DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop S2-12-25 Baltimore, Maryland 21244-1850



Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-09-43 ACTION by JUNE 30, 2009

DATE: June 12, 2009

TO: State Survey Agency Directors

FROM: Director Survey and Certification Group

SUBJECT: American Recovery and Reinvestment Act of 2009 (Recovery Act) Ambulatory Surgical Center Healthcare-Associated Infection (ASC-HAI) Prevention Initiative

Memorandum Summary

- The Centers for Medicare & Medicaid Services (CMS) and States will improve quality assurance of ASCs during FY 2009 and FY 2010 by implementing a new survey process to promote better infection control practices.
- Approximately \$10 million is available to States for this purpose over the course of the two years.
- By June 30, 2009, we request that States volunteering for implementation in 2009 submit key information to CMS. We plan to make allocations to States in July 2009 for implementation of the improved survey process in the last quarter of FY 2009.
- In FY 2010 all State Survey Agencies (SAs) will be required to implement the improved survey process and to survey about one-third of the ASCs as a high (Tier II) priority. SAs may receive Recovery Act funding to offset the additional costs of these surveys.
- Recovery Act funds may not be used to support work already required by CMS.

Background

The Recovery Act makes fifty million dollars available to States "to carry out activities to implement healthcare-associated infections reduction strategies." Ten million dollars of this funding is available to expand oversight of ASCs.

The need to improve oversight of ASCs arises from many factors. ASCs have been the fastest growing type of institutional provider/supplier participating in Medicare, increasing in number by more than 38 percent between 2002 and 2007. ASCs currently account for 43 percent of all same-day surgery in the United States. When ASCs are inspected, deficiencies are often cited. In FY 2008, for example, 15 percent of all ASCs inspected by the SAs for CMS were found to have serious (condition-level) deficient practices.

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In CY 2008, an outbreak of Hepatitis C in the State of Nevada was traced to poor infection control practices in two ASCs. Over 50,000 former patients had to be notified of potential exposure to Hepatitis C and other infectious diseases, and reportedly over 100 people developed Hepatitis C as a result of their exposure in the ASCs. Inspections of 28 Nevada ASCs for compliance with Medicare standards revealed 64 percent had serious problems, primarily in infection control.

We owe a debt of gratitude to the Centers for Disease Control and Prevention (CDC) and three States – Maryland, Oklahoma, and North Carolina – that collaborated with us in 2008 to pilot test a new infection control survey instrument and use of tracer methodology (following at least one patient through the entire course of their ASC experience). The survey instrument and tracer methodology form the foundation of the improved survey process, together with the new CMS regulations at 42 C.F.R. Part 416 that raise the importance of proper infection control and also require internal ASC systems of quality assessment and performance improvement (QAPI).

The new ASC survey process greatly improved the ability of SAs to recognize deficient practices in infection control. A representative sample of 68 ASCs in the three States was surveyed. Approximately 19 percent of ASCs were found to have condition-level deficiencies and 85 percent were found to have standard-level deficiencies, primarily in the area of infection control. Among the common deficient practices in the pilot were ASC use of single-dose vials of medication for multiple patients, improper sterilization practices (such as routine use of flash sterilization), general disinfection and sanitation problems, and failure to have any system for reporting notifiable diseases to their respective State health agency.

Supplemental Recovery Act Funding and New ASC Survey Process

Given evidence suggesting widespread problems in infection control practices in ASCs, CMS concluded that the improved survey process and more frequent inspections of ASCs will make a significant contribution to reducing the risk of healthcare-associated infections (HAIs) in the States. Onsite surveys focus management attention on infection control issues, identify evidence of lapses in infection control, require prompt remedy of identified issues, help educate ASCs through the provision of objective, trained observation of actual practice, deter relaxed infection control practices, and have great potential for the prevention of HAIs. We are therefore implementing the new survey process nationwide under Section 1864 of the Social Security Act to provide a higher and nationally consistent level of protection to the American public against HAIs.

HHS is making approximately \$10 million of Recovery Act funding available to the States in FY 2009 and FY 2010 to implement the new survey process and increase the frequency of inspections for ASCs. In addition to remedying current infection control lapses and preventing future HAIs, the funds will help States avoid otherwise planned layoffs or furloughs and/or recruit additional surveyors to inspect more of their ASCs.

Attachment 1 provides an estimate of the Recovery Act funds available to each SA. The exact amounts of funding will be determined based on the following:

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- (a) Whether the State wishes to participate in both FY 2009 and FY 2010, or only in FY 2010;
- (b) The number of ASCs that the State wishes and is able to survey in FY 2009 and FY 2010. In FY 2010, all SAs will be required to use the new survey process. However, some States may survey more than one-third of the ASCs in the State. To the extent such States wish to survey more than one-third of their ASCs in FY 2010, it may be possible to reduce the extent to which other States will need to conduct ASC surveys in FY 2010;
- (c) The State's projected costs.

