Liability Act Annual Report as of December 31, 2010*, accessed April 5, 2012, <http://www.doi.ne.gov/medmal/>. Additionally, in relation to the 2008 Nevada outbreak, a drug manufacturer also faced lawsuits and is expected to pay \$285 million in settlements involving about 150 patients. See B. Haynes, "Drug Maker to Pay \$285 Million to Settle Hepatitis Lawsuits," *Las Vegas Review Journal* (Feb. 21, 2012) accessed April 3, 2012, <http://www.lvrj.com/news/propofol-maker-teva-to-pay-250-million-to-settle-nevada-lawsuits-139856843.html>.

²⁹See, Indictment, *State of Nevada v. Desai*, No. 10C265107 (Dist. Ct. Clark County, June 4, 2010).

CMS Has Increased Oversight of Injection Practices in ASCs, but Its Decision to Stop Data Collection Will Limit Effectiveness

In 2009, CMS substantially expanded its oversight of unsafe injection practices in ASCs by increasing both the intensity of the examination of safe injection and other infection control practices and the number of on-site surveys conducted in ASCs to determine compliance with CMS's health and safety standards. Within these health and safety standards, those relating to infection control specifically require ASCs to maintain an infection control and prevention program designed to minimize the occurrences of HAIs, such as blood-borne pathogen infections resulting from unsafe injection practices, and have a qualified professional direct this program.³⁰ Safe injection practices are included under several of CMS's broader health and safety standards, which also address a number of other topics related to infection control and medication administration. To document whether ASCs are following CMS's health and safety standards related to infection control, which include safe injection practices, CMS directed all surveyors who inspect ASCs to use CMS's surveyor instrument—the Infection Control Surveyor Worksheet. The worksheet includes a section on injection practices that separately addresses such topics as the reuse of needles and syringes as well as using single- and multi-dose medication vials for multiple patients.³¹ CMS also directed the surveyors to use a tracer methodology in conjunction with the worksheet, which according to CMS officials involves observing a patient at the beginning and end of a procedure or through his or her entire procedure.³²

³⁰See 73 Fed. Reg. 68502 (Nov. 18, 2008) (requirement for infection control program codified at 42 C.F.R. § 416.51, effective 2009). While facilities have some flexibility in designing these programs, all are expected to adhere to nationally recognized and approved standards and guidelines for their infection control procedures, such as CDC's infection control guidelines, which describe safe injection practices. See Siegel et al., *2007 Guideline for Isolation Precautions*, accessed October 26, 2011, <http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>.

³¹The surveyor worksheet was developed in collaboration with CDC and is consistent with CDC's infection control guidelines. To view a copy of the worksheet, see CMS, "Exhibit 351 – Ambulatory Surgical Centers Infection Control Surveyor Worksheet," in Chapter 9 – Exhibits, *Medicare State Operations Manual*, accessed January 17, 2012, http://www.cms.gov/manuals/downloads/som107_exhibit_351.pdf.

³²CMS officials said that the agency has collaborated with CDC throughout the process of expanding its oversight of ASCs. Specifically, CDC has been involved in providing formal training to ASC surveyors on CMS's revised guidance and the surveyor worksheet and funding an infection preventionist position within CMS to provide infection-control-related expertise to CMS's survey and certification efforts in fiscal years 2011 and 2012.

In addition, for the large majority of ASCs that are surveyed by state survey agencies—about 75 percent—CMS expanded the number of ASCs that are to be surveyed each year. Specifically, for fiscal years 2011 and 2012, CMS expects that state survey agencies will survey at least 25 percent of nonaccredited ASCs each year, an increase from its expectation that at least 10 percent of nonaccredited ASCs would be surveyed annually in fiscal year 2009, and 5 percent in fiscal year 2008.³³ CMS also required in fiscal years 2010 and 2011 that some of the ASCs surveyed by state survey agencies be randomly selected by CMS so the agency could obtain a nationally representative sample.³⁴

As part of implementing the expanded oversight of ASCs, CMS collected and plans to analyze detailed information from the Infection Control Surveyor Worksheets, but only for fiscal years 2010 and 2011. Specifically for these 2 fiscal years, CMS required state surveyors to submit a completed copy of the worksheet for every ASC that they surveyed, in addition to their routine reporting of citations for lack of compliance with particular standards. According to the CMS officials, the agency plans to use the data collected from the surveyor worksheets to determine the differences in the type and level of citations given by state survey agencies to ASCs identified as noncompliant with the agency's health and safety standards. As of May 2012, CMS officials expected to have this analysis completed in July 2012. Additionally, CMS officials said that the agency has provided CDC with the surveyor worksheet data to examine the extent of infection control problems, including unsafe injection practices, in a sample of ASCs nationwide, from which CDC officials expect to create a baseline assessment of unsafe injection practices in these settings. As of April 2012, CDC officials did not have a firm deadline for when they plan to complete this analysis because they are uncertain of how long it will take to obtain access to usable data, but the officials expect that it will be completed at some point in 2012.

