

U.S. Department of Health and Human Services

**REPORT TO CONGRESS:
Medicare Ambulatory Surgical Center
Value-Based Purchasing Implementation Plan**

1. Introduction – Quality and Efficiency Improvement in Ambulatory Surgical Centers

Section 3006(f) of the Patient Protection and Affordable Care Act (Pub. L. 111-148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), enacted on March 30, 2010 (collectively known as the Affordable Care Act) (as added by section 10301(a) of the Affordable Care Act) requires the Secretary of Health and Human Services to develop a plan to implement a value-based purchasing (VBP) program for payments under the Medicare program for ambulatory surgical centers (ASCs). The Secretary must submit to Congress a report containing this plan not later than January 1, 2011.

Under the Affordable Care Act, the Secretary must consider the following issues in developing the plan:

- 1) The ongoing development, selection, and modification process for measures (including under section 1890 of the Social Security Act (the Act)¹ and section 1890A of the Act, as added by section 3014 of the Affordable Care Act),² to the extent feasible and practicable, of all dimensions of quality and efficiency in ASCs.
- 2) The reporting, collection and validation of quality data.
- 3) The structure of value-based payment adjustments, including the determination of thresholds or improvements in quality that would substantiate a payment adjustment, the size of such payments, and the sources of funding for the value-based bonus payments.
- 4) Methods for the public disclosure of information on the performance of ASCs.
- 5) Any other issues determined appropriate by the Secretary.

The Secretary is also required to consult with relevant affected parties and consider experience with demonstrations that the Secretary determines are relevant to the VBP program for ASCs.

The Centers for Medicare and Medicaid Services (CMS) view value-based purchasing as an important step to revamping how Medicare pays for health care services, moving the program toward rewarding better value, outcomes, and innovations, instead of merely volume.

¹ Section 1890 of the Act contains provisions regarding the process for developing and maintaining health care performance measures by a consensus-based entity.

² Section 1890A of the Act contains provisions regarding the process for selecting quality and efficiency measures with input from multi-stakeholder groups, and dissemination and review of the measures used by the Secretary.

CMS considered the following principles in developing this report to align with other value-based payment initiatives:

- Public reporting and value-based payment systems should rely on a mix of standards, process, outcomes, and patient experience measures. Across all programs, CMS seeks to move as quickly as possible to the use of primarily outcome and patient experience measures. To the extent practicable and appropriate, outcomes and patient experience measures should be adjusted for risk or other appropriate patient population or provider characteristics.
- To the extent possible and recognizing differences in payment system maturity and statutory authorities, measures should be aligned across Medicare's and Medicaid's public reporting and payment systems. CMS seeks to evolve to a focused core-set of measures appropriate to the specific provider category that reflects the level of care and the most important areas of service and measures for that provider.
- The collection of information should minimize the burden on providers to the extent possible. As part of that effort, CMS will continuously seek to align its measures with the adoption of meaningful use standards for health information technology (HIT), so the collection of performance information is part of care delivery.
- To the extent practicable, measures used by CMS should be nationally endorsed by a multi-stakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures.
- Providers should be scored on their overall achievement relative to national or other appropriate benchmarks. In addition, scoring methodologies should consider improvement as an independent goal.
- Measures or measurement domains need not be given equal weight, but over time, scoring methodologies should be more weighted towards outcome, patient experience and functional status measures.
- Scoring methodologies should be reliable, as straightforward as possible, and stable over time and enable consumers, providers, and payers to make meaningful distinctions among providers' performance.

2. Background

An ASC, for Medicare purposes, is a distinct entity that operates exclusively for the purpose of furnishing outpatient surgical services to patients who do not require hospitalization and whose duration of services in the ASC is unlikely to exceed 24 hours. To be eligible for Medicare payment, ASCs must meet the definition of an ASC, be certified as complying with the Conditions for Coverage, and enter into an agreement with the CMS. An ASC may be operated by a hospital; in such cases, its Medicare agreement is made effective the first day of the hospital's next cost-reporting period, but the ASC is paid only as an ASC and does not have the option of converting to a hospital outpatient department, unless CMS finds good reason to permit this. Additionally, the hospital must treat the ASC's costs as a non-reimbursable cost center in its Medicare cost report.

Exhibit 1 highlights the top 20 surgical procedures furnished to Medicare beneficiaries in ASCs in calendar year (CY) 2009, accounting for nearly 72 percent of total volume. Volume for

the top procedure, Cataract removal with intraocular lens insert, exceeded the second ranked procedure (upper GI endoscopy) by nearly a factor of three.

Exhibit 1

Top 20 Surgical Procedures by Volume, CY 2009 ASC Claims

| Rank | Procedure Short Descriptor | Volume | % of Total Volume |
|--|---|------------------|--------------------------|
| 1 | Cataract removal with IOL lens insert, 1 stage | 1,150,342 | 20.6% |
| 2 | Upper Gastrointestinal (GI) endoscopy with biopsy | 441,591 | 7.9% |
| 3 | Colonoscopy with biopsy | 341,161 | 6.1% |
| 4 | Colonoscopy, diagnostic | 290,385 | 5.2% |
| 5 | Laser surgery (lens) | 272,248 | 4.9% |
| 6 | Colonoscopy with lesion ablation or removal | 232,258 | 4.2% |
| 7 | Injection spine: lumbar, sacral (caudal) | 229,137 | 4.1% |
| 8 | Injection foramen epidural: lumbar, sacral | 207,053 | 3.7% |
| 9 | Inject paravertebral f jnt l/s, 1 lev | 125,918 | 2.3% |
| 10 | Colorectal cancer screening; high-risk individual | 92,715 | 1.7% |
| 11 | Cataract removal, IOL lens insert prosthesis, complex | 76,136 | 1.4% |
| 12 | Colorectal cancer screening; low-risk individual | 76,093 | 1.4% |
| 13 | Colonoscopy with lesion ablation or removal | 74,091 | 1.3% |
| 14 | Upper GI endoscopy, diagnostic | 73,003 | 1.3% |
| 15 | Cystoscopy | 72,286 | 1.3% |
| 16 | Injection, lumbar or sacral, add-on | 60,674 | 1.1% |
| 17 | Injection spine, single | 53,220 | 1.0% |
| 18 | Destruction paravertebral by neurolytic agent | 45,035 | 0.8% |
| 19 | Flaps with excessive skin weighting down lid | 44,936 | 0.8% |
| 20 | Injection procedure for sacroiliac joint | 41,499 | 0.7% |
| Total Surgical Procedure Volume | | 5,577,280 | 71.7% |

Source: derived from CMS analysis of ASC CY 2009 claims data

When stratified by specialty category, ASC volume for conditions related to Gastrointestinal, Eye, Nervous System, Musculoskeletal, Skin, and Genitourinary historically constitute the largest percent of total volume. These specialty categories, displayed in Exhibit 2 below, accounted for 98.5 percent of total volume in 2009.

Exhibit 2

Specialty Category by Volume, CY 2009 ASC Claims

| Rank | Specialty Category | Volume | % of Total Volume |
|------|---------------------|------------------|-------------------|
| 1 | Gastrointestinal | 1,823,520 | 32.7% |
| 2 | Eye | 1,792,334 | 32.1% |
| 3 | Nervous System | 1,059,304 | 19.0% |
| 4 | Musculoskeletal | 370,195 | 6.6% |
| 5 | Skin | 238,160 | 4.3% |
| 6 | Genitourinary | 207,482 | 3.7% |
| | Total Volume | 5,577,280 | 98.5% |

Source: derived from CMS analysis of ASC CY 2009 claims data

CMS has observed substantial recent growth in Medicare-certified ASCs. This growth has increased the role and importance of the ambulatory setting in providing low-risk surgical and diagnostic procedures to patients who do not require hospitalization. The statistics below describe the growing role of ASCs in the healthcare system³:

- ASCs served 3.3 million Medicare beneficiaries in 2008, an increase of 2.8 percent over 2007;
- The number of Medicare-certified ASCs totaled 5,175 in 2008, an increase of 3.7 percent over 2007;
- Medicare combined program and beneficiary spending on ASC services reached \$3.1 billion in 2008, an increase of 9.7 percent per fee-for-service (FFS) beneficiary over 2007;
- Between 2003 and 2008, ASCs grew at a compound annual growth rate of 5.1 percent; and
- Between 2003 and 2008, physicians and/or investors opened an average of 331 new facilities annually. In contrast, an average of 59 ASCs closed or merged with other facilities during this same time period.

The Medicare Payment Advisory Commission (MedPAC) attributes the growth in Medicare-certified ASCs to a number of factors, including the following:

- *Positive Patient Experience.* ASCs may offer some advantages compared to hospital outpatient departments (HOPD) providing same-day surgery services. For example, patients may experience the flexibility to schedule medical procedures with shorter waiting times, expediency to source of care, and lower cost sharing requirements.⁴ The

³ Medicare Payment Advisory Commission. *Medicare Payment Policy: Report to Congress*. March 2010. Report is available at: http://www.medpac.gov/documents/Mar10_EntireReport.pdf

⁴ Ibid

growing market concentration of ASCs is associated with increased access for Medicare beneficiaries to low-risk, common surgical procedures.⁵

- *Adequate Medicare Payments.* Between 2003 and 2008, combined Medicare spending and beneficiary cost sharing on ASC surgical procedures continued to grow despite no positive updates to ASC payment rates from 2004 through 2009.⁶ As required under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173), CMS implemented a revised ASC payment system effective January 1, 2008. Under the revised ASC payment system, the standard ASC ratesetting methodology bases payment for most services on the list of ASC covered surgical procedures on the outpatient prospective payment system (OPPS) relative payment weight multiplied by an ASC conversion factor. Despite the revised payment system, total Medicare spending for ASC services increased to \$3.1 billion in 2008 compared to \$2.2 billion in 2003.⁷ In addition, Medicare payments per FFS beneficiary increased to \$99 in 2008 compared to \$66 in 2003.⁸

In its March 2010 Report, MedPAC stated that several factors may explain why margins on Medicare payment rates have not been compressed enough to alter physicians' and/or investors' desire to operate ASCs. First, CMS does not require ASCs to collect, report, and validate cost and quality data to determine resource consumption and associated clinical outcomes.⁹ This eliminates the administrative burden and associated costs incurred through CMS compliance. Second, evidence suggests that ASCs treat Medicare beneficiaries who, on average, are healthier (e.g., less likely to experience comorbidities) and require less intensive medical procedures than HOPD-based patients.¹⁰ Finally, the referenced MedPAC report indicates that, in 2008, HOPDs also serve Medicare and commercially insured patients but treat a higher portion of Medicaid patients when compared to ASCs (10.4% vs. 3.4%).¹¹