The Recovery Act funds are in addition to and separate from the State's base budget for survey & certification funds. Recovery Act funds may not be used to support other SA work required by CMS, and must be used only for the additional work required by the new survey process and increased frequency. Regular reports on the use of Recovery Act funds will be required in order to support the Federal Government's efforts to provide transparency to the public on the use of Recovery Act funding.

Plan for Recovery Act Funding

The attached Planning Guide identifies the key information that we will need and will constitute the State's plan. Please respond to the questions and topic areas identified in the attached Planning guide and postmark the response to CMS no later than June 30, 2009 for States requesting both FY 2009 and FY 2010 funding, and August 30, 2009 for States requesting only FY 2010 funding. The plan must be signed by the Commissioner or Secretary of the Department/Agency in which the SA is located. FY 2010 plans may be amended by the State prior to implementation, with CMS' consent. The plans must be addressed to the CMS Regional Office, with a copy to:

Angela Mason-Elbert ASC Technical Lead Survey & Certification Group/DACS Centers for Medicare & Medicaid Services 7500 Security Boulevard Mail Stop S2-12-25 Baltimore, Maryland 21244-1850

Questions about the Recovery Act ASC initiative should be directed to Angela Mason-Elbert at <u>angela.mason-elbert@cms.hhs.gov</u>

/s/ Thomas E. Hamilton

cc: Survey and Certification Regional Office Management Attachments (2)

ATTACHMENT 1 - ESTIMATE of FUNDS AVAILABLE to EACH STATE - FY 2010

Region	State Agency	Total Number ASCs	Number Non-Deemed ASCs	FY 2010 S&C Budget for ASCs (Proposed)	FY 2010 Est. Add'l Recovery Act Funds	FY 2010 Estimated Total Funds (Except Validation Surveys)
	Connecticut	43	41	\$42,245	\$105,757	\$148,003
	Maine	17	15	\$17,840	\$17,068	\$34,909
1	Massachusetts	61	28	\$29,121	\$91,273	\$97,067
	New Hampshire	21	15	\$47,614	\$11,955	\$51,781
	Rhode Island	11	8	\$11,004	\$37,848	\$48,852
	Vermont	1	0	\$0	\$0	\$0
	New Jersey	219	133	\$75.795	\$475,052	\$508,009
2	New York	89	45	\$239,133	\$51,817	\$251,087
l f	Puerto Rico	24	24	\$47,876	\$2,790	\$50,665
l f	Virgin Islands	0	0	\$0	\$0	\$0
	Delaware	25	11	\$14,844	\$36,467	\$42,620
-	Dist. of Col.	4	4	\$7,031	\$1,941	\$8,972
3	Maryland	358	351	\$245,193	\$507,130	\$747,545
	Pennsylvania	229	216	\$149,004	\$336,479	\$480,493
	Virginia	52	44	\$28,584	\$90,823	\$113,615
	West Virginia	11	9	\$29,945	\$1,587	\$31,532
	Alabama	36	31	\$19,531	\$41,889	\$61,420
-	Florida	386	275	\$110,556	\$442,273	\$522,970
-	Georgia	266	252	\$313,140	\$392,057	\$698,975
4	Kentucky	35	32	\$4,638	\$97,456	\$102,094
	Mississippi	64	57	\$56,381	\$272,387	\$316,320
-	North Carolina	76	61	\$35,620	\$76,972	\$108,598
-	South Carolina	67	57	\$39,528	\$107,312	\$141,280
-	Tennessee	147	131	\$145,269	\$577,108	\$710,217
	Illinois	147	85	\$107,929	\$165,311	\$259,542
-	Indiana	121	92	\$98,070	\$84,350	\$259,542
5	Michigan	86	56	\$28,823	\$141,218	\$157,429
	Minnesota	54	50	\$47,988	\$117,625	\$165,613
-	Ohio	203	107	\$92,907	\$218,235	\$281,624
-	Wisconsin	58	37	\$27,694	\$96,615	\$117,204
	Arkansas	64	64	\$72,415	\$80,821	\$153,236
-	Louisiana	74	67	\$42,771	\$200,808	\$235,689
6	New Mexico	23	18	\$18,423	\$29,976	\$48,399
U U	Oklahoma	51	45	\$9,758	\$159,376	\$161,104
-	Texas	352	269	\$197,735	\$519,464	\$661,999
	lowa	25	209	\$7,896	\$14,986	\$18,317
7	Kansas	25 65	9 56	\$45,248	\$83,860	\$124,136
'	Missouri	106	94	\$85,832	\$03,000 \$157,334	\$237,499
ŀ	Nebraska	48	94 43	\$28,571	\$61,545	\$90,116
	Colorado	40 103	43 90	\$28,571	\$168,730	\$260,044
-	Montana	103	90 13	\$97,795 \$11,495	\$168,730 \$5,318	\$260,044 \$12,468
8		15			\$12,672	\$35,933
°	North Dakota South Dakota	16	16 13	\$23,261 \$28,176		\$31,355
-	Utah	48	43	\$28,176 \$93,108	\$3,179 \$59,954	\$153,062
-				\$5,557	\$42,182	\$47,739
	Wyoming Arizona	19 149	16 120	\$5,557 \$100,039	\$42,182 \$263,746	\$357,110
9	California				\$263,746	\$1,563,435
3	Hawaii	703 12	455 11	\$455,601 \$24,801	\$17,262	\$42,063
-		52	38			
	Nevada			\$76,743	\$46,233	\$109,991
10	Alaska	9	9	\$1,283	\$26,951 \$87,750	\$28,234
10	Idaho	58	43	\$4,590	\$87,759	\$83,625
-	Oregon	78	72	\$106,992	\$297,442	\$404,435
	Washington	225	192	\$153,202	\$655,996	\$781,799
	Total	5,195	4,063	\$3,804,594	\$8,856,372	\$12,074,165

