



CMS Burden Reduction II

Updates to AAAASF Standards as it Relates to CMS Regulation Changes for ASC's – December, 2019



- December 2019 CMS announced an approved set of changes referred to as “Burden Reduction III” affecting the following programs:

- **ASC**
- **RHC**
- **RA/OPT**

- The following presentation is a breakdown of the changes related to the CMS Burden Reduction in the ASC program including revised crosswalks with standards revisions.



ASC Changes

ASC: 400.021.025

- CMS now only requires:
 - "The ASC must periodically provide the local hospital with written notice of its operations and patient population served."
- AAAASF will utilize CMS's new language, but add to it an annual requirement.

AAAASF's ASC standard 400.021.025 now requires:

The ASC must provide the local hospital with written notice of its operations and patient population served at least annually."

ASC: 400.021.025 Survey Activities:

- While onsite, the surveyor must:
 - Review documentation/evidence that the ASC has provided the local hospital with the required written notice of its operations and patient population served at least annually.

ASC:
600.010.030

- CMS removed the 30-day time frame for pre-op H&Ps and modified regulations to require facilities to create a specific policy related to H&Ps.
- AAAASF believes that the 30-day time frame for patients determined to require an H&P is imperative to patient safety.
- AAAASF will utilize CMS's new language but modify it to maintain the 30-day time frame.
- Additionally, we will retain our standard requiring pre-op medical clearance.

ASC: 600.010.030

AAAASF's ASC standard 600.010.030 will now read:

The ASC must develop and maintain a policy that identifies those patients who require a comprehensive medical history and physical examination prior to surgery. The policy must:

- Include the 30-day timeframe for medical history and physical examination to be completed prior to surgery.
- Address, at minimum, the following factors: patient age, diagnosis, the type and number of procedures scheduled to be performed on the same surgery date, known comorbidities, and the planned anesthesia level.
- Be based on any applicable nationally recognized standards of practice and guidelines, and any applicable State and local health and safety laws.

ASC: 600.010.030 Survey Activities

- Onsite surveyors must request a copy of the ASC's H&P policy for review.
 - Review policy for compliance. All required elements must be present for the policy to be compliant. This includes:
 - Patient age, diagnosis, the type and number of procedures scheduled to be performed on the same surgery date, known comorbidities, and the planned anesthesia level.
 - For patients determined to require a comprehensive H&P, the policy must require that the complete/comprehensive H&P be completed and placed in the clinical record within 30 days prior to the day of surgery.
 - Ensure that the ASC has identified which nationally recognized standards have been used to develop this policy.
 - Ensure incorporation of any applicable State and local health and safety laws into the policy.
 - Ask the ASC to provide evidence that this policy has been fully implemented.
 - Assess for policy approval.
 - Assess for staff education on policy.
 - Assess medical records for evidence that H&Ps have been appropriately completed and documented in the medical record, per policy requirements.
 - Assess staff knowledge, as appropriate, via staff interview

ASC: 300.005.006

AAAASF's ASC standard 300.005.006 now requires:

Upon admission, each patient must have a pre-surgical assessment completed by a physician who will be performing the surgery or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

This assessment includes, at a minimum, the patient's medical history and physical examination (if any) and documentation of any allergies to drugs and biologicals. This assessment must be placed in the patient's medical record prior to the surgical procedure.

ASC: 300.005.006 Survey Activities

- Onsite surveyors must request a copy of the ASC's H&P policy for review.
 - Review policy for compliance. All required elements must be present for the policy to be compliant.
 - Reviewing for evidence that this policy has been fully implemented:
 - Assess medical records for evidence that pre-surgical assessments have been appropriately completed and documented in the medical record, prior to the surgical procedure and per policy requirements.

ASC: 1600.010

- CMS has modified multiple EPP requirements.
- AAAASF has modified our standards to align with the new CMS specified requirements and time frames (most of the annual requirements are now biennial requirements).

ASC:

1600.010.002

1600.010.007

AAAASF's standard 1600.010.002 now requires:

Emergency plan. The Provider/Supplier must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every two (2) years.