³³For fiscal years 2009 and 2010, CMS made available \$10 million to state survey agencies in additional funds to survey nonaccredited ASCs, and in fiscal year 2010 CMS expected the survey agencies to survey at least 33 percent of nonaccredited ASCs.

³⁴This was done in response to a 2009 GAO recommendation. See [GAO-09-213](#) for more information.

Although CMS will continue to direct surveyors to use the infection control worksheet to guide what surveyors observe in conducting their examinations of ASC practices, CMS officials said that the agency decided to stop collecting data directly from surveyor worksheets after fiscal year 2011. The officials said that this decision was, in part, because of the burden that this additional data collection process placed on surveyors. According to these officials, surveyor teams—which generally consist of at least two individuals—found it time consuming to consolidate and transcribe the observations of multiple surveyors into a single document and send the consolidated worksheet to CMS, in addition to their routine reporting of citations for noncompliance with particular standards. Additionally, CMS officials said the agency did not want to burden the surveyors with collecting more information from the worksheets until CMS had analyzed the information already collected.

However, without continuing to collect the data from the Infection Control Surveyor Worksheets after fiscal year 2011, CMS will lose its capacity to monitor ASC compliance specifically with respect to safe injection practices, which would be necessary to track the effectiveness of its increased efforts to prevent unsafe practices. CMS officials reported that they do not have access to information that would allow them to identify which citations stem in whole or in part from unsafe injection practices because the citation reports that are routinely submitted by surveyors after an ASC is inspected are based on standards that cover a mix of injection-related and other infection control or medication administration practices. Furthermore, the lack of the worksheet data will reduce CMS's ability to check the accuracy and completeness of surveyor assessments of unsafe injection practices going forward.³⁵ Finally, CMS's decision to stop collecting surveyor worksheet data will prevent CDC from using these data to conduct its own analyses of the extent of unsafe injection practices in ASCs over time. While CMS has noted that collecting these data has been burdensome for surveyors, there may be various ways to ameliorate this burden so that CMS could continue to collect the information needed to track the effectiveness of its increased oversight of ASCs. For example, after 2 years of requiring a completed worksheet for every ASC surveyed, CMS could reduce the burden placed on surveyors

³⁵Although CMS has other processes for checking the completeness and accuracy of surveys performed by state survey agencies, notably the federal monitoring surveys conducted by CMS regional office staff, CMS officials reported that they were not aware of any such surveys of ASCs in recent years.

by limiting this requirement to only those ASCs included in a random, nationally representative sample. In addition, it could adjust the size of the sample or collect the worksheet information less frequently than every year.³⁶

HHS Communicates Information on Safe Injection Practices to Clinicians, but Efforts Do Not Target Certain Higher-Risk Settings

In order to help encourage safe injection practices, various HHS agencies have developed efforts to communicate information on these practices to clinicians since our last report on HAIs was released in 2009. For example, to expand awareness and understanding of CDC's guidelines for infection control, CDC released tools targeted to specific health care settings in 2011. These tools include a summary guide for ambulatory care settings with an accompanying checklist and an infection control and prevention plan specifically for outpatient oncology centers, both of which provide basic infection prevention guidance and reaffirm adherence to CDC's infection control guidelines, including those related to safe injection practices.³⁷

In addition to communicating information on safe injection practices through guidance documents, CDC has also been involved in communicating such information to clinicians in various health care settings through an educational campaign, called the One and Only Campaign. CDC developed this educational campaign in collaboration with the Safe Injection Practices Coalition—a partnership of health-care-related organizations that was formed to promote safe injection practices in all U.S. health care settings. Organizations participating in the Safe Injection Practices Coalition include clinician and facility associations, patient advocacy organizations, foundations, industry partners, and

³⁶As noted in [GAO-09-213](#), results reported from smaller random samples are less precise, but they can still produce nationally representative information.

³⁷See CDC, *Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care and the Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Safe Care*, accessed October 21, 2011, <http://www.cdc.gov/HAI/settings/outpatient/outpatient-care-guidelines.html>. See CDC, *Basic Infection Control and Prevention Plan for Outpatient Oncology Settings*, accessed March 1, 2012, <http://www.cdc.gov/HAI/settings/outpatient/basic-infection-control-prevention-plan-2011/index.html>.