⁵ In 2008, the ten most frequently ASC-medical procedures performed on Medicare beneficiaries in descending order: Cataract surgery with intraocular insert, 1 stage (percent of volume, 18.3%), Upper gastrointestinal endoscopy, biopsy (7.9%), Colonoscopy and biopsy (5.5%), Diagnostic colonoscopy (5.1%), After cataract laser surgery (4.7%), Lesion removal colonoscopy (4.6%), Injection spine: lumbar, sacral (3.7%), Inject foramen epidural: lumbar, sacral (3.3%), Inject paravertebral: lumbar, sacral add on (2.8), and Inject paravertebral: lumbar sacral (1.9%). Medicare Payment Advisory Commission. *Medicare Payment Policy: Report to Congress*. March 2010

⁶ Ibid

⁷ Ibid

⁸ Ibid

⁹ Ibid

¹⁰ Ibid

¹¹ According to data from the Pennsylvania Health Care Cost Containment Council (2009), commercially insured and Medicare patients accounted for a higher portion of ASC than HOPD procedures (87.5% vs. 79.3%). Several factors may explain the differences, including a greater portion of Medicaid patients that receive care in hospital emergency departments and by ASCs' decisions to operate in areas with a higher proportion of privately insured patients. In addition, 2006 national data compiled for MedPAC by the Centers for Disease Control and Prevention

- *Newly Covered Services.* CMS regularly adds procedures and services to its ASC list of covered surgical procedures and covered ancillary services. This growing list of newly covered services accounts for some degree of the volume growth observed by MedPAC in ASCs. However, this growth in the volume of newly covered services is likely lower than the actual figure, as MedPAC's analysis of the impacts of newly covered services in ASCs focuses on the number of services per FFS beneficiary, and does not include the impact of Medicare Advantage's rapid growth.¹² Accordingly, ASC service volume per FFS beneficiary increased by 10.5 percent from 2007 to 2008.¹³

The average annual percent change in both volume of services per FFS beneficiary and proportion of beneficiaries served in ASCs substantially exceeded the changes observed in HOPDs from 2003 through 2008. The number of services per FFS beneficiary increased by 9.1 percent in ASCs while it declined by 0.1 percent in HOPDs.¹⁴ In addition, the number of beneficiaries served by ASCs increased at a higher rate compared with HOPDs (6.3% vs. -1.3%).¹⁵ Despite no positive payment updates to ASCs from 2004 through 2009, surgical procedures may be migrating from HOPD to ASC-based settings during this period.

Medicare-Certified Ambulatory Surgical Center Payment Policy

As required under the MMA, CMS implemented a revised ASC payment system effective January 1, 2008. Under the revised ASC payment system, the standard ASC ratesetting methodology bases payment for most services on the list of ASC covered surgical procedures on the OPPS relative payment weight multiplied by an ASC conversion factor. The ASC final rule (CMS-1517-F, 72 FR 42470, Aug. 2, 2007) implemented the policies for the revised payment system. This final rule also expanded the number and types of procedures eligible for payment in the ASC setting. It excluded from eligibility those procedures that would be expected to pose a significant safety risk to Medicare beneficiaries or would be expected to require active medical monitoring at midnight when furnished in an ASC. This rule also provided a four-year transition to the ASC payment rates calculated according to the ASC standard ratesetting methodology. The annual OPPS/ASC final rule provides the ASC payment rates and lists of covered surgical

indicates that Medicaid patients accounted for a higher portion of total visits to HOPDs compared to ASCs (8.1% vs. 3.9%). Medicare Payment Advisory Commission. *Medicare Payment Policy: Report to Congress*. March 2010

¹² MedPAC's analysis considers the effects of the number of services per FFS beneficiary rather than aggregate service volume due in part to significant enrollment increases in Medicare Advantage (i.e., indicates enrollment in Medicare FFS has progressively declined). By examining only the aggregate service volume, the figure would understate the frequency to which Medicare FFS beneficiaries seek care in ASCs.

¹³ Newly covered services accounted for 4.9 percent while services covered in both 2007 and 2008 accounted for the difference, or 5.6 percent. Medicare Payment Advisory Commission. *Medicare Payment Policy: Report to Congress*. March 2010

¹⁴ Ibid

¹⁵ Ibid

procedures and covered ancillary services that qualify for separate payment under the revised payment system.

Medicare payment is made for facility services and covered ancillary services furnished to Medicare beneficiaries by a participating ASC in connection with covered surgical procedures. Examples of facility services for which payment is packaged into the ASC payment for a covered surgical procedure include:

- Nursing, technician, and related services;
- Use of the facility where the surgical procedures are performed;
- Any laboratory testing performed under a Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate of waiver;
- Drugs and biologicals for which separate payment is not allowed under the OPPS;
- Medical and surgical supplies not on pass-through status under the OPPS;
- Equipment;
- Surgical dressings;
- Implanted prosthetic devices, including intraocular lenses, and related accessories and supplies not on pass-through status under the OPPS;
- Implanted DME and related accessories and supplies not on pass-through status under the OPPS;
- Splints and casts and related devices;
- Radiology services for which separate payment is not allowed under the OPPS, and other diagnostic tests or interpretive services that are integral to a surgical procedure;
- Administrative, recordkeeping, and housekeeping items and services;
- Materials, including supplies and equipment for the administration and monitoring of anesthesia; and
- Supervision of the services of an anesthetist by the operating surgeon.

Covered ancillary services include ancillary items and services that are integral to a covered surgical procedure for which separate payment is allowed. Covered ancillary services include:

- Brachytherapy sources;
- Certain implantable items that have pass-through status under the OPPS;
- Certain items and services that CMS designates as contractor-priced, including, but not limited to, the procurement of corneal tissue;
- Certain drugs and biologicals for which separate payment is allowed under the OPPS; and
- Certain radiology services for which separate payment is allowed under the OPPS.

The beneficiary coinsurance for ASC covered surgical procedures and a covered ancillary service is 20 percent except as discussed below. Under section 1833(a)(1) and (b) of the Act (as amended by sections 4104 and 10406 of the Affordable Care Act), CMS waives the coinsurance, the Part B deductible or both for certain preventive services recommended by the United States

Preventive Services Task Force¹⁶ with a grade of A or B for any indication or population and that are appropriate for the individual, and the Part B deductible for colorectal cancer screening tests that become diagnostic.

Quality of Care Issues in ASC Settings

ASCs account for the fastest growing type of hospital- and/or physician-owned facility that participates in Medicare. In 2008, over three million Medicare beneficiaries relied on approximately 5,200 ASCs across the United States for surgical procedures ranging from cataract surgery to gastrointestinal endoscopy to diagnostic colonoscopy. However, the increasing incidence of healthcare associated infections (HAIs) in ASCs signals the need for CMS and stakeholders to expand industry oversight in order to improve the quality of care and provide better health outcomes.

In 2008, a large HAI outbreak in an ASC ignited CMS' efforts to implement the initial stages of a sustained nationwide response to improve the agency's ability to detect deficient practices in infection control in ASCs. Specifically, investigators attributed the Hepatitis C outbreak that occurred in two Nevada-based ASCs to poor infection control practices.¹⁷ This egregious safety lapse potentially exposed over 50,000 former ASC patients to Hepatitis C and other infectious diseases. Reportedly, over 100 people developed Hepatitis C as a result of their exposure in the ASCs. Federal regulators inspected 28 Nevada ASCs for compliance with Medicare standards and subsequent findings revealed 64 percent had serious problems, primarily in infection control.

The Centers for Disease Control and Prevention (CDC) and three States – Maryland, Oklahoma, and North Carolina – collaborated with CMS in 2008 to pilot test a new infection control survey instrument and use of tracer methodology.¹⁸ The survey instrument and tracer

¹⁶ The U.S. Preventive Services Task Force (USPSTF) is an independent panel of non-Federal experts in prevention and evidence-based medicine and is composed of primary care providers (such as, internists, pediatricians, family physicians, gynecologists/obstetricians, nurses, and health behavior specialists). The USPSTF conducts scientific evidence reviews of a broad range of clinical preventive health care services (such as screening, counseling, and preventive medications) and develops recommendations for primary care clinicians and health systems. These recommendations are published in the form of "Recommendation Statements." AHRQ's Prevention and Care Management Portfolio provides ongoing administrative, research, technical, and dissemination support to the USPSTF. For additional information, please refer to: <http://www.uspreventiveservicestaskforce.org/>

¹⁷ Based on investigations, unsafe injection practices consisted of reuse of syringes for individual patients, reuse of single-use vials of propofol for multiple patients, and poor hand hygiene practices. Costs associated with investigation, testing, counseling, and remedial medical care for patients amounted to between \$16.3 million and \$21.9 million (Philip S. Barie. "Infection Control Practices in Ambulatory Surgical Centers." JAMA. 2010;303 (22):2295-2297).

¹⁸ The Team Coordinator should make it a priority at the beginning of the survey to select one or more surgical cases scheduled during the survey for observation. CMS recommends observing a case on the first day of the survey in order to accurately document ASC's routine practices. Because ASC patients remain in the ASC up to a maximum of 24 hours, following individual cases from start to recovery or discharge is an effective tool for assessing the ASC's compliance with the CfCs. The number of cases selected will depend on the size of the team, the scheduled length of the survey, and the expected duration of the surgical case. Depending on the timing of the

methodology enhanced the original survey process, and combined with the new CMS regulations at 42 C.F.R. Part 416¹⁹ raised the importance of proper infection control. Prior to May 18, 2009, ASC's infection control under § 416.44 Condition for coverage—Environment included:

- Standard: Physical environment. The ASC must provide a functional and sanitary environment for the provision of surgical services [...]
- The ASC must establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities.

The regulations that took effect on May 18, 2009, contained the following language requiring an infection control program in addition to § 416.44(a)(3):

§ 416.51 Conditions for coverage—Infection control

The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.

(a) Standard: Sanitary environment. The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.

(b) Standard: Infection control program. The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevention program must include documentation that the ASC has

case selected, one surveyor may begin a case observation immediately.