Note: FY 2009 amounts for volunteer States that participate in the last quarter of FY 2009 will be eligible to receive a pro-rated amount of the total funds available, adjusted for the estimated total of ASC surveys the State expects to conduct in the months of July, August, and Sept. 2009. To calculate the expected FY 2009 amount, see the instructions at Section B.3 of the following Guidance and Planning Documents for State Survey Agencies (Objectives and Uses of Funds).

Ambulatory Surgical Centers

Healthcare-Associated Infection Initiative

Guidance and Planning Documents for State Survey Agencies

June 2009

HEALTHCARE-ASSOCIATED INFECTIONS PROGRAM RECOVERY PROGRAM PLAN Planning Document

A. FUNDING TABLE

(dollars	(dollars in millions) Program Planned Obligations					
Project/Activity	Level	FY 2009	FY 2010			
Improvement of State Survey Agency	\$10.0	\$1.0	\$9.0			
inspection capability of Ambulatory						
Surgical Centers (CMS)						

Table 1: (dollars in millions)

B. OBJECTIVES AND USE OF FUNDS

The American Recovery and Reinvestment Act (Recovery Act) appropriated \$50 million to the Department of Health and Human Services (HHS) Office of the Secretary. These funds will be provided to States for the execution and implementation of healthcare-associated infection (HAI) reduction strategies. They will also be used for State prevention activities and enhancing oversight at the State level.

This program is aligned to the HHS Action Plan to Prevent HAIs which represents a culmination of research, deliberation, and public comment to identify the key actions needed to achieve and sustain progress in protecting patients from the transmission of serious and, in some cases, deadly infections. For more information, visit: http://www.hhs.gov/ophs/initiatives/hai/infection.html.

1. Objectives and Importance of this Initiative: Of the total \$50 million appropriated to reduce HAIs, \$10 million is provided for State Survey Agencies (SAs) to improve the survey process for Medicare-participating Ambulatory Surgical Centers (ASCs).

ASCs in the United States have been the fastest growing provider type participating in Medicare, increasing in number by more than 38% between 2002 and 2007. A 2008 Hepatitis C outbreak in Nevada was traced to poor infection control practices at various ASCs (potentially affecting more than 50,000 people). Follow-up Medicare surveys throughout Nevada found serious deficiencies at 64% of the ASCs surveyed, primarily with infection control practices.

The focus of this document is to provide guidance to the SAs on the ASC initiative and the planning process. CMS' goal is to allocate Recovery Act funding in the amount of \$9.95 million to SAs (the remaining \$0.05 million will support CMS training activities related to this initiative) to support the activities associated with this project nationwide.

This initiative will significantly expand the awareness of proper infection control practices among ASCs and SAs, increase the extent to which infection control deficiencies are both identified and remedied, and prevent future serious infections in ASCs by:

- (a) Improving SA inspection capability and frequency for onsite surveys of ASCs nationwide,
- (b) Using a new infection control survey tool developed by the CDC and CMS,

- (c) Improving the survey process through the use of a CMS tracer methodology, and
- (d) Using multi-person teams for ASCs over a certain size or complexity.

A CMS pilot program tested the above survey process improvements in three States in 2008 and demonstrated superior results in the identification and remedy of serious infection control deficiencies. The particular focus on ASCs for this funding was chosen because:

- ASCs have not been surveyed with the frequency and attentiveness to infection control that is needed (current survey frequencies are about once every ten years on average nationally);
- ASCs represent the fastest-growing facility type participating in Medicare, with about 15 million same-day procedures performed each year (43% of the national total); and
- SA experience indicates the likely prevalence of infection control deficiencies in this setting (based on the findings of the pilot program).

