



Hospital Attestations for New Services and New or Replacement Equipment

Updated March 22, 2024

In June 2020, the Division of Acute and Ambulatory Care (DAAC) established protocols for hospitals to submit attestations for new services and new or replacement equipment related to these services in accordance with Chapter 51 of the Health Care Facility Regulations. Since then, DAAC has assessed its interpretation of Chapter 51's notification provisions relating to equipment and is providing this updated guidance as a result of that assessment.

Through this updated guidance, DAAC is narrowing the scope of new and replacement equipment that require notification and an attestation; clarifying the use of attestations when acquiring multiple pieces of equipment; and providing guidance on acquiring or replacing equipment in emergency situations.

Equipment Requiring Notice and Attestation

Effective immediately, notification and an attestation for equipment are only required for medical equipment that is used directly in the provision of a health care service to a patient. For purposes of this guidance, medical equipment is defined consistently with [guidance from the World Health Organization](#) and means medical devices requiring calibration, maintenance, repair, user training, and decommissioning. It is limited to equipment used for the specific purpose of diagnosis and treatment of disease or rehabilitation following disease or injury and does not include implantable, disposable, or single-use medical devices.

Hospitals should consider the proposed use of the medical equipment and the manufacturer's instructions to determine whether equipment they are acquiring or replacing may amount to medical equipment requiring notice and an attestation.

Replacement Equipment

Notification and an attestation are still required for replacement medical equipment if the replacement is a new make or model. If the replacement medical equipment is the same make and model as the medical equipment previously attested to, additional attestations are not required.

If an on-site survey is required to assess compliance of renovations or construction and new or replacement medical equipment will be used within that space, the notification and attestations must be provided at the time of or before the request for occupancy has been made. This will reduce the time needed to complete the on-site portion of the survey and prevent delays in the use of the new or replacement medical equipment.

Emergency Situations

If a hospital is experiencing an emergency situation that requires new or replacement medical equipment to be obtained to respond, the hospital should immediately contact its Field Office (FO) to explain the emergency situation and describe the actions the hospital anticipates needing to take to effectively respond to the emergency, including the medical equipment it may need to

acquire or replace. On the call, the FO will give verbal confirmation that the hospital can proceed with acquiring or replacing medical equipment as necessary to respond to the emergency. The FO will follow up the call with written confirmation. As soon as practical after the verbal notification to the FO, the hospital must submit notification and an attestation for the new and replacement medical equipment.

For purposes of this guidance, an emergency situation is any unanticipated or unplanned event that requires an immediate acquisition or replacement of medical equipment so as not to delay or impact the quality of patient care. Examples of emergency situations include:

- A piece of medical equipment fails during a procedure, and a replacement is being brought from another facility.
- A hospital facility experiences physical damage to medical equipment within the building (fire damage, water damage, etc.).
- A manufacturer recalls medical equipment.

Use of Attestation Forms

DAAC's attestation forms for new or replacement medical equipment must still be used. The DAAC HFQE Surveyors will still review the attestation, provide the hospital with approval, and create a 2567 for the new or replacement medical equipment.

The Equipment Attestation form can be submitted for one piece of medical equipment. The Multiple Equipment Attestation form should be used if a hospital intends to attest to more than one and up to one hundred (100) pieces of **unique** new or replacement medical equipment. If a hospital has acquired more than 100 pieces of unique medical equipment for use in the hospital, an additional Multiple Equipment Attestation form must be submitted.

On the Multiple Equipment Attestation form, the columns on the Equipment Grid correspond to each numbered question. The red boxes indicate items that must be filled out for each unique piece of medical equipment. It will be important to have the questions handy as you complete the grid. Regardless of whether you purchased 1 or 100 pieces of identical medical equipment (same make, model, manufacturer), you will only need to enter the medical equipment once for Q01; then, you will enter the number of pieces in Q01A. A large comment box has been provided for you to enter any important details for DAAC to know about the attestation or equipment.

The attestation forms are posted on the Department's Hospital webpage:

<https://www.health.pa.gov/topics/facilities/hospitals/Pages/Hospitals.aspx>

Other Information

Submission of notice and an attestation to DAAC will satisfy a health care facility's notice and approval requirements for a new health care service under 28 Pa. Code § 51.3. The notice must contemplate at least 60 days' notice before the hospital intends to use the equipment, but the hospital may begin using the new or replacement medical equipment as soon as the 2567 is released.

An attestation can only be used for the DAAC portion of an occupancy survey. If a project involves any renovations, new construction, or use of space that DAAC has not previously

surveyed, the hospital will still need an onsite survey for the Facility Guidelines Institute (FGI) portion of the project.

If a hospital is found out of compliance relating to an attestation, a citation may be written under 28 Pa. Code § 103.33 and any other regulations associated with the hospital's non-compliance. Depending on the severity of the non-compliance, DAAC may impose sanctions, such as suspension of attestation privileges, provisional license, and/or a civil penalty.

Should your hospital have any questions regarding the attestation process, please contact the DAAC Division Director. The Division Director's email address is ggladfelte@pa.gov or by phone at 717-783-8980.