The surveyor will follow the patient from pre-operative preparation and assessment to discharge (or at least through post-anesthesia recovery). For larger ASCs, i.e., those with more than 2 operating or procedure rooms, or multi-specialty ASCs, surveyors should consider following two cases. In selecting cases to follow, surveyors should choose more complex cases, based on the type of procedure or patient age or co-morbidities. It may also be useful to avoid selecting cases where surveyors anticipate that patient modesty concerns may make it harder to obtain the patient's consent. As a general practice, to make efficient use of onsite time, surveyors should not select cases where they expect the operative time to exceed 90 minutes. Surveyors may opt not to observe the whole surgery from start to finish, but in such cases they must assure they are in the operating room (OR) when the patient is brought in, in order to observe the start of the surgery, and they must return to the OR before the case concludes. It may be useful for a surveyor to remain in the OR after the patient leaves, in order to observe how the OR is cleaned and prepped for the next case. In such cases the team should arrange for another surveyor to pick up the observation of the patient's care after leaving the OR.

In following the case(s) surveyors will look for evidence of compliance related to the various CfC requirements, e.g., infection control, physical environment, medication administration, assessment of anesthesia and procedure risk as well as the required pre-operative update assessment of changes from the history and physical, provision of surgical and anesthesia services, post-surgical assessment, recovery from surgery and anesthesia, and discharge orders.

¹⁹ ASC regulations at 42 C.F.R. Part 416 expanded infection control requirements and also require internal ASC systems of quality assessment and performance improvement provided CMS with important tools to hold ASCs accountable for a high quality of care. For detailed analysis of 42 C.F.R. Part 416, refer to <http://www.dhhs.ne.gov/crl/medfac/hc/416.pdf>

considered, selected, and implemented nationally recognized infection control guidelines. The program is—

- (1) Under the direction of a designated and qualified professional who has training in infection control;
- (2) An integral part of the ASC's quality assessment and performance improvement program; and
- (3) Responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.

ASCs in Maryland, Oklahoma, and North Carolina experienced common lapses in infection control. The findings from the sixty-eight ASCs involved in the pilot include²⁰:

- 46 of 68 ASCs were impacted by at least 1 lapse in infection control;
- 12 of 68 ASCs had lapses identified in 3 or more of the 5 infection control categories;
- Common lapses included using single-dose medication vials for more than 1 patient (18 of 64; 28.1%), failing to adhere to recommended practices regarding reprocessing of equipment (19 of 67; 28.4%), and lapses in handling of blood glucose monitoring equipment (25 of 54; 46.3%).

3. CMS' Current Efforts Promoting Quality in ASCs

CMS seeks continuous quality improvement in ASCs by implementing a series of policies and programs including Changes in Conditions for Coverage, changes in Survey and Certification oversight methodologies, with the assistance of the CDC, and consideration of measures for ASC quality data reporting (e.g., through legislative provisions contained in the Medicare Improvements and Extension Act of 2006, Division B of Title I of the Tax Relief and Health Care Act of 2006 (Pub. L. 109-432) (MIEA-TRHCA)).

Changes in Conditions for Coverage. As the single largest payer for healthcare services in the United States, CMS plays a critical role in promoting high quality care for Medicare beneficiaries. CMS ensures that the Conditions for Coverage (CfCs) of ASC services, and enforcement of those conditions, are adequate to protect the health and safety of the individuals treated in ASCs.²¹ Any regulatory changes that CMS contemplates must consider patient health and safety along with the administrative burden placed on Medicare-participating facilities.

²⁰ Sixty-eight ASCs participated in the CMS ASC pilot study: 32 in Maryland, 16 in North Carolina, and 20 in Oklahoma. State Surveys implemented a CDC-developed instrument to document clinical practices during on-site inspections through interviews, inspection and observation. Melissa K. Schaefer, MD et al. Infection Control Assessment of Ambulatory Surgical Centers. JAMA. 2010;303(22):2273-2279.

²¹ Section 1832(a)(2)(F)(i) of the Act specifies that an ASC must meet health, safety, and other requirements specified by the Secretary in regulation if it has an agreement in effect with the Secretary to perform procedures covered by Medicare. Under the agreement, the ASC agrees to accept the standard Medicare amount determined under section 1833(i)(2) of the Act as full payment for services, and to accept assignment of benefits as described in section 1842(b)(3)(B)(ii) of the Act for payment for all services furnished by the ASC to enrolled individuals. Substantive requirements are set forth in 42 CFR part 416 subpart B and subpart C of the regulations. The

On November 18, 2008, CMS published a final rule (73 FR 68502), entitled “Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates” that among other changes finalized the new CfCs for patient rights in ASCs. The rule included discussion of public comments received regarding the new CfCs. Specifically, commenters expressed concern regarding the amount of paperwork patients would be required to complete for same-day procedures, and stated that patients would benefit from reviewing pertinent information before they arrived at the ASC (see 73 FR 68718).²² In response to these public comments, and overall with the intent of clarifying existing regulations at §416.50 of the regulations, CMS revised the proposed requirement for patient rights at §416.50(a)(1), (a)(1)(ii) and (a)(2)(i), to specify that ASCs must provide patient rights information to the patient or the patient’s representative in advance of the date of the procedure. It continues to be CMS’ intent to require that ASCs provide patients with information they need in order to make an informed choice about the facility that will perform their procedure, while whenever possible minimizing any potential for disruption that Medicare beneficiaries may experience while seeking care at an ASC.²³

Changes in Survey and Certification Oversight Methodologies, with the Assistance of Centers for Disease Control and Prevention. As previously noted, the enhanced survey process tested in the three-State ASC pilot program, and the adoption in November 2008 of new ASC regulations at 42 C.F.R. Part 416 that expanded infection control requirements and also require internal ASC systems of quality assessment and performance improvement, provided CMS with important tools to hold ASCs accountable for a high quality of care. Further, given evidence from the pilot program suggesting widespread problems in infection control practices in ASCs, CMS concluded that implementing this improved survey process and more frequent inspections of ASCs could significantly contribute to reducing the risk of HAIs in the States.

States, which have agreements under Section 1864 of the Social Security Act to conduct Medicare inspections (surveys) on behalf of CMS, are responsible for ASC survey activities within their State. CMS agrees to provide funds for the reasonable and necessary costs to the

regulations at 42 CFR part 416 subpart B describe the general conditions and requirements for ASCs, and subpart C describes the specific CfCs for ASCs.

²² CMS proposed these CfCs in order to promote and protect patient health and safety. Under the first standard, §416.50(a)(1), “Notice of rights,” CMS proposed that ASCs be required to provide the patient or the patient’s representative with verbal and written notice of the patient’s rights in a language and manner the patient understood in advance of providing care to the patient. In addition, CMS set out what information would be required and where the ASC would have to post the information for the patient to see while waiting for treatment.

²³ In an NPRM published on April 23, 2010, CMS proposed to retitle and reorganize the requirements of § 416.50, “Patient rights,” as follows: (a) *Standard*: Notice of rights; (b) *Standard*: Disclosure of physician financial interest or ownership; (c) *Standard*: Advance directives; (d) *Standard*: Submission and investigation of grievances; (e) *Standard*: Exercise of rights and respect for property and person; (f) *Standard*: Privacy and safety; (g) *Standard*: Confidentiality of medical records; and (h) *Standard*: Exception to the timing of the notice of patient rights. We believe this reorganization would eliminate confusion about the patient rights information provided to patients. We note that these are not new requirements. Refer to 75 Fed. Reg. 21209 at: <http://edocket.access.gpo.gov/2010/pdf/2010-8903.pdf>

States to perform these inspections, with payments made from the Federal Hospital and Supplementary Medical Insurance Trust Funds. However, Congressional appropriations must authorize expenditures from the Trust Funds for inspection functions. For four consecutive years (2005 – 2008) Congress did not fully fund the President’s Medicare survey and certification budget request. At the same time, for certain types of health care facilities, including ASCs, the number of participating facilities significantly expanded in Medicare. As a result, the interval between surveys for some types of facilities, including ASCs, grew, with many ASCs not receiving a survey for five years or longer. In FY 2009 – FY 2010 Congress funded a survey and certification budget increase.

In addition, the American Recovery and Reinvestment Act of 2009 (Recovery Act) provided ten million dollars to CMS to be used specifically to support a greater number of ASC surveys, using an enhanced survey process, as a means of improving infection control practices and reducing HAIs in ASCs. CMS piloted the enhanced survey process in FY 2008, and, using these Recovery Act funds, began implementing it nationwide in the latter part of FY 2009.²⁴ Onsite surveys that identify deficient practices and related enforcement actions by CMS focus ASC management attention on improving their infection control practices, and have great potential to prevent HAIs. CMS required the States to survey one third of all non-accredited ASCs in FY 2010.

Consideration of Measures for ASC Quality Data Reporting. Section 109(b) of the MIEA-TRHCA²⁵ states that the Secretary may implement a quality reporting system for ASCs in a manner so as to provide for a reduction in any annual update for failure to report on quality measures. Specifically, for an ASC that does not submit to the Secretary data required to be submitted on measures selected with respect to a year, the Secretary shall reduce any annual increase provided by the revised ASC payment system by 2.0 percentage points with respect to the year involved.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66875), the CY 2009 OPPS/ASC final rule with comment period (73 FR 68780), the CY 2010 OPPS/ASC final rule with comment period (74 FR 60656), and the CY 2011 OPPS/ASC final rule with comment period (75 FR 72109), CMS did not implement quality data reporting. CMS determined that it would be more appropriate to allow ASCs to acquire some experience with the revised payment system before implementing new requirements such as public reporting of quality measures.²⁶

²⁴ The Centers for Medicare and Medicaid Services’ Director of Survey and Certification Group issued a letter to State Survey Agency Directors on June 12, 2009 in response to Recovery Act Ambulatory Surgical Center Healthcare-Associated Infection (ASC-HAI) Prevention Initiative. The letter can be accessed at: https://www.cms.gov/SurveyCertificationGenInfo/downloads/SCLetter09_43.pdf

²⁵ Section 109(b) of the MIEA-TRHCA amended section 1833(i) of the Act by redesignating clause (iv) as clause (v) and adding new clause (iv) to paragraph (2)(D) and by adding new paragraph (7).

²⁶ By first implementing quality reporting under the OPPS, CMS would gain experience, which would help identify the most appropriate indicators for quality reporting in ASCs.