CDC.³⁸ The campaign was developed in 2009 in response to patients who have been notified of possible exposure to blood-borne pathogens, in order to help ensure that patients are protected each and every time they receive a medical injection.³⁹ The One and Only Campaign is led by CDC and the Safe Injection Practices Coalition and is funded by members of the coalition and the agency through the CDC Foundation⁴⁰—an independent, nonprofit organization that connects CDC with private-sector organizations and individuals to build public health programs.⁴¹

Since starting in 2009, the campaign's education and awareness efforts have included developing educational materials for clinicians and patients, such as brochures, posters, a video, and a continuing education webinar on safe injection practices for clinicians. Additionally, CDC funded positions in state health departments to partner with the Safe Injection Practices Coalition to help disseminate information from the One and Only Campaign and develop state-based activities to raise

³⁸FDA serves as an advisor to the Safe Injection Practices Coalition and supports the activities of the One and Only Campaign through the agency's Safe Use Initiative. The Safe Use Initiative is a collaborative effort between FDA and relevant stakeholders to measurably reduce preventable harm from medications to improve patients' health.

³⁹From 2001 through 2011, more than 130,000 patients have been notified of possible exposure to blood-borne pathogens from inpatient and ambulatory care settings. See A. Guh et al., "Patient Notification for Bloodborne Pathogen Testing due to Unsafe Injection Practices in the US Health Care Settings, 2001-2011," *Medical Care*, (2012).

⁴⁰Since starting the campaign in September 2009, CDC has invested a total of about \$3 million in the One and Only Campaign's activities, with \$1.3 million awarded to the CDC Foundation for the campaign.

⁴¹In addition to being focused on education and awareness efforts, CDC and FDA have taken some actions to prevent unsafe injection practices by working to engineer safety into health care processes and products. For example, according to FDA officials, in 2009 FDA—in collaboration with CDC—met with professional organizations whose members draw up and administer injectable medications. These organizations identified confusion over medication vial labeling as a factor that contributed to misuse of medication vials, specifically the use of the terms single use, single dose, and single patient use. FDA and CDC are working with the United States Pharmacopeial Convention—a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, among other things—to update the terminology and definitions for medication vials containing sterile preparations of pharmaceutical drug products.

awareness of safe injection practices.⁴² In message-testing the educational materials for the campaign, these state health department partners utilized focus groups and surveys to ensure that the contents were understandable to both clinicians and patients. According to CDC and CDC Foundation officials, the state health department partners also developed varied approaches to reach health care clinicians, such as developing work groups to target insurance companies to make them aware of safe injection practices and developing tool kits for clinicians and state and local health departments to promote safe injection practices. For example, the State and Local Health Department tool kit was released in April 2012 and includes injection safety specific resources from CDC and the Safe Injection Practices Coalition, such as an educational video, posters, brochures, as well as other resources specific to state and local health department needs, such as information on how to build a work group and working with the media.

CDC and the Safe Injection Practices Coalition have used the One and Only Campaign to target certain types of clinicians and health care settings that have previously experienced blood-borne pathogen outbreaks related to unsafe injection practices as well as to focus on clinicians more broadly. For example, the Safe Injection Practices Coalition disseminated the campaign's educational materials through the American Association of Nurse Anesthetists and the Accreditation Association for Ambulatory Health Care, both of which are coalition members. Additionally, according to CDC Foundation officials, the One and Only Campaign's educational efforts are also focused generally on all health care clinicians, and the demand for the campaign's educational materials does not appear to be driven by a particular group of clinician types or health care settings. For example, according to CDC nearly 50,000 people viewed the Safe Injection Practices Coalition's continuing medical education activity on unsafe injection practices from July 2011 to February 2012. Viewers included a wide range of clinicians, such as anesthesiologists, surgeons, pediatricians, nurse practitioners, physician

⁴²CDC officials said that they used a competitive process to enter into cooperative agreements with state health departments for the One and Only Campaign. From fiscal years 2009 through 2012, CDC awarded about \$1.7 million to two to three state health department partners to participate in the campaign. For fiscal year 2012 specifically, CDC awarded three state health departments (New Jersey, New York, and North Carolina) \$434,000 to partner with the One and Only Campaign. Nevada previously participated in the One and Only Campaign as a funded partner from fiscal years 2009 through 2011 and according to CDC officials now participates in a voluntary capacity.

assistants, pharmacists, and other types of health care clinicians, although CDC does not have information on the health care settings in which these clinicians practice.⁴³