The Recovery Act funds will enable the application of the above four-component new survey process nationwide.

2. Type of Financing: Payments will be made to States under a process that is separate from (but in the same manner as) the standard process for providing funding for survey and certification activities under §1864 of the Social Security Act. A worksheet based on a modified version of Form CMS-435, State Survey Agency Budget/Expenditure Report (which CMS uses as an accounting tool for survey and certification activities of the States) will be used to capture activities related to the ASC HAI initiative. Of the total funds available, \$9.95 million will be allocated to States and \$50,000 will be used for Federal administration (e.g., training of States). In both FY 2009 and FY 2010, the Recovery Act funds will be tracked and monitored separately from funds allocated for standard Survey and Certification program activities.

3. Uses of Funds: Recovery Act funds are available to the State immediately upon CMS approval of their plan.

- <u>FY 2009</u> funds are available and will be provided to States promptly after they are notified of approval of an FY 2009 plan. All funds must be obligated by September 30, 2009.
- <u>For FY 2010</u>, unlike the overall FY 2010 Medicare budget for survey & certification, the supplemental Recovery Act funds are available now and do not need to wait for passage of the Federal FY 2010 budget. We therefore will act on the State ASC survey plans prior to the start of FY 2010 and provide States with the assurance that the funds will be on hand as soon as their plan is approved. All FY 2010 funds must be obligated by September 30, 2010.

If approved by CMS necessary supports may include funding that will enable the State SA to enlist the services of State physicians or certified infection control specialists who will be oriented to the ASC survey process, accompany surveyors on several of their first surveys conducted under the new process, and, if needed, on a sample of subsequent surveys, and be available to consult with surveyors as part of the survey process.

An important aspect of the successful three-State pilot in 2008 was the availability of CDC physicians to accompany the survey teams on their first few surveys and then to be available for quick consultation as additional surveys occurred. While some CDC and CMS physician

assistance may be available for the 2009 and 2010 surveys, the coverage will be very limited. We therefore strongly encourage and support State SA outreach to other components of the State public health departments and other State resources that may be able to offer similar physician support to the effort.

Funds may be used not only to save or create jobs directly within the SA, but also for the SA to contract with experienced surveyors, for example, retired SA or retired Federal surveyors, who will be trained in the new ASC survey process. States may also contract for individuals with certified infection control expertise, who could be paired with an experienced surveyor on a team. There may also be other sources of expertise available under contract to the SAs; however, contracting to use personnel with neither health care facility survey experience nor expertise in infection control will not be eligible for funding.

Estimation of Survey Costs and Recovery Act Funding

The new survey process includes some additional features for the health component of the survey, illustrated as follows:

	Additional Features of New Survey Process				
Content of Survey	Infection Control Instrument				
	Tracer Methodology				
	Additional Surveyor (for most States, most ASCs)				
Frequency of Surveys	33% of ASCs to be surveyed using the new process in FY 2010,				
	v. 16.5% in 2010 Medicare S&C budget.				

For both FY 2009 and FY 2010, the Recovery Act will fund the new ASC-HAI survey process costs that exceed the amount included for ASC surveys in the State's regular Medicare S&C budget. We will work with each State to calculate the exact amount. The mathematical concept for standard surveys can be expressed very simply as:

Net Recovery	=	Total cost of new survey process	minus	Funds budgeted in normal S&C
Act Funds		at 33% of all ASCs being		Medicare budget at 10%
		surveyed each year (frequency)		frequency for FY 2009 and 16.5%
				for FY 2010.

We estimate that it will require an average of 46 hours per survey (on a national basis) for the health component of surveys using the new survey process, and that the health component will require two surveyors for all but the very small ASCs. The life-safety code portion of the survey is not affected by the new content of the ASC survey protocol, and generally requires a third person. The number of hours required for the health portion of an ASC survey, of course, is affected by other factors, such as the volume of procedures performed in an ASC and the complexity of the ASC activities (e.g., the number of different types of procedures and the type of procedure). The precise average hours of survey time will therefore vary State-by-State (and some States already average more than 46 hours under the existing survey process). We will work with each State to estimate the hours that will be required, and then track the survey time needed for the new survey process to optimize the extent to which we can assure that actual costs are covered (such as by making supplemental adjustments during the year).