AAAASF's standard 1600.010.007 now requires:

The plan must include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

ASC:
1600.010.002
1600.010.007
Survey
Activities

- Onsite surveyors must request a copy of the ASC's Emergency Preparedness Plan:
 - Review Emergency Preparedness Plan for documentation/evidence that it has been reviewed and updated at least every 2 years.
 - Review plan for inclusion of a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

ASC: 1600.010.009

AAAASF's standard 1600.010.009 now requires:

Policies and procedures. The Provider/Supplier must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in standard **1600.010.002** of this section, risk assessment in standard **1600.010.003** of this section, and the communication plan in standard **1600.010.023** of this section. The policies and procedures must be reviewed and updated at least every two (2) years.

ASC: 1600.010.009 Survey Activities

- Onsite surveyors must request a copy of the ASC's Emergency Preparedness Policies and Procedures:
 - Review for evidence that policies and procedures include all required elements as outlined in **1600.010.002**, **1600.010.3**, and **1600.010.023**.
 - Review for documentation/evidence that policies and procedures have been fully implemented:
 - Assess for policy & procedure approval.
 - Assess for staff education on policies & procedures.
 - Assess staff knowledge, as appropriate, via staff interview.
 - Review policies and procedures for evidence that they have been reviewed and updated at least every 2 years.

ASC: 1600.010.023

AAAASF's standard 1600.010.023 now requires:

Communication plan. The Provider/Supplier must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every two (2) years.

ASC: 1600.010.023 Survey Activities

- Onsite surveyors must request a copy of the ASC's Emergency Preparedness Communication Plan:
 - Review for evidence that the Communication Plan complies with applicable Federal, State, and local laws.
 - Review policies and procedures for evidence that they have been reviewed and updated at least every 2 years.

ASC:
1600.010.031
1600.010.033
1600.010.034

AAAASF's Standard 1600.010.031

Training and testing. The Provider/Supplier must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in standard **1600.010.002** of this section, risk assessment in standard **1600.010.003** of this section, policies and procedures in standard **1600.010.009** of this section, and the communication plan in standard **1600.010.023** of this section. The training and testing program must be reviewed and updated at least every two (2) years.

AAAASF's Standard 1600.010.033

The training program must provide emergency preparedness training at least every two (2) years.

AAAASF's Standard 1600.010.034

If the emergency preparedness policies and procedures are significantly updated, the ASC must conduct training on the updated policies and procedures.

ASC:

1600.010.031

1600.010.033

1600.010.034

Survey
Activities

- Onsite surveyors must request a copy of the ASC's Emergency Preparedness Training Plan.
 - Review for evidence that the Training Plan has been reviewed and updated at least every 2 years.
 - Review documentation/evidence that staff training on the Emergency Preparedness Plan has taken place at least every 2 years.
 - Review Emergency Preparedness policies and procedures for interim updates. If significant updates in policies and procedures have taken place, request that the ASC provide documentation/evidence that staff training on these significant revisions to the plan have occurred.
 - Review policies and procedures for evidence that they have been reviewed and updated

ASC:
1600.010.037
1600.010.038

AAAASF's standard 1600.010.037 now requires:

Testing. The Provider/Supplier must conduct exercises to test the emergency plan at least annually.

AAAASF's standard 1600.010.038 now requires:

The Provider/Supplier must participate in a full-scale exercise that is community-based every two (2) years; **or**

When a community based exercise is not accessible, conduct a facility-based functional exercise every two (2) years; **or**

If the Provider/Supplier experiences an actual natural or man-made emergency that requires activation of the emergency plan, the Provider/Supplier is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the emergency event.