Though CDC and the Safe Injection Practices Coalition have targeted the One and Only Campaign at certain types of clinicians and health care settings that have experienced blood-borne pathogen outbreaks in the past, these targeted efforts at the national level have generally not included other settings that have experienced outbreaks and are not overseen by CMS.⁴⁴ All health care settings are at risk for using unsafe injection practices, but the settings not overseen by CMS, such as physician offices, may be particularly at risk for unsafe injection practices because they have not been subject to CMS's increased oversight efforts, including the use of the Infection Control Surveyor Worksheet. Furthermore, CDC does not have information on the extent to which the general efforts of the campaign have reached these settings not overseen by CMS. As a result, it is not clear if these specific settings are being reached by the campaign.

Many of these education and awareness efforts conducted by CDC and the One and Only Campaign are part of HHS's larger, ongoing efforts to prevent HAIs. Specifically, HHS is expanding the agency's consolidated effort as described in the *National Action Plan to Prevent HAIs: Roadmap to Elimination* to include certain ambulatory care settings.⁴⁵ Specifically, in this next phase, HHS addresses prevention of blood-borne pathogen outbreaks related to unsafe injection practices and other HAIs in ASCs

⁴³Additionally, from June 2010 through March 2012, CDC and the CDC Foundation also distributed over 50,000 hard copy educational materials from the One and Only Campaign to patients, clinicians, and health care facilities.

⁴⁴According to CDC, each of the state health department partners has targeted clinicians and health care settings that were identified as problem areas in its states, which in some cases included ambulatory care settings that are not overseen by CMS.

⁴⁵HHS, Department of Defense, and Department of Veterans Affairs, *National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination (Draft)* (April 2012) accessed May 22, 2012, <http://www.hhs.gov/ash/initiatives/hai/infection.html>.

and end-stage renal disease facilities.⁴⁶ In April 2012, HHS released a draft plan that describes various next steps to prevent HAIs in these settings and proposes measurable outcomes and 5-year goals to assess progress. For ASCs this includes continuing to disseminate evidence-based guidelines and training for infection control and safe injection practices through CDC and the One and Only Campaign. With respect to end-stage renal disease facilities, the draft plan calls for identifying the prevalence and incidence of hepatitis infections and recommendations to prevent hepatitis infections. HHS officials expect this next phase of the agency's consolidated effort to prevent HAIs to be finalized by fall 2012.

Conclusions

Available data from CDC, though limited, indicate that there have been repeated, widespread blood-borne pathogen outbreaks related to unsafe injection practices in the United States from 2001 through 2011. In these outbreaks patients have been infected with blood-borne pathogens—specifically hepatitis—when receiving health care in ambulatory care settings, and these infections are likely more common than is currently identified. These infections have long-term consequences that can affect a patient's health and ultimately lead to death, and the costs to all involved can be substantial. In light of the blood-borne pathogen outbreaks that have occurred, HHS agencies have taken some steps in the last few years to help prevent unsafe injection practices that can lead to blood-borne pathogen outbreaks in ambulatory care settings. CMS has expanded its oversight of health and safety standards in ASCs in ways that should help to prevent unsafe injection practices that can lead to blood-borne pathogen outbreaks, such as by using the detailed Infection Control Surveyor Worksheet to determine if facilities are following safe injection practices. If CDC and CMS proceed with their plans to analyze data collected from these worksheets, 2 years of data that CMS has already collected will be used to establish a baseline assessment of the

⁴⁶The first phase of the HAI action plan focused on certain HAIs in acute care hospitals and was released in 2009 by the Federal Steering Committee for the Prevention of HAIs. According to HHS officials this is intended to be a living document that continues to adapt to additional priorities as they arise, as well as the most recent scientific evidence, evolving policies and programs, and changing cultural norms in health care. For example, in late 2009, the steering committee approved an expansion of the HAI Action Plan extending its scope to the ambulatory care environment, such as efforts focused on ASCs and end-stage renal disease facilities. HHS initiated the steering committee and the action plan in response to a 2008 GAO recommendation that HHS provide leadership to improve HAI prevention practices and improve data on these infections. For more information, see [GAO-08-283](#).

extent of unsafe injection practices in ASCs and help CMS assess its oversight efforts to improve infection control.