In estimating their projected plans and costs eligible for Recovery Act funding, SAs may find it useful to take the approach in the worksheet below:

Estimation Worksheet: Recovery Act Funding – Only a Rough Guide (Does Not Include Supplemental Funding for Validation Surveys)

Step	FY 2009	FY 2010
		(See Note below)
1. ASCs: Enter the number of non-deemed ASCs		
2. Surveys Done Under Regular Budget: Enter the number of surveys already done in		
2009. For FY 2010, enter 16.5% of row 1.		
3. Additional Surveys Expected: For 2009, enter the number of surveys you expect to do		
using the new Recovery Act survey process during July-Sept 2009. For 2010, enter at least		
1/3 of the total number of non-deemed ASCs (from row 1).		
4. Total Surveys: For 2009: Add rows 2 and 3. For 2010: enter only the number in row 3.		
5. Current Hrs/Health Survey: Enter the most recent 12-month average number of hours		
per survey for: (a) the health portion of the survey that is (b) attributable to Medicare.		
However, if row 2 is less than 12 surveys, use the most recent multi-year period to generate a		
more reliable average.		
6. New Hrs per Health Survey: We expect the health survey portion to take between 6-44		
more hours compared to the current surveys, depending on how extensive your current		
surveys are. Pilot States in FY 2008 averaged between 37 and 63 total hours. A rule of		
thumb is to expect surveys to average 46 hours at first. Some States have surveys already		
taking more than 46 hours. In such a case, we expect the added hours to be less than for a		
State whose surveys currently average fewer than 46 hours. Use your judgement and enter		
here the total hours you expect the new survey will take in your State based on the		
information you have on hand now. If unsure, use 46 hours.		
7. Hourly Rate: Enter the average hourly rate for health survey costs in your state that you		
file on the CMS cost reports (CMS-670).		
STEPS 8-12 BELOW ARE OPTIONAL !!!!		
8. Recovery Act Partial Funding: (a) For <u>2009</u> , take 10% of <u>row 1</u> , and then subtract <u>row 2</u> .		
(b) If a negative number, enter 0. (c) If a positive number, multiply by the <u>difference</u>		
<u>between row 5 and row 6</u> . (d) Then multiply the result times row 7. These are the added funde that the Bacavary A at would supply for survey that the State is expected to do under		
funds that the Recovery Act would supply for surveys that the State is expected to do under its require Medicare hydrot for EV 2000 (if the State participates in 2000). For 2010 (a)		
its regular Medicare budget for FY 2009 (if the State participates in 2009). For 2010 , (a)		
start with the number in row 2 and then follow steps (c) and (d).		
9. Recovery Act Full Funding: (a) For 2009, subtract from row 4 the greater of (i) the		
number in row 2 or (ii) a number equal to 10% of row 1. (b) If a negative number, enter 0		
here. (c) If a positive number, multiply the result times $row 6$. (d) Then multiply the result		
times row 7. For 2010 (aa) Subtract from row 3 a number equal to 16.5% of row 1. (bb) If		
the result is a negative number, enter 0 here. (cc) If a positive number, multiply the result (12) (12)		
times row 6. (dd) Then multiply the result times row 7. This is the amount of Recovery Act		
funds estimated for surveys that exceed the number upon which the Medicare S&C budget is		
constructed.		
10. Life-Safety Code-Partial Funding: Repeat step 8 but use the average hours per LSC		
survey portion, then multiply times the average hourly cost for LSC surveys. This is the		
amount of Recovery Act funds (for the LSC portion) estimated for surveys that exceed the		
number upon which the Medicare S&C budget is constructed.		
11. LSC-Full Funding: Repeat step 9 but use the average hours per LSC survey portion,		
then multiply times the average hourly cost for LSC surveys. This is the amount of Recovery		
Act funds (for the LSC portion) estimated for surveys that exceed the number upon which the		
Medicare S&C budget is constructed.		
12. Total Estimated Recovery Act Supplemental Funding: Add rows 8, 9, 10, and 11.		
Note: For FY 2010, we have estimated the numbers in Attachment 1 to the S&C Memo		
using figures currently available to us. We will verify the numbers with you and work out		
the final budget based on the most recent verifiable number to ensure that costs are		
covered.		

C. DELIVERY SCHEDULE

The table below shows the schedule of milestones for major phases (e.g., the procurement phase, planning phase, project execution phase, etc.) with expected completion dates.

l able 2:						
Major Milestone	Expected					
	Completion Date					
Notice to State Survey Agencies	May 2009					
• First Training on new Evidence-based tool + New	May 14, 2009					
Regulations	(completed)					
Survey Agency Conference Call to address State SA	June 2009					
questions and identify issues that require resolution						
• May 14 th training made available for download – see	June 4, 2009					
http://surveyortraining.cms.hhs.gov/pubs/archive.aspx						
Submission of Plan for FY 2009 funding	June 30, 2009					
• Selection of States for 2009 Implementation Submission of	July 2009					
Plan for FY 2009 funding						
Notice to States of FY 09 Approval & Funding Levels	July 2009					
Start Implementation in 2009 Volunteer States	July 2009					
Submission of Plan for FY 2010 funding	August 30, 2009					
Notice to States of FY 2010 Approval & Funding Levels	September, 2009					
In-Person Training – All States	October 2009					

Table 2:

D. MEASURES AND REPORTING

All SAs must be able to track and report ASC-HAI project activities, program participant data, and spending separate from other survey and certification activities. Minimum reporting requirements will include quarterly reports, annual reporting, and close-out reporting. CMS will capture from Survey and Certification data bases output and outcome measures as shown in Table 3; SAs are responsible for furnishing data on the number of jobs created or saved. Template worksheets will be provided for SA completion.