CMS believes that promoting high quality care in the ASC setting through quality reporting is both highly desirable and fully consistent with efforts underway in other payment systems. However, in the CY 2011 OPPS/ASC final rule with comment period, CMS again expressed concerns regarding ASCs readiness for quality reporting and the administrative burden associated with reporting, and thus did not finalize ASC quality reporting for CY 2011. As discussed in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72109), CMS intends to propose in CY 2012 rulemaking implementing an ASC quality measure reporting program under section 109(b) of the MIEA-TRHCA. CMS in the CY 2011 rulemaking cycle invited and responded to the public comments on the following (75 FR 46383; 75 FR 72109):

- a. The timing of implementing quality data reporting for ASCs;
- b. Suggestions for quality measures for services provided by ASCs;
- c. Potential reporting mechanisms for ASC quality data, including electronic submission of these data; and,
- d. The following measures under future consideration for ASC quality data reporting:
 1. Patient fall in the ASC;
 2. Patient burn;
 3. Hospital transfer/admission;
 4. Wrong site, side, patient, procedure, implant;
 5. Prophylactic IV antibiotic timing;
 6. Appropriate surgical site hair removal;
 7. Surgical site infection;
 8. Medication administration variance;
 9. Medication reconciliation; and
 10. Venous thromboembolism measures: outcome/assessment/prophylaxis.

4. Consideration of Existing Medicare Quality Data Reporting Programs

CMS believes that promoting high quality care in the ASC setting is highly desirable and aligns with the agency's efforts under other payment systems. Public disclosure and transparency are part of a broad-scale CMS effort intended to provide Medicare beneficiaries with information on quality of care measures in order to help them make informed decisions about their healthcare consumption. CMS currently oversees three Quality Data Reporting Programs (QDRPs) in other payment systems to promote a high-value driven healthcare system.

QDRP 1: Hospital Inpatient Quality Reporting (IQR) Program. Section 1886(b)(3)(B)(vii) of the Act (added by section 501(b) of the MMA) authorized the Secretary to reduce the annual percentage increase that would otherwise be paid to a subsection (d) hospital if the hospital did not submit data on a set of 10 quality indicators. Section 1886(b)(3)(B)(vii)(I) of the Act provided for a 0.4 percentage point reduction in the annual percentage increase (which was, at that time, defined as the market basket percentage increase for hospitals in all areas) for hospitals that did not successfully submit the data. The DRA of 2005 required the Secretary to increase that reduction to 2.0 percentage points. In addition to giving hospitals a financial incentive to report quality measure data, CMS makes the data it collects under the Hospital IQR program public, which helps consumers make more informed decisions about their healthcare. In FY

2009, 96 percent of hospitals participated successfully in the Hospital IQR program and received the full market basket update for FY 2010.

Section 1886(o) of the Act (added by section 3001(a) of the Affordable Care Act) authorizes the Secretary to establish a hospital value-based purchasing program under which value-based incentive payments are made in a fiscal year to hospitals that meet performance standards for the performance period for such fiscal year. Payments made under the program apply to discharges occurring on or after October 1, 2012. Under the program, the measures must be selected from the measures specified under the Hospital IQR program, and must include measures that cover myocardial infarction, heart failure, pneumonia, and the prevention of surgical complications as measured by the Surgical Care Improvement Project as well as measures that relate to patients' experience of care as measured by the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey.²⁷

The Hospital Value-Based Purchasing (HVBP) program, which is under development in accordance with the provisions of section 3001(a)(1) of the Affordable Care Act²⁸, intends to link payment to quality outcomes under the Medicare program. Under the HVBP program, hospitals achieving higher levels of performance will receive higher value-based incentive payments.²⁹

QDRP 2: Physician Quality Reporting System. Section 101 of MIEA-TRHCA established the Physician Quality Reporting System.³⁰ CMS provides an incentive payment for eligible

²⁷ Provisions of Affordable Care Act can be accessed at HealthCare.gov (<http://www.healthcare.gov/index.html>)

²⁸ The Centers for Medicare & Medicaid Services issued a proposed rule that would establish a new hospital value-based purchasing program that would reward hospitals for providing high quality, safe care for patients. Under the program, hospitals that perform well on quality measures relating both to clinical process of care and to patient experience of care, or those making improvements in their performance on those measures, would receive higher payments. The proposed rule appeared in the Federal Register on January 13, 2011, and can be accessed at: <http://www.gpo.gov/fdsys/pkg/FR-2011-01-13/pdf/2011-454.pdf>

²⁹ Under section 1886(o)(7) of the Act, the value-based incentive payments would be funded by a reduction to the hospital base operating Diagnosis Related Group payment amount. The amount of the base operating DRG reduction changes over time, starting with 1 percent with respect to FY 2013 and increasing to 2 percent with respect to FY 2017 and beyond. The value-based incentive payments for each hospital each year will be calculated using the formula specified in statute. CMS will inform each hospital annually of its performance scores, and will report on hospital performance information on the Hospital Compare website. The Secretary must also establish an appeals process so that hospitals may appeal the calculation of their performance assessment with respect to the performance standards and their performance score. For additional information on different provisions related to VBP: http://www.healthcare.gov/center/authorities/health_reform_and_hhs.html

³⁰ A detailed discussion of the 2011 Physician Quality Reporting System, including the Physician Quality Reporting System reporting mechanisms, the criteria for satisfactory reporting, the measures, and measures groups is contained in the 2011 Medicare Physician Fee Schedule (PFS) proposed and final rules, which appeared in the Federal Register on July 13, 2010 and November 29, 2010. The link below contains a list of legislation that have amended the Physician Quality Reporting System, including, most recently, the Affordable Care Act, which made a

professionals who satisfactorily report data on quality measures for covered professional services furnished during a specified reporting period. Specifically, eligible professionals who satisfactorily report quality measures data during a Physician Quality Reporting System reporting period are eligible to earn an incentive payment equal to a percentage of the estimated total allowed charges for all such Medicare Part B covered professional (Physician Fee Schedule) services furnished by the eligible professional during the reporting period. The authorized incentive percent amounts for each program year include:

- 2007 – 1.5% subject to a cap;
- 2008 – 1.5%;
- 2009 – 2.0%;
- 2010 – 2.0%;
- 2011 – 1.0%;
- 2012 – 0.5%;
- 2013 – 0.5%; and
- 2014 – 0.5%.

For the 2011 Physician Quality Reporting System, eligible professionals may submit data on individual quality measures or measures groups through claims, a qualified registry, or qualified electronic health record or participate in the Physician Quality Reporting System via one of two group practice reporting options. As CMS has increased the number of measures and measures groups available to report and the number of reporting options, the number of eligible professionals participating in the Physician Quality Reporting System has grown along with the number of eligible professionals satisfactorily reporting Physician Quality Reporting System measures.

Section 3002(b) of the Affordable Care Act also requires a payment adjustment beginning in 2015 for eligible professionals who do not satisfactorily report data on quality measures under the Physician Quality Reporting System. The Medicare Part B Physician Fee Schedule amount for services furnished by an eligible professional who does not satisfactorily report will be subject to a reduction of:

- 1.5% in 2015; and
- 2.0% in 2016 and each year thereafter.

QDRP 3: Hospital Outpatient Quality Data Reporting Program. Section 109(a) of the MIEA–TRHCA amended section 1833(t) of the Act by adding a new subsection (17) that affects the payment rate update applicable to OPPS payments for services furnished by hospitals in outpatient settings on or after January 1, 2009. This section requires that hospitals failing to

number of changes to the program, including authorizing incentive payments through 2014 and requiring a payment adjustment (penalty), beginning in 2015, for eligible professionals who do not satisfactorily report: http://www.cms.gov/PQRI/05_StatuteRegulationsProgramInstructions.asp

report certain specified quality data will receive a 2.0 percentage point reduction to their annual Medicare payment update factor.

CMS believes that ASC facilities are similar, insofar as the delivery of surgical and related nonsurgical services, to hospital outpatient departments. In 2007, CMS developed measures for use under the outpatient prospective payment system (OPPS). Seven measures were developed, based on related inpatient measures already in use. In 2008, CMS implemented five AMI measures applicable to outpatient care provided in the emergency department along with two outpatient surgery measures. The ED-AMI measures were based on the inpatient AMI measures and are supported by a technical expert panel comprised of national experts and stakeholders. The technical expert panel for the Surgical Care Improvement Project (SCIP), a national quality partnership of stakeholders committed to improving surgical care by reducing surgical complications, supports the surgery measures collected in the outpatient setting.³¹ Similar standards and guidelines can be applied between hospital outpatient departments and ASCs in regards to surgical care improvement, given that many of the same surgical procedures overlap.

5. Information Gained from October 14th ASC Open Door Forum

CMS held a Special Open Door Forum on October 14, 2010, to solicit public comment in the development of the plan for implementing VBP in ASCs. Nearly 200 stakeholders participated in the public listening session. Further, CMS created a special mailbox so that participants could submit written comments.

The public listening session sought comments on the key elements related to developing a plan for an ASC VBP program. Specifically, CMS invited the public to provide suggestions on the following:

1. The development of measures of quality and efficiency;
2. The reporting, collecting, and validation of quality data;
3. The structure of value-based payment adjustments;
4. Methods for public disclosure of the information; and
5. Any other issues of interest to the public on this topic.

Several stakeholders provided very useful responses to these key elements.

The Development of Measures of Quality and Efficiency. According to the American Urological Association (AUA), ASC quality measures development should focus on appropriate metrics that account for surgery- and procedure-specific patient safety measures. Quality measures should

³¹ Ten national organizations have pledged their full support for this initiative. They include the Agency for Healthcare Research and Quality, American College of Surgeons, American Hospital Association, American Society of Anesthesiologists, Association of periOperative Registered Nurses, Centers for Disease Control and Prevention, CMS, Institute for Healthcare Improvement, The Joint Commission, and Veterans Health Administration. Additional information on SCIP measures can be accessed at:

<http://www.jointcommission.org/PerformanceMeasurement/PerformanceMeasurement/SCIP+Core+Measure+Set.htm>

include specialty-specific measures and reflect the diverse ASC settings in order to allow for appropriate comparison of performance among ASCs and across healthcare delivery systems (e.g., ASC vs. HOPD). In order to address the validity of proposed quality measures, AUA recommended that CMS convene an expert advisory group with relevant specialty representation. In addition, AUA and American Society for Gastrointestinal Endoscopy (ASGE) proposed that efficiency measures should reflect the cost of surgical procedures (e.g., Medicare rates plus patients' out-of-pocket costs) across the ASC and HOPD delivery systems.