However, CMS may be undermining its efforts by stopping data collection after fiscal year 2011, in part because of concerns that the time and effort required in collecting the data placed a burden on surveyors. Information provided by CMS and CDC indicate that reducing unsafe injection practices is a long-term project, and their efforts may take several years to show clear results. Without some form of continued data collection, CMS will lose its capacity to monitor ASC compliance with its health and safety standards related to safe injection practices and to monitor how well the state surveyors collect and assess information about unsafe injection practices. In addition, CDC would not have a source of nationally representative data with which to track overall trends in injection safety in ASCs. Instead of eliminating this unique source of data on injection practices altogether, CMS could address concerns regarding the burden on surveyors through other means. For example, rather than collecting the data from all surveyed ASCs, CMS could limit this data collection to a random sample of ASCs, and the size of the sample could be adjusted. In addition, it may be possible to collect the data less frequently than every year.

In addition to CMS's oversight of health and safety standards for ASCs, CDC is leading important efforts to encourage safe injection practices through the One and Only Campaign. The campaign has focused on making information generally available to all clinicians, as well as targeting some types of clinicians and health care settings that have been involved in prior blood-borne pathogen outbreaks. While raising awareness among clinicians and health care facilities will not, by itself, ensure the adoption of safe injection practices, it is an important first step. The One and Only Campaign is especially important because CMS's oversight of health and safety standards—one primary way for HHS to influence clinicians and health care facilities to use safe practices—is only statutorily authorized for certain settings, such as ASCs. Therefore, the One and Only Campaign represents a unique opportunity to reach clinicians and facilities, such as physician offices, that are not subject to CMS's standards. While the campaign's efforts so far have targeted some types of clinicians and health care settings that have been involved in prior outbreaks, additional targeting of the campaign's efforts to settings that are not overseen by CMS, such as physician offices, could help to focus available resources on the best opportunities to improve patient safety.

Recommendations for Executive Action

To help strengthen HHS efforts aimed at protecting patients from infection by preventing unsafe injection practices in ambulatory care settings, we recommend that the Secretary of HHS take the following three actions:

- Direct CMS and CDC to work together to resume collecting data on unsafe injection practices from the Infection Control Surveyor Worksheet, or from any alternative source of comparable data, that will permit continued monitoring and assessment of unsafe injection practices in ASCs beyond fiscal year 2011.
- Direct CMS and CDC to use the data collected on unsafe injection practices for CMS to continue monitoring ASC compliance with health and safety standards related to infection control and for CDC to continue monitoring trends in the prevalence of unsafe injection practices in ASCs.
- Direct CDC to strengthen its targeting of the One and Only Campaign to health care settings that CDC has identified as having blood-borne pathogen outbreaks related to unsafe injection practices that are not overseen by CMS.

Agency Comments and Our Evaluation

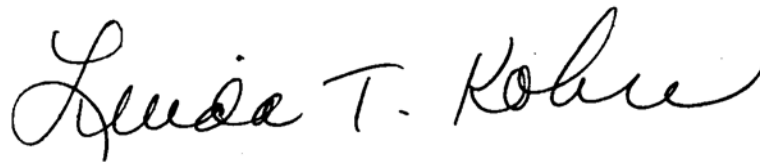
We provided a draft of this report to HHS for review, and HHS provided written comments, which are reprinted in appendix II. In its comments, HHS concurred with our recommendations and stated that CMS and CDC have worked together to improve injection safety practices in ASCs, as well as other settings, such as dialysis facilities, nursing homes, and hospitals. HHS stated that CMS intends to resume collection of the Infection Control Surveyor Worksheet data beginning in fiscal year 2013 for a state-stratified, randomly selected subset of ASCs surveyed in that year and repeat this sampling and data collection approximately every 3 years thereafter. Additionally, HHS stated that CMS will use the data collected on unsafe injection practices to continue to monitor ASC compliance with the agency's health and safety standards related to infection control. HHS also believes that the data it collects can be used to assess trends in injection practices in ASCs over time. Lastly, HHS stated that CDC supports targeting the outreach of the One and Only Campaign toward specific clinician groups and setting types, though the agency further noted that broad outreach also remains critical as demonstrated by the wide variety of settings where blood-borne pathogen outbreaks and unsafe injection practices have been identified. We agree that broad outreach is important and should be ongoing; however, additional targeted outreach to settings that are not overseen by CMS represents an opportunity to help focus available resources to reach

clinicians and facilities that have not been reached through other means, such as CMS's oversight. HHS also provided us with technical comments, which we incorporated as appropriate.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Secretary of Health and Human Services and other interested parties. In addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or kohnl@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix III.

Sincerely yours,

A handwritten signature in black ink that reads "Linda T. Kohn". The signature is written in a cursive style with a large initial "L".