CMS will produce quarterly reporting on what work has been completed, including milestones such as training, outreach efforts, and allotments to SAs. To gauge effectiveness of the project, CMS will issue an evaluative report on the new ASC survey process. The report shall include SA input on the value from the enhanced survey infection control tool and other important aspects of the new survey process. CMS will post the report on its Web site at www.cms.hhs.gov.

The measures shown in Table 3 will likely be publicly displayed on Recovery.gov

Table 3. CMS - Healthcare-Associated Infections Recovery Act Performance Measures: Type, Target, and Frequency

Goal	Measure
<u>1. Expand the State Survey</u> <u>Agency's capability for</u>	Ensure that all ASC survey staff nationwide are trained on the use of the new survey tool and protocols, and participation is verified.
<u>conducting ASC surveys</u> : Train	new survey toor and protocols, and participation is verned.
all applicable Federal & State surveyors on HAIs survey tool.	
2. Improve Infection Control Deficiency Identification & Corrective Action: Improve the	(a) Increase by 100% the number of ASCs surveyed onsite compared to the same time period in the previous year in participating States in 2009.
extent to which ASC infection control deficiencies are identified (through use of a new survey process) and are corrected	(b) Ensure that at least one-third of all non-accredited ASCs have an onsite survey using the new survey process in FY 2010, and at least a 5% sample of accredited ASCs are surveyed.
through Plans of Correction.	(c) For ASCs surveyed under the new survey process, increase by 50% the percentage of ASCs in which existing infection control deficiencies are identified.
	(d) Ensure that 100% of identified Condition-level (serious) deficiencies are remedied within the time period specified in the State Operations Manual pursuant to a Plan of Correction.

Reporting Methods: The following special reporting procedures will apply.

- Worksheet Based on modified Form CMS-435: On a quarterly basis, a worksheet based on a modified version of form CMS-435 must be sent to the CMS Regional Offices. Timely electronic submission is strongly encouraged.
- CMS-2567 and CMS-670: 10 working days after the exit date of the health/LSC survey, Forms CMS-2567 and CMS-670 will be completed. The CMS-2567 will be available to be furnished to the CMS Regional Office via e-mail, if requested. ASPEN kits with the new ASC tags are now available.
- **Infection Control Instrument:** 30 days after the exit date of the health/LSC survey a copy of the completed infection control survey instruments will be sent to a contact to be identified by CMS. More detailed instructions will be provided later.
- **Deficiency Citation Summary:** SAs are responsible for promptly uploading completed Forms CMS-2567 and CMS-670 and ensuring that they are uploaded to the national data base. On a quarterly basis, CMS Central Office will produce summary data derived from a review of the completed forms.

E. MONITORING AND EVALUATION

All Recovery Act programs will be assessed for risk and to ensure that appropriate internal controls are in place throughout the entire funding cycle. These assessments will be done consistent with the statutory requirements of the Federal Manager's Financial Integrity Act and the Improper Payments Information Act, as well as OMB's circular A-123 "Management's Responsibility for Internal Control."

Plan Information

Plan Review Criteria

All FY 2009 plans received by the June 30, 2009 deadline that meet minimum requirements as shown below will be reviewed and decisions will be made on the award of Recovery Act funds for the 4th quarter FY 2009. FY 2010 plans are due by August 30, 2009. Funding decisions for FY 2010 will be made in September, 2009. FY 2010 funds awarded will be available shortly after October 1, 2009.

Minimum Criteria

- A. Complete information has been provided.
- B. Plan has been received on or before deadlines for FY 2009 and FY 2010.
- C. Only eligible activities are included in the plan and implementation actions.
- D. Budget is within cost category limitations.
- E. Required assurances, signatures, and certifications are provided.

Eligibility

Any SA under an 1864 agreement in good standing with the Secretary of Health and Human Services is eligible. SA applicants must demonstrate the ability to manage Recovery Act funds and comply with all applicable State and Federal policies and procedures, including all applicable Federal and State laws.

SAs must demonstrate the ability to meet all reporting and record-keeping requirements for these funds.

The SAs are required to:

- Train new, current or additional SA surveyors on the new survey tool and protocols.
- Increase significantly the number of ASCs surveyed in the State.
- Where inspections have identified infection control deficiencies, ensure that the ASC remedies the deficiencies in a timely manner, paying particular attention to Condition-level (serious) deficiencies.
- Conduct validation surveys as assigned, up to 7% of their deemed ASCs; the final volume is dependent on accreditation organization survey schedules.