ASC: 1600.010.039

AAAASF's standard 1600.010.039 now requires:

The Provider/Supplier must conduct an additional exercise at least every two (2) years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section **1600.010.038** is conducted, that may include, but is not limited to the following:

- A) A second full-scale exercise that is community-based, or an individual, facility-based functional exercise; **or**
- B) A mock disaster drill; **or**
- C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

ASC:

1600.010.037
1600.010.038
1600.010.039

Survey Activities

- Onsite surveyors must review documentation/evidence that the ASC has tested the emergency plan at least annually:
 - Participation in a full-scale community-based exercise, at least every 2 years; or a facility-based functional exercise has been conducted every 2 years.
 - If the facility has experienced an actual emergency requiring the activation of its EPP, the facility is exempt from participating in the required community-based or facility-based functional exercise following that emergency event. Documentation of this activation must be available for review, in order to be deemed compliant.
- Review documentation/evidence that the ASC has completed one of the following exercises at least every 2 years, opposite the year that the full-scale or functional exercise was conducted:
 - A second full-scale exercise that is community-based, **or**
 - An individual, facility-based functional exercise; **or**
 - A mock disaster drill; **or**
 - A tabletop exercise or workshop, meeting all requirements identified in **1600.010.039**



AAAASF's ASC Crosswalk for CMS Burden Reduction III December, 2019

AAAASF's Updated ASC Crosswalk for CMS Burden Reduction III

| <u>CFR</u> | <u>CMS Regulation</u> | <u>AAAASF Standard</u> | <u>Revised AAAASF Standard Language</u> |
|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 416.41(b)(3) | The ASC must periodically provide the local hospital with written notice of its operations and patient population served. | 400.021.025 | The ASC must provide the local hospital with written notice of its operations and patient population served at least annually. |
| 416.47(b)(2) | Significant medical history and results of physical examination (as applicable). | 600.010.035 | Significant medical history and a physical examination covering the organs and systems commensurate with the procedure(s) are recorded on all patients and placed in the clinical record prior to the surgical procedure. |
| 416.52(a)(1) | The ASC must develop and maintain a policy that identifies those patients who require a medical history and physical examination prior to surgery. The policy must-- | 600.010.030 | <p>The ASC must develop and maintain a policy that identifies those patients who require a comprehensive medical history and physical examination prior to surgery.</p> <p>The policy must:</p> <ul style="list-style-type: none"> -Include the 30-day time frame for medical history and physical examination to be completed prior to surgery. -Address, at minimum, the following factors: patient age, diagnosis, the type and number of procedures scheduled to be performed on the same surgery date, known comorbidities, and the planned anesthesia level. -Be based on any applicable nationally recognized standards of practice and guidelines, and any applicable State and local health and safety laws. |
| 416.52(a)(1)(i) | Include the timeframe for medical history and physical examination to be completed prior to surgery. | | |
| 416.52(a)(1)(ii) | Address, but is not limited to, the following factors: patient age, diagnosis, the type and number of procedures scheduled to be performed on the same surgery date, known comorbidities, and the planned anesthesia level. | | |
| 416.52(a)(1)(iii) | Be based on any applicable nationally recognized standards of practice and guidelines, and any applicable State and local health and safety laws. | | |
| 416.52(a)(2) | Upon admission, each patient must have a pre-surgical assessment completed by a physician who will be performing | 300.005.006 | <p>Upon admission, each patient must have a pre-surgical assessment completed by a physician who will be performing the surgery or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy.</p> <p>This assessment includes, at a minimum, the patient's medical history and physical examination (if any) and documentation of any allergies to drugs and biologicals. This assessment must be placed in the patient's medical record prior to the surgical procedure.</p> |
| 416.52(a)(3) | The pre-surgical assessment must include documentation of any allergies to drugs and biologicals. | | |
| 416.52(a)(4) | The patient's medical history and physical examination (if any) must be placed in the patient's medical record prior to the surgical procedure. | | |