ASGE recommended CMS recognize the unique role of endoscopic ASCs in its development of quality metrics. ASGE does not consider endoscopic procedures as surgical in nature and therefore measures of surgical quality, such as appropriate surgical site hair removal, prophylactic IV antibiotic timing, and wrong site surgery, are not relevant. Instead, ASGE proposed the following measures currently under NQF review as most appropriate for endoscopic ASCs: (1) Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients; (2) Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use; and (3) Comprehensive Colonoscopy Documentation. ASGE considers these as appropriate measures for an ASC VBP program that would enable CMS to distinguish quality differences between ASCs and HOPDs.

ASGE also proposed developing a measure of patient experience to help gauge the overall quality of care delivered to Medicare beneficiaries by ASCs.

The Reporting, Collecting, and Validation of Quality Data. Accreditation Association for Ambulatory Health Care (AAAHHC) commented that the current level of ASCs' data collection and submission capabilities differs when compared to hospitals. ASGE highlighted ASCs' low adoption rate for electronic health records (EHRs). Both stakeholders and also the American Association of Nurse Anesthetists (AANA) noted that ASCs do not qualify for the EHR meaningful use incentive payments under the American Recovery and Reinvestment Act.

The Structure of Value-Based Payment Adjustments. Commenters acknowledged that CMS should link payments for surgical procedures to the quality of care rendered in ASCs. In addition, VBP could allow patients, physicians, and decision makers to compare quality and value across healthcare delivery settings offering similar services. Commenters emphasized that CMS should introduce VBP payments incrementally by first making only a small percentage of total Medicare ASC payments contingent on performance. As the system evolves, CMS can increase the ratio of VBP payments to total payments.

Methods for Public Disclosure of the Information. The AUA and ASGE suggested that CMS consider a confidential feedback program as the first step towards the long-term goal of publicly reporting quality data. They stated the ASC VBP program should inform patients and physicians on the quality and efficiency of common surgical procedures performed in the hospital outpatient departments and ASCs. Alternatively, ASGE proposed an incremental approach based on process measures reported annually or quarterly rather than on the basis of each patient encounter.

Any Other Issues of Interest to the Public on this Topic. The ASC Quality Collaboration (QC), AUA, and ASGE recommended an incremental approach to implementing an ASC VBP program.

In addition to the above topics, during the course of the listening session, CMS solicited comments from participants for in-depth feedback on the following questions related to reporting of quality measures:

1. What is the feasibility of collecting data for chart abstracted measures in the ASC setting?
2. What is the feasibility of collecting data for outcome measures in the ASC setting? For example, what is the follow-up care after discharging a patient following a three day stay in an ASC?
3. What is the feasibility of reporting on claims-based measures using ASC data?

1. What is the feasibility of collecting data for chart abstracted measures in the ASC setting?

The ASC QC, AUA, and ASGE emphasized that chart abstracted measures, especially those derived from retrospective chart abstraction, require significant investment in resources and additional staffing. Commenters stated that the chart-abstracted measures CMS implemented for the inpatient and outpatient settings require identification of the denominator population based on tables of codes. The measures require retrospective medical record review because providers assign these codes after the patient's episode of care has concluded. In contrast, the measures developed by the ASC QC do not identify the target population using coded data assigned after the episode of care. Instead, concurrent data are collected as the patient moves through the care process and minimizes the amount of allocated staff time to the collection of quality data.

2. What is the feasibility of collecting data for outcome measures in the ASC setting? For example, what is the follow-up care after discharging a patient following a three day stay in an ASC? The ASC QC concluded it is feasible to collect quality data for outcome measures in the ASC setting. The ASC QC states that NQF-endorsed measures all evaluate immediate outcomes. Nevertheless, it becomes increasingly challenging to collect reliable data for outcome measures during post-operative care. The ASC QC attributed several factors for the increased challenge such as minimal resources to sustain post-operative care surveillance and no specific guidelines for follow-up care (e.g., when a provider should make a post-operative telephone call).

3. What is the feasibility of reporting on claims-based measures using ASC data? The ASC QC supported using HCPCS Level II G Code or the AMA's Category II CPT Code currently used by Physician Quality Reporting System. The ASC QC stated this approach was a feasible and efficient way to collect and report quality data without requiring additional resource because physicians already submit quality data on a CMS-1500 claim using either HCPCS Level II G or the AMA's Category II CPT Codes. ASCs would be able to report data using these quality reporting codes given that they already submit a CMS-1500 form for each Medicare beneficiary encounter.

ASGE suggested that registry-based reporting will become the preferred method for endoscopic ASCs. ASGE partnered with the American College of Gastroenterology to

implement the GI Quality Improvement Consortium (GIQuIC).³² GIQuIC collects clinical data to provide a standardized and objective method to score performance for the most common endoscopic procedures. ASGE indicated that these data will be used to inform clinical outcomes research including initiating both public and private payer quality performance incentives.

6. Options to Explore for ASC VBP Implementation Plan

In developing the ASC VBP implementation plan, the Secretary under the Affordable Care Act must consider the following issues:

- A. The ongoing development, selection, and modification process for measures (including under section 1890 of the Social Security Act (the Act) and section 1890A of the Act, as added by section 3014 of the Affordable Care Act), to the extent feasible and practicable, of all dimensions of quality and efficiency in ASCs.
- B. The reporting, collection, and validation of quality data.
- C. The structure of value-based payment adjustments, including the determination of thresholds or improvements in quality that would substantiate a payment adjustment, the size of such payments, and the sources of funding for value-based bonus payments.
- D. Methods for public disclosure of information on the performance of ASCs.
- E. Any other issues determined appropriate by the Secretary.

A: Development, Selection and Modification Process for Quality Measures. Section 1890 of the Act contains provisions regarding the process for developing and maintaining health care performance measures by a consensus-based entity. In addition, section 1890A of the Act contains provisions regarding the process for selecting quality and efficiency measures with input from multi-stakeholder groups, and dissemination and review of the measures used by the Secretary. CMS and stakeholders could explore developing a continuous quality improvement framework for ASCs that promotes higher standards and new measures development over time (Section 7 of this Report expands on this concept). To the extent practicable, measures used by CMS could be nationally endorsed by a multi-stakeholder organization. This framework among other features could contain new risk-adjusted quality metrics that capture multiple measure domains (e.g., clinical, outcome, and patient experience) to expand the set now available.

In its 2010 Report to Congress, MedPAC expressed concern with further postponing the implementation of ASC Medicare quality data reporting. In recent years, ASCs have rapidly become a critical component of the United States healthcare system by improving Medicare beneficiaries' access to care and providing surgical procedures. Based on quality measures currently adopted by ASCs for internal evaluation and performance benchmarking, MedPAC

³² In the public comment submitted to CMS, ASGE stated that the framework which guides GIQuIC includes: designing, developing and using multiple measurements arising from endoscopic techniques performed by practicing gastroenterologists. This benchmarking initiative began with the collection of quality indicators for colonoscopy. GIQuIC has plans to launch modules to collect quality indicators for esophagogastroduodenoscopy, endoscopic retrograde cholangiopancreatography, and endoscopic ultrasonography.

stated that it would be “technically feasible without imposing an undue administrative burden”³³ to begin quality data reporting in 2010. In addition, MedPAC concluded that ASCs have the technical capacity to report on facility-level quality measures which the ASC Quality Collaboration³⁴ supports and have the endorsement of the National Quality Forum.³⁵ The quality measures include³⁶:

1. Patient burn;
2. Patient fall in the ASC;
3. Wrong site, wrong side, wrong patient, wrong procedure, wrong implant;
4. Prophylactic intravenous antibiotic timing;
5. Hospital transfer/admission; and
6. Appropriate surgical site hair removal.

The first three measures encompass patient safety indicators identified by NQF as “Never Events,”³⁷ which pose serious health implications for patients. These patient safety indicators would be identifiable and measurable for reporting purposes without imposing undue administrative burden on ASCs. CMS recognizes the ASC industry’s efforts to implement these standardized metrics. This initiative could benefit Medicare beneficiaries by allowing them to compare the quality of surgical care across HOPDs and ASCs. While some of the measures may be feasible to collect using claims data, others (e.g., patient safety measures) may not be meaningful to report unless measures capture all patients treated, and hence all-payer claims collect all to generate the measures.

Four of the NQF-endorsed measures (patient burn; patient fall; wrong site, wrong side, wrong patient, wrong procedure, wrong implant; and hospital/transfer admission) correspond to

³³ Glenn M. Hackbarth, Chairman of MedPAC. Public comment submitted to CMS dated August 28, 2009 on “Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2010 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2010 Payment Rates.”

³⁴ Formed in 2006, ASC QC unites both the ASC industry and organizations with a focus on healthcare quality and safety. ASC QC’s efforts focus on standardized quality measures, public reporting of quality data, high quality care, and advocacy. For a detailed description of the components, it can be accessed at: <http://ascquality.org/>

³⁵ [The National Quality Forum](#), which includes consumer groups, public and private purchasers, physicians, nurses, hospitals, accrediting and certifying bodies, and healthcare research and quality improvement organizations, aims to improve the quality of healthcare by (1) establishing national goals for performance improvement; (2) endorsing national consensus standards for measuring and publicly reporting on performance; and (3) promoting the attainment of goals through education and outreach programs.

³⁶ For detailed analysis of these measures, refer to the ASC Quality Collaboration’s report on *ASC Quality Measures: Implementation Guide*: <http://ascquality.org/documents/ASCQualityCollaborationImplementationGuide.pdf>

³⁷ The fiscal year 2009 inpatient prospective payment system (IPPS) final rule implemented a payment reduction for certain hospital-acquired conditions (HACs) beginning for discharges on or after October 1, 2008. The policy prohibits payment for the additional costs of a hospitalization due to these HACs.

only one measure domain (safety).³⁸ Since these measures are limited to one measure domain, it will be necessary to supplement with measures from other domains to provide meaningful information on quality.

B: Reporting, Collection, and Validation of Quality Data. Stakeholders expressed concern with identifying appropriate quality measures and the complexity associated in implementing a full-scale VBP program that accounts for ASCs' administrative ability, increased compliance costs, personnel, and electronic health records.