Linda T. Kohn
Director, Health Care

Appendix I: Blood-borne Pathogen Outbreaks Related to Unsafe Injection Practices in Ambulatory Care Settings, 2001-2011

Setting (state)	Year	Type of infection	Number of individuals notified	Number of individuals infected	Infection control lapses
Endoscopy clinic (NY) ^a	2001	Hepatitis C	2,009	19	Suspected syringe reuse contaminating medication vials
Physician office (NY) ^b	2001	Hepatitis B	1,042	38	Mishandling of medication vials and injection equipment; medication preparation in contaminated environment
Hospital outpatient pain management clinic (OK) ^c	2002	Hepatitis C, hepatitis B, or both	908	102	Overt syringe reuse from one patient to another
Hematology-oncology clinic (NE) ^d	2002	Hepatitis C	613	99	Syringe reuse contaminating saline bags used as a source of flush for more than one patient
Endoscopy clinic (NY) ^e	2002	Hepatitis C	1,199	4	Suspected needle or syringe reuse contaminating medication vials
Ambulatory surgical center (pain management clinic) (CA) ^f	2003	Hepatitis C	52	4	Suspected syringe reuse contaminating medication vials
Alternative medicine clinic (FL) ^g	2005	Hepatitis B	253	7	Mishandling of medication vials; failure to prepare and store intravenous infusions under aseptic conditions
Alternative medicine clinic (CA) ^h	2005	Hepatitis C	15	7	Reuse of syringes, resulting in contamination of a saline bag used for more than one patient
Endoscopy and outpatient surgery clinics (NY) ⁱ	2006	Hepatitis C, hepatitis B, or both	4,490	12	Suspected syringe reuse contaminating medication vials; use of single-dose vials of propofol for more than one patient
Pain management clinic and physician office (NY) ^j	2007	Hepatitis C	9,000	3	Syringe reuse contaminating medication vials; use of single-dose vials of contrast (and possible Ketorolac) for more than one patient
Ambulatory surgical centers (endoscopy clinics) (NV) ^k	2008	Hepatitis C	63,000	9	Syringe reuse contaminating medication vials; use of single-dose vials of propofol for more than one patient
Cardiology clinic (NC) ^l	2008	Hepatitis C	1,205	5	Suspected syringe reuse contaminating multi-dose vials of saline used for more than one patient
Alternative medicine clinic (FL) ^m	2009	Hepatitis C	163	9	Syringe reuse contaminating medication vials; mishandling of medication preparation; use of single-dose vials of magnesium sulfate for more than one patient
Hematology-oncology clinic (NJ) ⁿ	2009	Hepatitis B	4,600	29	Mishandling of medication vials; medication preparation in contaminated environment; common-use saline bag for multiple patients; use of single-dose vials for more than one patient

**Appendix I: Blood-borne Pathogen Outbreaks
Related to Unsafe Injection Practices in
Ambulatory Care Settings, 2001-2011**

Setting (state)	Year	Type of infection	Number of individuals notified	Number of individuals infected	Infection control lapses
Endoscopy clinics (NY) ^o	2009	Hepatitis C	3,287	2	Suspected syringe reuse contaminating medication vials; use of single-dose vials of propofol for more than one patient
Pain management clinic (CA) ^p	2010	Hepatitis C, hepatitis B, or both	2,293	2	Syringe reuse contaminating medication vials; use of single-dose vials of contrast, lidocaine, and sodium bicarbonate for more than one patient; failure to use aseptic technique when accessing medication vials
Hospital-based outpatient radiology clinic (FL) ^q	2010	Hepatitis C	3,929	5	Syringe reuse; narcotics diversion by clinician
Pain management clinic (NY) ^r	2011	Hepatitis C	466	2	Suspected syringe reuse contaminating medication vials; single-dose vials of propofol used for more than one patient

Source: Centers for Disease Control and Prevention (CDC) data.

Notes: According to Centers for Disease Control and Prevention (CDC) officials, there were no known HIV infections linked to unsafe injection practices from 2001 through 2011.

^oCDC, "Transmission of Hepatitis B and C Viruses in Outpatient Settings—New York, Oklahoma, and Nebraska, 2000-2002," *Morbidity and Mortality Weekly Report*, vol. 52, no. 38 (2003): 901-906. New York City Department of Health and Mental Hygiene, unpublished data.

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^qR. D. Comstock, S. Mallonee, J. L. Fox, R. L. Moolenaar, T. M. Vogt, J. F. Perz, et al., "A Large Nosocomial Outbreak of Hepatitis C and Hepatitis B among Patients Receiving Pain Remediation Treatments," *Infection Control and Hospital Epidemiology*, vol. 25, no. 7 (2004): 576-583. CDC, "Transmission of Hepatitis B and C Viruses in Outpatient Settings—New York, Oklahoma, and Nebraska, 2000-2002."