AAAASF's Updated ASC Crosswalk for CMS Burden Reduction III

| <u>CFR</u> | <u>CMS Regulation</u> | <u>AAAASF Standard</u> | <u>Revised AAAASF Standard Language</u> |
|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 416.54(a) | Emergency plan. The ASC must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following: | 1600.010.002 | Emergency plan. The Provider/Supplier must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every two (2) years. |
| 416.54(a)(1) | Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach. | 1600.010.003 | The plan must be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach. |
| 416.54(a)(4) | Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation. | 1600.010.007 | The plan must include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation. |
| 416.54(b) | Policies and procedures. The ASC must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following: | 1600.010.009 | Policies and procedures. The Provider/Supplier must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in standard 1600.010.002 of this section, risk assessment in standard 1600.010.003 of this section, and the communication plan in standard 1600.010.023 of this section. The policies and procedures must be reviewed and updated at least every two (2) years. |
| 416.54(c) | Communication plan. The ASC must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following: | 1600.010.023 | Communication plan. The Provider/Supplier must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every two (2) years. |

AAAASF's Updated ASC Crosswalk for CMS Burden Reduction III

| <u>CFR</u> | <u>CMS Regulation</u> | <u>AAAASF Standard</u> | <u>Revised AAAASF Standard Language</u> |
|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 416.54(d) | Training and testing. The ASC must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years. | 1600.010.031 | Training and testing. The Provider/Supplier must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in standard 1600.010.002 of this section, risk assessment in standard 1600.010.003 of this section, policies and procedures in standard 1600.010.009 of this section, and the communication plan in standard 1600.010.023 of this section. The training and testing program must be reviewed and updated at least every two (2) years. |
| 416.54(d)(1)(ii) | Provide emergency preparedness training at least every 2 years. | 1600.010.033 | The training program must provide emergency preparedness training at least every two (2) years. |
| 416.54(d)(1)(v) | If the emergency preparedness policies and procedures are significantly updated, the ASC must conduct training on the updated policies and procedures. | 1600.010.034 | If the emergency preparedness policies and procedures are significantly updated, the ASC must conduct training on the updated policies and procedures. |
| 416.54(d)(2) | Testing. The ASC must conduct exercises to test the emergency plan at least annually. The ASC must do the following: | 1600.010.037 | Testing. The Provider/Supplier must conduct exercises to test the emergency plan at least annually. |
| 416.54(d)(2)(i) | Participate in a full-scale exercise that is community-based every 2 years; or | 1600.010.038 | The Provider/Supplier must participate in a full-scale exercise that is community-based every two (2) years; or When a community based exercise is not accessible, conduct a facility-based functional exercise every two (2) years; or If the Provider/Supplier experiences an actual natural or man-made emergency that requires activation of the emergency plan, the Provider/Supplier is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the emergency event. |
| 416.54(d)(2)(i)(A) | When a community-based exercise is not accessible, conduct a facility-based functional exercise every 2 years; or | | |
| 416.54(d)(2)(i)(B) | If the ASC experiences an actual natural or man-made emergency that requires activation of the emergency plan, the ASC is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the emergency event. | | |

AAAASF's Updated ASC Crosswalk for CMS Burden Reduction III

| <u>CFR</u> | <u>CMS Regulation</u> | <u>AAAASF Standard</u> | <u>Revised AAAASF Standard Language</u> |
|---------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 416.54(d)(2)(ii) | Conduct an additional exercise at least every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following: | 1600.010.039 | <p>The Provider/Supplier must conduct an additional exercise at least every two (2) years, opposite the year the full-scale or functional exercise (standard 1600.010.038) is conducted, that may include, but is not limited to the following:</p> <p>A) A second full-scale exercise that is community-based, or an individual, facility-based functional exercise; or</p> <p>B) A mock disaster drill; or</p> <p>C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.</p> |
| 416.54(d)(2)(ii)(A) | A second full-scale exercise that is community-based, or an individual, facility-based functional exercise; or | | |
| 416.54(d)(2)(ii)(B) | A mock disaster drill; or | | |
| 416.54(d)(2)(ii)(C) | A tabletop exercise or workshop that is led by a facilitator and includes a group discussion using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan. | | |
| 416.54(d)(2)(iii) | Analyze the ASC's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the ASC's emergency plan, as needed. | 1600.010.040 | The Provider/Supplier must analyze the Provider/Supplier's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the Provider/Supplier's emergency plan, as needed. |