Recent ASC analysis³⁹ recommended the use of Current Procedural Terminology (CPT) Category II codes or G-codes to implement a claims-based QDRP.⁴⁰ This process presents a more feasible method for data abstraction for ASCs compared to Medical Record Review (MRR).⁴¹ For example, for small or freestanding ASCs, the MRR data abstraction method may be a costly and burdensome process. Only clinical staff can oversee MRR, which is a problem for small ASCs because the majority of small ASCs have limited resources to conduct data abstraction using this method. By contrast, hospital-owned ASCs could leverage the system's administrative capability or MRR department to assist in data abstraction and submission.⁴²

ASCs currently use the form CMS-1500 to submit Medicare claims data. The physician bills for the surgery while the ASC bills for the facility and ancillary charges. Both the ASC and the physician use the appropriate CPT/HCPCS codes on the CMS-1500 form. Contractor analysis of ASC claims indicate that ASCs are capable of using the current claims submission process for Medicare data without imposing undue administrative burden.⁴³ Further, an estimated 80 percent of ASCs submit claims electronically.⁴⁴ Accordingly, it appears that a claims-based electronic submission process would not impose an additional financial and resource burden for ASCs.⁴⁵

³⁸ Florida Medical Quality Assurance, Inc., and Health Services Advisory Group. Ambulatory Surgery Center Environmental Scan (July 2008). Contract No. GS-10F-0096T.

³⁹ In 2008, Florida Medical Quality Assurance, Inc. and Health Services Advisory Group conducted an ASC environmental scan for CMS.

⁴⁰ Florida Medical Quality Assurance, Inc., and Health Services Advisory Group. Ambulatory Surgery Center Environmental Scan (July 2008). Contract No. GS-10F-0096T.

⁴¹ Over 60 percent of ASCs employ less than 20 clinical and non-clinical FTEs, and on average, small volume ASCs (less than 1,999 cases per year) employ less than seven FTEs (Florida Medical Quality Assurance, Inc. and Health Services Advisory Group. Ambulatory Surgery Center Environmental Scan (July 2008). Contract No. GS-10F-0096T).

⁴² Ibid

⁴³ Ibid

⁴⁴ Ibid

⁴⁵ Under the Physician Quality Reporting System, only half of physicians correctly submit data. This method requires additional analysis to determine how accurately ASCs can submit data to Medicare using a claims-based

Section 3006(f) of the Affordable Care Act states that the Secretary must consider the validation of quality data. CMS could introduce both a random and targeted audit of ASCs to focus on assessing the accuracy of performance measure rates. CMS could select an appropriate number of ASCs each year for the random component of the validation and an equally effective sample size for targeted audit. The audit selection methodology could enable CMS to assess the overall quality of data submissions and minimize gaming.

C: Structure of Value-Based Payment Adjustments. The methodology could use the Hospital VBP program as a template for structuring ASC value-based payments but such design could vary. As an example, the VBP program could score each of the measure domains including clinical, outcome, and patient experience. The final score could combine the different domains to produce an ASC's Total Performance Score (TPS). When a TPS is determined, the VBP program could convert an ASC's TPS into incentive payment, which could align payments with the quality of care furnished to Medicare beneficiaries.

An ASC receives a performance score on each measure included in the incentive payment measure set, as long as it meets the required minimum number of cases for the measure set. An ASC's performance on each measure could be based on the higher of an attainment score in the measurement period or an improvement score determined by comparing the ASC's current measure score with its prior-period baseline performance. Section 7 of this Report discusses additional options for how CMS could structure value-based payment adjustments (see Performance Scoring and Evaluation Model).

D: Methods for the Public Disclosure of Information on ASC Performance. A template for public disclosure of ASC information could include establishing an "ASC Compare" website similar to the Compare websites now available to Medicare beneficiaries for hospitals, nursing homes, HHAs, and ESRD facilities.⁴⁶ This program could publicly disclose the performance of the ASC with respect to each measure that applies to the ASC, the performance of the ASC with respect to each condition or procedure, and the ASC performance score assessing the total performance of the ASC.⁴⁷ Prior to publicly reporting such information, ASCs could have the opportunity to review and submit corrections.

submission process (Florida Medical Quality Assurance, Inc., and Health Services Advisory Group. Ambulatory Surgery Center Environmental Scan (July 2008). Contract No. GS-10F-0096T).

⁴⁶ For the first time, Medicare beneficiaries can access three critical elements they need to make effective decisions on the quality and value of health care for hospitals' procedures that include quality information, patient satisfaction survey information, and pricing information. In another example, CMS released quality ratings in 2008 for each of the nation's 15,800 nursing homes that participate in Medicare and Medicaid. CMS assigns facilities star ratings from a low of one star to a high of five stars based on health inspection surveys, staffing information, and quality of care measures. See Nursing Home Compare for analysis of quality, cost, and patient measures: <http://www.medicare.gov/default.aspx?AspxAutoDetectCookieSupport=1>

⁴⁷ The methods for public disclosure of ASC performance information could adopt the framework under paragraph 10(A)(i) of Section 3001: The Hospital Value-Based Purchasing Program.

In addition, The Joint Commission (TJC)⁴⁸ recommended that publicly reported data could be stratified by type of ASC resulting from the variation in the populations served and procedures performed. TJC stated that multispecialty ASCs could have different results than single-specialty ASCs, and single specialty ASCs could have results that vary by type of specialty. As an example described by TJC, endoscopic ASCs could have lower surgical site infection rates when compared to single specialties involving incisions, such as cataract centers, and cataract centers have no surgical site hair removal variances to measure.

E: Other Issues and/or Relevant Demonstrations. In developing the plan for the ASC VBP program, the Affordable Care Act requires the Secretary to consider the experience with demonstrations and also to consider the ongoing development, selection and modification process for measures under sections 1890 and 1890A of the Act. The Hospital VBP program, which is under development in accordance with the provisions of section 3001 of the Affordable Care Act, and Home Health Pay-for-Performance Demonstration (HHP4P) would both use incentives to encourage high-quality and cost-efficient care and provide options for CMS to explore in designing the ASC VBP program.

Hospital Value-Based Purchasing (HVBP) Program

Section 1886(o) of the Act⁴⁹ authorizes the Secretary to establish a hospital value-based purchasing program under which CMS makes value-based incentive payments in a fiscal year to hospitals that meet performance standards for the performance period for such fiscal year. The program applies to payments for discharges occurring on or after October 1, 2012. The Hospital VBP program, which is under development in accordance with the provisions of section 3001(a)(1) of the Affordable Care Act⁵⁰, intends to link payment to quality outcomes under the Medicare program.

⁴⁸ The Joint Commission (TJC), an independent, not-for-profit organization, accredits and certifies more than 18,000 health care organizations and programs in the United States. Additional information on TJC can be accessed at: <http://www.jointcommission.org/>

⁴⁹ Congress added Section 1886(o) of the Act by section 3001(a) of the Affordable Care Act. Under section 1886(o)(5)(B)(1), the Secretary must ensure that the scoring methodology under the Hospital VBP program results in an appropriate distribution of value-based incentive payments among hospitals, with hospitals achieving the highest hospital performance scores receiving the largest value-based incentive payments. The following links include both Section 3001(a) of the Affordable Care Act and the Reconciliation bill which amended section 3001(a). The Affordable Care Act can be accessed at: http://www.healthcare.gov/center/authorities/patient_protection_affordable_care_act_as_passed.pdf and Reconciliation bill at: <http://www.gpo.gov/fdsys/pkg/PLAW-111publ152/html/PLAW-111publ152.htm>

⁵⁰ The Centers for Medicare & Medicaid Services issued a proposed rule that would establish a new hospital value-based purchasing program that would reward hospitals for providing high quality, safe care for patients. Under the program, hospitals that perform well on quality measures relating both to clinical process of care and patient experience of care, or those making improvements in their performance on those measures, would receive higher

The Hospital VBP program builds upon the Medicare Hospital Inpatient Quality Reporting Program (Hospital IQR program), formerly known as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program. CMS has also gained several years of experience using financial incentives to promote improvements in the quality of hospital inpatient care through the CMS/Premier Hospital Quality Incentive Demonstration (HQID).⁵¹

The average composite quality scores (CQS), an aggregate of all quality measures within each clinical area, improved significantly between the inception of the program and the end of Year 4 (October, 2007)⁵²:

- From 87.5 percent to 96.3 percent for patients with acute myocardial infarction;
- From 84.8 percent to 98.5 percent for patients with coronary artery bypass graft;
- From 64.5 percent to 92.2 percent for patients with heart failure;
- From 69.3 percent to 92.6 percent for patients with pneumonia;
- From 84.6 percent to 97.2 percent for patients with hip and knee replacement.

The total improvement in average CQS over HQID's first three years is 17.2 percentage points. Between HQID's third and fourth years, the average CQS increase is 2.2 percentage points.

In 2007, CMS submitted a Report to Congress detailing the Hospital VBP Performance Assessment Model. The performance model set out in the 2007 Report included the following key elements:

- Quality measures are included for 3 purposes: to determine incentive payment, for public reporting, and for future measure development;
- For incentive payment, domains are selected, and measures chosen within each domain. These domains include clinical process of care and patient experience of care (as measured by HCAHPS);
- A hospital receives a performance score on each measure included in the incentive payment measure set, as long as it has the required minimum number of cases for the

payments under the program. The proposed rule appeared in the Federal Register on January 13, 2011, and can be accessed at: <http://www.gpo.gov/fdsys/pkg/FR-2011-01-13/pdf/2011-454.pdf>

⁵¹ As a precursor to the Hospital IQR Program, CMS implemented the Premier Hospital Quality Incentive Demonstration (HQID) in October 2003. This demonstration project includes hospitals across the United States. Premier Inc. operates a nationwide organization of not-for-profit hospitals. Under the demonstration, Premier collects and submits to CMS patient and hospital-level quality data from participating member hospitals. CMS uses these data to create an aggregate quality score for each participating hospital, and the top performers each year receive a quality incentive bonus payment. Additional information on CMS' Premier Hospital Quality Incentive Demonstration including the number of participating hospitals and states can be accessed at: http://www.cms.gov/HospitalQualityInits/35_HospitalPremier.asp

⁵² Results of CMS' Premier Hospital Quality Incentive Demonstration can be accessed at: http://www.cms.gov/HospitalQualityInits/35_HospitalPremier.asp

measure set. A hospital's performance on each measure may be based on the higher of an attainment score in the measurement period or an improvement score determined by comparing the hospital's current measure score with its prior-period baseline performance;

- A score is calculated for each domain by combining the measure scores within that domain, weighting each measure equally. The domain score reflects the percentage of points earned out of the total possible points for which a hospital is eligible;
- A hospital's VBP Total Performance Score is determined by aggregating the scores across all domains, with the possibility of weighting domains unequally; and
- The Total Performance Score is translated into a percentage of VBP incentive payment earned by a hospital using a mathematical "exchange function."