^rA. Macedo de Oliveira, L. K. White, D. P. Leschinsky, B. D. Beecham, T. M. Vogt, R. L. Moolenaar, et al., "An Outbreak of Hepatitis C Virus Infections among Outpatients at a Hematology/Oncology Clinic," *Annals of Internal Medicine*, vol. 142, no. 11 (2005): 898-902. CDC, "Transmission of hepatitis B and C viruses in outpatient settings—New York, Oklahoma, and Nebraska, 2000-2002."

^sM. Marx, E. Rizzo, R. Stricof, D. Welss, M. Kacica, K. Bornschlegel, et al., "Acute Hepatitis C Infection in Patients of a Private Gastroenterology Clinic—New York [Abstract]" (paper presented at the 53rd Annual Epidemic Intelligence Service Conference, Atlanta, Ga., April 2004). New York City Department of Health and Mental Hygiene, unpublished data.

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**Appendix I: Blood-borne Pathogen Outbreaks
Related to Unsafe Injection Practices in
Ambulatory Care Settings, 2001-2011**

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^rNew York City Department of Health and Mental Hygiene, unpublished data.

Appendix II: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

JUN 22 2012

Linda T. Kohn
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Kohn:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled: "PATIENT SAFETY: HHS Has Taken Steps to Address Unsafe Injection Practices, but More Action Needed" (GAO-12-712).

The Department appreciates the opportunity to review this draft section of the report prior to publication.

Sincerely,

A handwritten signature in cursive script that reads "Jim R. Esquea".

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "PATIENT SAFETY: HHS HAS TAKEN STEPS TO ADDRESS UNSAFE INJECTION PRACTICES, BUT MORE ACTION NEEDED" (GAO-12-712)

The Department appreciates the opportunity to comment on this draft report. HHS appreciates GAO's recognition of the role unsafe injection practices can play in the spread of bloodborne pathogens, and of the steps the Centers for Medicare & Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC) have taken to address the widespread lapses in sound infection control practices that they have identified in ambulatory surgical centers (ASCs).

Since 2008, CMS and CDC have worked together to address infection control issues, including unsafe injection practices. They collaborated to develop the ASC Infection Control Surveyor Worksheet that was used for surveys of all ASCs in Nevada after the large-scale outbreak of hepatitis C associated with unsafe injection practices in that state. They then revised the Worksheets and recruited three volunteer states to pilot test an improved ASC Medicare survey process. The results of that pilot program were well described in the *Journal of the American Medical Association (JAMA)*¹ in 2010, and prompted an editorial in the same JAMA issue calling for further action.

In fiscal year (FY) 2010, CMS expanded its oversight of infection control practices in ASCs by requiring surveyors in all states to utilize an improved survey process consisting of--(a) More frequent ASC surveys; (b) Multiple person teams; (c) A tracer methodology designed to incorporate information about the experience of at least one patient throughout the course of his or her patient experience; and (d) The revised ASC Infection Control Surveyor Worksheet. The use of this surveyor tool has enabled surveyors to focus consistently on key areas of infection control practices, including safe injection practices. In FY's 2010 and 2011, states conducted over 3200 ASC surveys using the Worksheet. Those surveys reached approximately 80 percent of the non-accredited ASCs that participate in the Medicare program. To date, the surveys conducted have found that deficient infection control practices are widespread in ASCs and, affected ASCs have been required to correct these deficient practices. CMS believes that its efforts to date are increasing the quality of care and patient safety in ASCs, and it is monitoring the ASC survey results on an on-going basis to determine the extent to which the corrective actions are sustained. Once the improved survey process was incorporated as a matter of standard survey practice for all CMS ASC surveys, CMS-approved accrediting organizations were obliged to maintain an equivalent practice for accredited facilities where the accreditation is intended to demonstrate compliance with the Medicare ASC certification standards.

The improved CMS survey process and widespread use of the infection control tool have garnered the attention of the ASC industry as a whole. CMS has also been gratified by the response of leading infection control organizations, such as the Association for Professionals in Infection Control and Epidemiology (APIC) and the Association of Perioperative Registered Nurses (AORN). The infection control experts in these organizations developed infection

¹ See Schaefer et al, *Journal of the American Medical Association*, vol. 303, No. 22 (2010). The editorial may be found at Barie, Philip S., *Journal of the American Medical Association*, vol. 303, No. 22 (2010).