Format of the Plan

Please submit your plan using the following formats:

- The electronic copy must be in Microsoft Word format Times New Roman, 12 point font, double-spaced, with one-inch margins on all sides.
- The hard copy must be on white paper that is 8 ¹/₂ by 11 inches in Times New Roman, 12 point font, double-spaced.
- Total hard copy plan package should not exceed 5 pages.

How to Submit the Plan:

Please submit the plan in two forms:

- An electronic copy should be submitted the appropriate CMS Regional Office and also to: <u>angela.mason-elbert@cms.hhs.gov</u>
- A hard paper copy of the plan, including signed letters of support as described in the attached memo, should be submitted to your CMS Regional Office, with a copy to:

Angela Mason-Elbert ASC Technical Lead Survey & Certification Group/DACS Centers for Medicare & Medicaid Services 7500 Security Boulevard Mail Stop S2-12-25 Baltimore, Maryland 21244-1850

Deadlines and Special Content:

FY 2009 Volunteer States: All hard copy plans postmarked by **June 30, 2009** will be considered in the selection of States eligible for additional funding in FY 2009 for ASC surveys. States volunteering for FY 2009 may also include their FY 2010 funding request by June 30, 2009, or may wait until August 30, 2009 to file information needed for FY 2010. However, since the final FY 2009 plan approved by CMS may differ from the plan submitted, States submitting both plans in June will have the opportunity to modify their FY 2010 requests accordingly prior to August 30th.

States choosing to submit for both years by June 30th should submit separate plans for each year, including the number of surveys to be performed in FY 2009 and FY 2010. CMS will make separate decisions on the FY 2009 and FY 2010 funding. Please note that all FY 2009 funds must be expended by September 30, 2009, and all FY 2010 funds must be obligated by September 30, 2010.

The SA will be eligible for Recovery Act funding for the additional costs associated with using the new survey process. These surveys will include both the health and the LSC components. Basically, the following calculation will be made for 2009:

- 1. Total estimated cost of the new survey process *times* the estimated number of surveys the State will conduct in July-Sept 2009 using the new process;
- 2. <u>Minus</u> the funds already allocated in the Medicare S&C budget for ASC surveys in 2009 and not already spent for ASC surveys by the State. The basis for the calculation of funds allocated for ASC surveys will be the State's 2009 budget approved by the CMS regional office and will include the 10% Tier II targeted surveys.

FY 2010 - All States: All States will be required to implement the new survey process in FY 2010 <u>and</u> survey one-third of the non-deemed, non-accredited ASCs and a sample of deemed accredited ASCs (up to 7%). All States should submit a plan for FY 2010 postmarked by **August 30, 2009** that describes how they plan to implement the new survey and any special funding requests. States may request funding to survey more than one-third of their non-deemed ASCs.

The ASC surveys will include both the health and the LSC components. As applicable, the SA will also be required to use the new inspection process for complaint surveys in FY 2010, e.g., the infection control tool will be used for complaint surveys related to the infection control requirements.

The SA will be eligible for funding for those costs that are above Medicare survey work that is funded through CMS' regular survey and certification budget. Two main types of additional costs are involved: content (i.e., for the additional cost associated with use of the new inspection process for surveys of the non-deemed, non-accredited ASCs) and frequency (the additional cost associated with an increased survey frequency for ASCs). For more information on how to calculate the costs that are eligible for Recovery Act funding, see the description above in Section B.

For FY 2010, CMS will identify, by random selection, certain ASCs that must be included in the 33% of non-accredited ASCs that are surveyed. The identified sample will be less than the full 33%. CMS will also assign a sample of deemed, accredited ASCs to be surveyed, and these surveys may or may not involve validation of a recent survey by an accreditation organization. States may request to survey fewer than 33% of non-accredited ASCs, and we will seek to honor such requests to the extent that we receive sufficient interest from other States that wish to survey more than 33% of such ASCs in their State.

Training

The SA will be required to assure that current and new ASC surveyors will receive training necessary to conduct the improved ASC surveys. Completion of training will be reported on the modified form CMS-435, and entered into the Learning Management System (LMS). CMS will conduct:

- *May 14, 2009:* One live distance learning training session related to the new inspection process on May 14, 2009; this session is available to SAs for downloading and repeat use as needed thereafter.
- June 2009 Conference Call: A national conference call for State survey agencies in June (prior to the deadline for FY 2009 plans) in order to address questions and identify issues that require resolution. The focus of the call will primarily be on administrative and design issues.
- *October In-Person Training:* One comprehensive in-person training, planned for October, 2009, on all ASC Conditions for Coverage and the new survey process, with the exception of Life Safety Code requirements.
- *Other*: Subsequent to the May and June events, we will work with States to identify any additional training events that will be useful.