Home Health Pay-for-Performance Demonstration (HHP4P)

The ASC industry cites the HHP4P Demonstration⁵³ as one that could provide relevant experience for designing ASC VBP measures and payment mechanisms. The two-year demonstration, which began in January 2008 and ended in December 2009, demonstrated the impact of financial incentives on the quality of care provided to home health patients in traditional fee-for-service Medicare and their overall Medicare costs. The shared savings program distributed funds across home health agencies (HHAs) that either maintained high levels of quality or achieved significant improvement in quality of care. Accordingly, 166 HHAs achieved more than \$15 million in Medicare savings based on their performance during the first year of the HHP4P demonstration.⁵⁴

Under this voluntary demonstration, HHAs received incentive payments for providing the highest level of patient care or for the greatest improvement in patient care as measured by seven Outcome and Assessment Information Set (OASIS)⁵⁵ measures. The availability of the incentive payments depended on whether the demonstration resulted in savings to the Medicare

⁵³ Recruitment for participation began in October 2007, with implementation of the demonstration in January 2008, and continued through December 2009. The following states participated in the demonstration: Connecticut and Massachusetts in the Northeast region; Illinois in the Midwest region; Alabama, Georgia, and Tennessee in the South region; and California in the West region. Participating agencies represented more than 30 percent of all Medicare-certified HHAs in the participating states. Additional background about the Centers for Medicare and Medicaid Services' Home Health Pay for Performance Demonstration can be accessed at: <http://www.hhp4p.com/>

⁵⁴ One can access Year 1 results on the HHP4P Demonstration at: <http://www.hhp4p.com/>. The results sort top performers by region and then score within state. Abt Associates assisted CMS with the implementation of the HHP4P demonstration. The incentive payment is contingent on the demonstration generating Medicare savings in the HHA's region to fund those payments.

⁵⁵ OASIS is the instrument/data collection tool used to collect and report performance data by home health agencies. The seven OASIS measures in the HHP4P include: (1) Incidence of Acute Care Hospitalization; (2) Incidence of Any Emergent Care; (3) Improvement in Bathing; (4) Improvement in Ambulation / Locomotion (5) Improvement in Transferring; (6) Improvement in Management of Oral Medications; and (7) Improvement in Status of Surgical Wounds.

program overall in HHA's region. CMS could generate these savings by reduced use of hospital, emergency room, nursing facility, home health, and other Medicare-covered services as a consequence of improved home health outcomes for patients served by a comparison group of HHAs.

7. Roadmap for ASC VBP Program Implementation

This section describes a range of issues that CMS must consider in order to develop and implement an ASC VBP program. These recommended steps build upon existing CMS efforts in other Medicare settings to minimize the financial and administrative burden associated with designing and implementing such a program. As with other VBP programs, CMS will consider a phased-in timeframe for implementing an ASC VBP program. The initial efforts could start with developing and measuring quality, and implementing a quality measure reporting program. Section 109(b) of the MIEA-TRHCA states that the Secretary may implement a quality reporting system for ASCs in a manner so as to provide for a reduction in any annual update for failure to report on quality measures. As discussed in the CY 2011 OPPTS/ASC final rule with comment period (75 FR 72109), CMS intends to propose in CY 2012 rulemaking implementing an ASC quality measure reporting program under section 109(b) of the MIEA-TRHCA. These efforts combined with a number of key elements (as described below) will link payment to performance to improve value for Medicare beneficiaries.

In preparing a plan to implement VBP in ASCs, CMS will consider the challenges and length of time involved with respect to developing new measures, soliciting multi-stakeholder input, seeking consensus endorsement (e.g., NQF), releasing a proposed and final rule, and accounting for differences in payment system maturity and statutory authorities across Medicare settings. In addition, consideration for when quality data could begin to be collected and displayed to the public, the proposed performance period for VBP, and when value-based payments could begin needs to be reflected in the timeframe and design prior to implementation. An incremental approach for ASC VBP program implementation could allow stakeholders time to adjust under the new system. CMS and stakeholders can mitigate the complexity and uncertainty under each VBP component by considering the following examples that reflect the agency's experience with measure development in the hospital inpatient and outpatient settings:

1. For measure development, the process has historically taken up to one year for development of a new measure, and another year for NQF endorsement, if needed. CMS would also need to propose and finalize a new measure through the rulemaking process for a reporting program around the same time the measure is submitted for endorsement in order to minimize excess delay to the timeline.
2. For claims based measures under the current reporting cycle for the Hospital Inpatient Quality Reporting and Hospital Outpatient Quality Data Reporting Programs, measure calculation and public reporting can occur about 9 months after finalization of the reporting program. This allows sufficient time for claims runout and to calculate measures using complete claims data. Under this assessment, it could take up to 2.5 years total for measure development, NQF endorsement, finalized through the rulemaking process, and calculated and publicly reported.

3. For chart abstracted measures, based on CMS' historical experience implementing hospital quality data reporting programs, the timeframe also requires up to an additional 12 months after a measure is finalized in a rule that the first quarter of data would be publicly reported. This entire process including measure development, NQF endorsement and finalizing it in a regulation, infrastructure development, data submission, measure calculation by CMS, review of the measures, and public reporting of the measure data requires up to three years. Public reporting of the chart abstracted process of care measures occurs quarterly. CMS starts with one quarter of data, and continues adding quarters until the agency accumulates a single year aggregate. CMS continues updating the one year rate on a quarterly basis, removing the oldest quarter from calculation.

Using the OPSS as an example, if the proposed measures receive NQF endorsement by the spring, CMS would incorporate such measures into the OPSS/ASC Notice of Proposed Rule Making (NPRM) that would be published in the Federal Register sometime in early summer. The OPSS/ASC Final Rule (which includes a summary of the public comments and CMS' responses to the comments) finalizes policies proposed in the NPRM and is published in the fall. The OPSS/ASC Final Rule discusses any changes that were made to the proposed policies, due to further consideration of the proposed policies and public comments received. Policies finalized in the OPSS/ASC Final Rule are typically implemented about two months after the rule is published. In addition, if CMS implements an ASC VBP program analogous to CMS' experience with hospital quality reporting programs, the agency and stakeholders could expect to experience additional time constraints due to the need to establish the infrastructure and processes to operate the program. The additional time constraint accounts for the limited resources available to ASCs in comparison to the hospital setting. However, the draft timeline discussed above could possibly be abbreviated if the ASC VBP program adopts existing measures that are already endorsed. Under the assumption that the proposed measures for the ASC reporting program do not require NQF endorsement, and assuming that no significant changes do not emerge during the planning process, expectations under the other two timeframes could also be shortened.

- A. Statutory Authority** will be required for the Secretary to establish the ASC VBP program and allow performance-based payments. Section 109(b) of the MIEA-TRHCA permits the Secretary to implement a quality reporting system for ASCs in a manner so as to provide for a reduction in any annual update for failure to report on quality measures. However, the authority limits the Secretary to reducing the annual update for failure to report – not based on performance. The subsequent issues presume that Congress acts to give the Secretary authority to pay for better value, outcomes, and innovations instead of merely volume.
- B. Continuous Quality Improvement Framework** that develops new quality measures will be essential to expand the set now available. To the extent practicable, measures used by CMS should be nationally endorsed by a multi-stakeholder organization. CMS will explore developing a continuous quality improvement framework for ASCs that promotes higher standards, improved health outcomes, and new measures development over time. This framework could feature new risk-adjusted quality metrics that capture multiple measure

domains (e.g., clinical, outcome, and patient experience) and metrics with high incidence rates.⁵⁶ To the extent practicable and appropriate, outcomes and patient experience measures should be adjusted for risk or other appropriate patient population or provider characteristics.

This framework could also help CMS and stakeholders identify appropriate measures and establish performance standard. For instance, a quality metric could target improvements for high-risk and/or high volume surgical procedures. In addition, incorporating new quality metrics that align across different delivery sites (e.g., ASCs and HOPDs) and diverse ASC structures (free-standing and multispecialty to physician-owned ASCs to joint ventures between hospitals and physicians) would ensure that reliable, valid, and meaningful data could be subsequently relied upon for evaluation.

To the extent possible and recognizing differences in payment system maturity and statutory authorities, ASC measures should align across Medicare's quality reporting and payment systems (e.g., Hospital Inpatient Quality Reporting Program, Physician Quality Reporting System and Hospital Outpatient Quality Data Reporting Program). By aligning the ASC VBP program with other Medicare quality programs, this ensures the VBP program could coordinate incentives to improve quality and minimize provider burden across delivery systems. In its June 2008 Report, MedPAC stated that the current Medicare fee-for-service payment system (e.g., strong incentives to increase unnecessary utilization of services) and payment system "silos" (e.g., the physician fee schedule or the inpatient prospective payment system) could pose as barriers to improve quality and care coordination across Medicare's systems.⁵⁷ Accordingly, differences in Medicare's payment system could limit the success in which ASCs harmonize the measures used in the ASC VBP program with the Hospital Inpatient Quality Reporting Program, Physician Quality Reporting System, and Hospital Outpatient Quality Data Reporting Program.

Current quality measurement frameworks in ASCs fail to recognize and reward facilities that accept accountability for patient experience and outcomes across the continuum of care. An ASC VBP program using a continuous quality improvement framework would reward high-quality ASCs and align with initiatives under other Medicare quality incentive programs.

The measures listed below were proposed and CMS responded to public comments on these in the final rule stating that CMS would consider them in the planning process for ASC quality measure data reporting (75 FR 72108-72109):

(1) Patient fall in the ASC; (2) patient burn; (3) hospital transfer/admission; (4) wrong site, side, patient, procedure, implant; (5) prophylactic IV antibiotic timing; (6) appropriate surgical site hair removal; (7) surgical site infection; (8) medication administration variance; (9) medication reconciliation; and (10) VTE measures: outcome/assessment/prophylaxis.

⁵⁶ Florida Medical Quality Assurance, Inc. and Health Services Advisory Group. Ambulatory Surgery Center Environmental Scan (July 2008). Contract No. GS-10F-0096T.

⁵⁷ Medicare Payment Advisory Commission. *Report to Congress: Reforming the Delivery System. June 2008*. The Report is available at: http://medpac.gov/documents/Jun08_EntireReport.pdf

The above measures could make a meaningful difference if ASCs and physicians change their behavior to respond to the VBP quality payment incentives. An incremental approach for ASC VBP program implementation could allow stakeholders (including CMS) to adjust under the new system. Such an approach could (1) provide ASCs with adequate notice about the set of measures and performance thresholds, (2) accrue baseline performance data on all VBP measures required for determining improvement scores, (3) establish appropriate benchmarks and thresholds for computing attainment scores, and (4) use benchmarks to determine financial incentive payment.