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "PATIENT SAFETY: HHS HAS TAKEN STEPS TO ADDRESS UNSAFE INJECTION PRACTICES, BUT MORE ACTION NEEDED" (GAO-12-712)

control training programs for ambulatory surgery facilities, and CMS has reached out to both states and providers to take full advantage of these important training events.

Consistent with prior recommendations of GAO calling for greater inter-agency cooperation to address healthcare-infections, the informal collaboration between CMS and CDC that developed in 2008 was subsequently formalized. The resulting formal agreements have enabled CMS to benefit from the exceptional expertise of CDC professionals and to increase the probability that providers and suppliers are aware of CDC guidelines. This collaboration has extended well beyond ASCs, and includes close cooperation in dialysis facility, nursing home, and hospital initiatives. In 2011, for example, CMS and CDC collaborated to develop a new surveyor tool to support assessment of infection control practices in hospitals (building upon the experiences with the ASC tool). CMS is currently testing that tool in all of the states, and also expects to make the completed worksheets from this project available to CDC for analysis.

The following are HHS's response to each individual GAO recommendation.

Recommendation 1

To help strengthen HHS efforts aimed at protecting patients from infection by preventing unsafe injection practices, in ambulatory care settings, we recommend that the Secretary of HHS direct CMS and CDC to work together to resume collecting data on unsafe injection practices from the Infection Control Surveyor Worksheet, or from any alternative source of comparable data, that will permit continued monitoring and assessment of unsafe injection practices in ASCs beyond fiscal year 2011.

HHS Response

HHS concurs. As GAO notes in its report, CMS stopped collecting individual Worksheets from State Survey Agencies for each ASC survey conducted after FY 2011. With over 3,000 Worksheets collected, we believe there is sufficient data to support detailed analysis of ASC infection control practices nationally. CMS was also interested in relieving the State Survey Agencies, which are operating in a resource-constrained environment, of the burden associated with preparing a consolidated Worksheet and submitting it to our contractor after each ASC survey. In its recommendation, GAO has been sensitive to CMS's concerns about the burden on State Survey Agencies, suggesting that CMS could limit this data collection to a random sample of ASCs, adjusting the sample size, and collecting the data less frequently than every year. Consistent with these GAO suggestions, CMS plans to resume collection of the Infection Control Surveyor Worksheet beginning in FY 2013 for a state-stratified, randomly selected subset of ASCs surveyed in that year, and will repeat this sampling and data collection approximately every three years thereafter.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "PATIENT SAFETY: HHS HAS TAKEN STEPS TO ADDRESS UNSAFE INJECTION PRACTICES, BUT MORE ACTION NEEDED" (GAO-12-712)

Recommendation 2

To help strengthen HHS efforts aimed at protecting patients from infection by preventing unsafe injection practices, in ambulatory care settings, we recommend that the Secretary of HHS direct CMS and CDC to use the data collected on unsafe injection practices for CMS to continue monitoring ASC compliance with health and safety standards related to infection control and for CDC to continue monitoring trends in the prevalence of unsafe injection practices in ASCs.

HHS Response

HHS concurs. CMS will use the data collected on unsafe injection practices to continue to monitor ASC compliance with health and safety standards related to infection control. CMS notes as a point of information that such monitoring is not reliant upon centralized, aggregated data collection and that survey-specific data collection will continue to take place in every ASC survey conducted by the states, since surveyors will continue to use the content of the Worksheet when assessing infection control compliance. Through periodic collection of a representative sample of completed ASC worksheets, CMS will be able to aggregate the reported data in order to assess trends in injection practices in ASCs over time. Such information may be useful in determining the need for additional interventions, such as additional rounds of intensive training and outreach that may be done by professional associations to further advance patient safety.

Recommendation 3

To help strengthen HHS efforts aimed at protecting patients from infection by preventing unsafe injection practices, in ambulatory care settings, we recommend that the Secretary of HHS direct CDC to strengthen its targeting of the One and Only Campaign to health care settings that CDC has identified as having bloodborne pathogen outbreaks related to unsafe injection practices that are not overseen by CMS.

HHS Response

HHS concurs. As demonstrated by the wide variety of settings where bloodborne pathogen and bacterial outbreaks and unsafe injection practices have been identified, unsafe injection practices can occur in any type of health care setting. Therefore, broad outreach remains critical. CDC supports targeting the outreach of the One and Only Campaign toward specific provider groups and setting types.

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

Linda T. Kohn, (202) 512-7114 or kohnl@gao.gov

Staff Acknowledgments

In addition to the contact named above, Will Simerl, Assistant Director; George Bogart; Leonard Brown; Rebecca Hendrickson; Krister Friday; Eric Peterson; and Pauline Seretakis made key contributions to this report.

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