ASC Planning and Information Form

SECTION I - IDENTIFYING INFORMATION

State:	Name of State survey agency						
Director: State survey agency director name:							
	Director: State survey agency director name:						
Telephone:		FAX	.:				
E-mail:							
Point of contact for	or ASC Surveys-Re	ecovery Act I	Funding				
Name:							
Street:							
City:		State	2:	Zip:			
Telephone:		FAX	FAX:				
E-mail:							
State Hosting Age	State Hosting Agency: Name of State agency in which the survey agency is located:						
Name/Title of the Agency Head:							
Street:							
City:	City:						
Telephone:		E-mail					

SECTION II – STAFFING PLAN

Please complete the following table and add narrative notes where clarifying information is advisable. "ASC-Primary" surveyors are those for whom ASC surveys comprise the majority of their work. "Multiple Provider" surveyors are those whose primary duty consists of surveys of other provider types (e.g. hospitals) but who are trained and conduct some ASC surveys.

	Category	Total # <u>People</u>	<u># FTE</u> in June	Expected Additional <u>FTE</u> Conducting ASC Surveys (<i>Above 6/1/09 Level</i>)		
	Time Period	in June '09 '09	' 09	By Sept 1, 2009	By Jan. 1, 2010	By June 1, 2010
th	1. ASC-Primary Surveyors					
. Health	2. Multiple Provider Surveyors – FTE conducting ASC Surveys					
Ā	Subtotal-Health					
fety	1. ASC-only Surveyors					
<u>Life-Safety</u> <u>Code</u>	2. Multiple Provider Surveyors – FTE conducting ASC Surveys					
<u>B</u> .	Subtotal-Life-Safety Code					
<u>Grand</u> Total	 ASC-only Surveyors Multiple Provider Surveyors – FTE conducting ASC Surveys 					
	Grand Total-Health + LSC					

Capability Expansion and Hiring Plan

- (a) Description: Please include a detailed description, with projected implementation dates, of how the SA will expand its capacity to accomplish the additional ASC work to be funded through the initiative. This may include the hiring of new health surveyors, new LSC surveyors, and non-surveyor staff (e.g., supervisory or administrative support staff) for the SA. Also, any plans for entering into a contract or inter-agency agreement to conduct ASC surveys should be described fully.
- (b) Status of Any State Personnel Restrictions: Please describe any State personnel restrictions that currently apply to the SA, such as planned layoffs, across-the-board hiring freezes, furloughs, or out-of-state travel prohibitions, including any quantifiable aspects (e.g. furloughs 1 day per month) and how long the restrictions are expected to apply. Please describe any exceptions to the restrictions that will apply to the ASC initiative. If applicable, the plan should itemize the number of FTEs that represents exemptions from State staffing restrictions, if the SA is approved to receive Recovery Act funding.

SECTION III – TRAINING PLAN

Please include a detailed plan of how many surveyors have already or will receive training on the new survey process, making use of the distance learning training provided by CMS, and how many surveyors will receive training provided by CMS in-person in the fall of 2009. The SA should confirm that it has access to the necessary technology for surveyors to participate in the distance learning training.

SECTION IV – SURVEY PLAN

Please include the following:

For 2009: the number of ASCs that will be surveyed using the new survey process on a voluntary basis during the fourth quarter of federal FY 2009 (July, August, Sept.).

For FY 2010: whether the SA is applying for funding to survey more than 33 percent of nondeemed, non-accredited ASCs in FY 2010 and, if so, the number of surveys that the SA expects to complete for each quarter from October 1, 2009 to September 30, 2010. The plan should also accommodate revisits that may be required.

SECTION V: BARRIERS AND PROSPECTIVE SOLUTIONS

Please describe any barriers that State expects to face in implementing the new survey process and the methods by which the State expects to address those barriers.

SECTION VI – BUDGET ANALYSIS

The plan must include a budgetary proposal that will show how the SA will use Recovery Act funds for each quarter, from July 1, 2009 to September 30, 2010. The SA should assume that the new survey process generally requires a three-person survey team (two health and one LSC) and takes, on average, a total of 46 hours to complete the health component (more if the State average survey time is higher than 46 hours). See Section B of this Planning Guide ("Objectives and Use of Funds") that describes methods of estimating costs, as well as Attachment 1 of the S&C memo. Include in your application a copy of the budget estimation worksheet on page 9, with at least rows 1-7 completed.

SECTION VII – SIGNATURES

The undersigned have reviewed, approved and commit to support the State survey agency in full implementation of the new survey process for Ambulatory Surgical Centers.

Most senior appointed official of the agency in which the State survey agency is located:

Name

Title

Date

State survey agency director:

Name

Title

Date