The Joint Commission (TJC) noted the ASC Quality Collaboration publicly reports clinical quality data reflecting patient admissions that capture aggregated performance data for six ASC facility-level quality measures: patient fall in the ASC, patient burn, hospital transfer/admission, wrong site, side, patient, procedure, implant, prophylactic IV antibiotic timing and appropriate surgical site hair removal. Hospital transfer/admission measure is collected by passive (the hospital or physician notifies the ASC) rather than assertive (the ASC surveys all area hospitals for admissions) means and, therefore, may not capture the actual rate of hospital admission as observed by TJC. In addition, TJC stated that hospital transfer/admission measure is an intermediate outcome measure, and may not reflect an outcome of the process of care in an ASC. Surgical site infection measure, as constructed, should reflect the most common definitions of surgical site infections as defined by CDC and incorporates patients without inclusions into the denominator. For future measure development, TJC recommended the following: surgical site infections, which assesses surgical wound infections related to specific procedures, such as knee arthroscopy, and antibiotic use in specific procedures, a measure accounting for appropriateness of antibiotics ordered for common ambulatory surgical procedures, such as laparoscopy or arthroscopy, for which evidence-based, specific antibiotic recommendations guide effective usage.

Under the continuous quality improvement framework, CMS could concurrently implement and align ASC value based purchasing strategies, including infection control measures, with existing systems that require ASCs to maintain an infection control program in accordance with changes in Conditions of Coverage and Survey and Certification oversight methodologies.

CMS received comments in support of adding infection control measures to the ASC quality data reporting system as part of the outpatient PPS final rule published November 24, 2010. The agency plans to consider how to incorporate them in the planning process for the ASC quality data reporting system and value based purchasing program.

- C. Appropriate Data Abstraction and Submission Methods** could allow for maximum ASC participation and ensure that facilities submit data accurately and in a timely manner without imposing undue administrative burden on them. The collection of information should minimize the burden on providers to the extent possible. As part of that effort, CMS will continuously seek to align its measures with the adoption of meaningful use standards for electronic health records, so the collection of performance information is part of care

delivery. Analysis by Florida Medical Quality Assurance, Inc. and Health Services Advisory Group recommended that the use of CPT Category II codes and G-codes would be a more feasible option for data abstraction for ASCs compared with an administratively burdensome method such as MRR.⁵⁸ In addition, a claims-based submission process represents a feasible method for ASCs to submit data.

Data submission methods for measures should align across Medicare's public reporting systems (e.g., inpatient and outpatient settings). For example, three out of the ten measures listed above that were proposed and CMS responded to public comments for ASC quality measure data reporting (75 FR 72108-72109) cross over to the inpatient setting. CMS tracks antibiotic timing, surgical site hair removal, and VTE prophylaxis measures as part of the inpatient SCIP measures. To the extent feasible and practicable, these three measures could leverage existing infrastructure in other Medicare public reporting systems to reduce the burden of data collection and ensure timely and accurate data submission for ASCs. As discussed above with measure development, the length of time and costs resulting from building a completely new system for ASCs could be significantly reduced if CMS identifies proposed measures that rely on Medicare's existing data and reporting infrastructure.

Electronic Health Records would allow ASC staff with technical expertise to coordinate, collaborate, and focus more seamlessly on patient-centered care. The technology will also mitigate the administrative burden associated with data collection and submission. The Medicare EHR incentive program will provide incentive payments to eligible professionals, eligible hospitals, and critical access hospitals that are meaningful users of certified EHRs. ASCs do not qualify for this funding.

However, there are barriers to implementing an electronic data reporting system within the rapidly growing ASC industry. Common reasons cited by ASCs as barriers to implementation of EHRs include (1) inability of existing systems and software to interface; (2) inadequate capital investment; (3) inaccessible software that captures their patient mix; and (4) lack of patient continuity.

D. Enhanced Data Infrastructure and Validation Process under a VBP program would link payment to quality of care and ensure data oversight for CMS to appropriately calculate performance incentives, rather than just simply linking payment to CMS receiving ASC quality data. CMS could introduce both a random and targeted audit of ASCs to focus on assessing the accuracy of performance measure rates. In this hybrid validation methodology, CMS would select an appropriate number of ASCs each year for the random component of the validation and an equally effective sample size for targeted audit. The audit selection methodology would enable CMS to assess the overall quality of data submissions and minimize gaming.

⁵⁸ Florida Medical Quality Assurance, Inc. and Health Services Advisory Group. Ambulatory Surgery Center Environmental Scan (July 2008). Contract No. GS-10F-0096T.

E. Performance Scoring and Evaluation Model would score an ASC's performance on a defined set of quality measures. Scoring methodologies should be reliable, as straightforward as possible, and stable over time. They should enable consumers, providers, and payers to make meaningful distinctions among providers' performance. Providers could be scored on their overall achievement relative to national or other appropriate benchmarks. In addition, scoring methodologies should consider improvement as an independent goal. Measures or measurement domains need not be given equal weight, but over time, scoring methodologies could be more weighted towards outcome, patient experience and functional status measures.

The ASC VBP program could be designed both to reward high performing ASCs and encourage improvement in ASCs that may be initially low performers. The value-based incentive payment could be determined both on the level of quality attainment and improvement in performance over time. However, ASCs that fail to meet quality targets within a performance period could face payment reductions.

The funding source for value-based payments could be generated from within current spending levels. For example, the availability of value-based payments could depend on whether the program achieves overall reduction in Medicare expenditures. Under budget neutrality, CMS could take existing ASC payments and subject a percentage of payments to be at risk.

The Hospital VBP program (performance model set out in the 2007 Report to Congress) could serve as a framework for the ASC VBP Performance Scoring and Evaluation Model. As in the Hospital VBP model, CMS would convert the total performance score into the percentage of VBP incentive payment earned, which aligns payments with the quality of care furnished to Medicare beneficiaries. An ASC receives a performance score on each measure included in the incentive payment measure set, as long as it meets the required minimum number of cases for the measure set. An ASC's performance on each measure could be based on the higher of an attainment score in the measurement period or an improvement score determined by comparing the ASC's current measure score with its prior-period baseline performance.

Alternatively to the Hospital VBP program, CMS could structure ASC value-based payments using a number of different options. Consistent with other Medicare quality demonstrations and proposed VBP programs, the ASC program could make bonus payments and collect penalties at the end of the year. A second option for distributing value-based incentive payments could rely on withholding a percentage of all payments and distributing accumulated funds to high performers. This would eliminate the need to collect payments from poor-performing ASCs and minimize the administrative burden for CMS.

CMS could also propose to incrementally increase the size of value-based incentive payments over time. Value-based incentive payments should be sufficiently large to encourage ASCs to improve the quality of care for Medicare beneficiaries. Incentive payments differ across private sector VBP programs. For example, payments under

Intermountain Health Care's Diabetes Quality Improvement Financial Incentive program represented between 0.5 percent and 1 percent of total physician compensation.⁵⁹ By comparison, Blue Cross Blue Shield of Massachusetts' Alternative Quality Contract sets performance incentive payments up to 10 percent above a provider's (e.g., physician or hospital) global budget for meeting clinical performance measures related to process, outcomes, and patient experience, including inpatient and ambulatory care.⁶⁰ CMS could also consider an alternative option for the payment spread using lessons learned from Medicare VBP programs. For example, under the Medicare Home Health Pay-for-Performance, 75 percent of the incentive pool would be shared with those agencies in the top 20 percent of the highest level of patient care. 25 percent of the incentive pool would be shared with the top 20 percent of those making the biggest improvements in patient care. If there are no savings, there are no incentive payments.

F. Transparency and Public Reporting would enable CMS to collect and validate data from ASCs and subsequently apply quality, efficiency, and cost measures for performance comparison. Public reporting should rely on a mix of standards, process, outcomes, and patient experience measures. CMS could publicly report quality measures in the early stages prior to being included in the financial incentive portion. Public disclosure and transparency encompass a broad-scale effort intended to provide consumers with facilities' performance scores in order to enhance their ability to make informed decisions about their healthcare consumption.

An incremental approach could be used to appropriately test and have ASCs submit data for new measures before these measures would be included in the set used for public reporting and then for the financial incentive. CMS would apply screening criteria against candidate measures to determine their suitability for inclusion in the VBP program and specifically for the financial incentive. To qualify for the financial incentive, an ASC would have to report on all measures relevant to its service mix, including new measures in the testing stage for possible introduction into the VBP Program, public reporting measures that are not included in the measure set for the financial incentive, and those measures used for determining the financial incentive.

Currently, ASCs do not collect and submit CAHPS data under a national, standardized publicly reported survey to determine patients' perspectives of their ASC experience. A

⁵⁹ David L. Larsen, RN, MHA; Wayne Cannon, MD; and Steven Towner, MD. Longitudinal Assessment of a Diabetes Care Management System in an Integrated Health Network. *J Managed Care Pharm.* 2003;9(6):552-58

⁶⁰ Blue Cross Blue Cross Blue Shield of Massachusetts' Alternative Quality Contract holds doctors and hospitals accountable for the quality, not just the quantity of the care they provide to its members. The Alternative Quality Contract rewards doctors and hospitals for keeping patients healthy and for effectively managing chronic illnesses. The Fact Sheet can be accessed at: <http://www.bluecrossma.com/visitor/pdf/alternative-quality-contract.pdf>

survey instrument and data collection methodology could be developed that allow for meaningful and objective results of patients' experience of care in ASCs.

8. Conclusion

CMS seeks continuous quality improvement in ASCs through Changes in Conditions for Coverage, changes in Survey and Certification oversight methodologies, and consideration of measures for ASC quality data reporting (e.g., under legislative provisions contained in the MIEA-TRHCA). They represent critical developments toward a longer-term goal of improvements in ASC quality of care. An ASC VBP program will go the next step in linking payment to performance to improve value for Medicare beneficiaries.

Several steps will be involved in designing and implementing a VBP program for ASCs:

1. Statutory authority;
2. Continuous quality improvement framework;
3. Appropriate data abstraction and submission methods, including electronic health records;
4. Enhanced data infrastructure and validation process;
5. Performance scoring and evaluation model; and
6. Transparency and public reporting.

As described above, the "Roadmap for ASC VBP Program Implementation" addresses each of these steps, taking advantage of Hospital VBP, Home Health P4P Demonstration, and the Physician Quality Reporting System to inform the design and implementation of the ASC VBP program.