The Issue

In the 2009 outpatient prospective payment system (PPS) final rule, the Centers for Medicare & Medicaid Services (CMS) mandated a new policy for “direct supervision” of outpatient therapeutic services that hospitals and physicians recognized as a burdensome and unnecessary policy change. CMS’s policy required that a supervising physician be physically present in the department at all times when Medicare beneficiaries receive outpatient therapeutic services.

Further, CMS characterized the change as a “restatement and clarification” of existing policy in place since 2001. As a result, hospitals and critical access hospitals (CAHs) found themselves at increased risk for unwarranted enforcement actions, particularly brought by opportunistic whistleblowers claiming that a hospital did not have appropriate direct physician supervision arrangements in place in some or all of its affected departments dating back to 2001.

Through multiple letters, meetings and other advocacy in the intervening years, the AHA and other national hospital and physician organizations have urged CMS to rescind or significantly modify the policy and to mitigate the new and inappropriate enforcement risks that its “clarification” created. At the urging of the AHA and others, CMS has since adopted several positive changes. Specifically, the agency:

- Delayed enforcement of the direct supervision policy through 2014 for CAHs and small and rural hospitals with fewer than 100 beds. Please note that since Jan. 1, 2017, CMS has permitted its contractors to enforce the direct supervision policy in all hospitals and CAHs.
- Allowed certain types of non-physician practitioners (NPPs) to provide direct supervision for hospital outpatient services, according to their state license and scope of practice and hospital - or CAH-granted privileges. This includes physician assistants, nurse practitioners, clinical nurse specialists, certified nurse-midwives and licensed clinical social workers;
- Modified the definition of direct supervision to remove all references to the physical boundaries within which the supervising professional must be located as long as he or she is “immediately available to furnish assistance and direction throughout the performance of the procedure;”
- Adopted a two-tiered policy for the supervision of certain “nonsurgical extended duration therapeutic services” such as observation services and various infusions and injections. This policy requires direct supervision only for the initiation of the service, followed by general supervision once the patient is medically stable; and
- Established an independent review process that allows the Advisory Panel on Hospital Outpatient Payment (HOP Panel) to recommend, and CMS to adopt, alternate supervision levels including general supervision, for individual hospital outpatient therapeutic services. CMS added four new members to the HOP Panel to represent CAHs and small and rural prospective payment system (PPS) hospitals. Based on recommendations made by hospitals that presented at previous HOP Panel meetings, CMS reduced the level of supervision for 50 outpatient therapeutic services from “direct” to “general” supervision.

AHA POSITION

The AHA is deeply disappointed that, despite our urging, CMS has moved forward with enforcement of its direct supervision policy in all hospitals and CAHs as of Jan. 1, 2017. Given the shortage of medical professionals, this policy may force small and rural hospitals and CAHs to limit their hours of operation or cut services to comply with the provision, resulting in reduced access to outpatient care in communities across America.

The AHA continues to urge Congress to provide relief from this short-sighted policy by enacting bipartisan legislation (S. 243/H.R. 741) that would permanently extend the enforcement moratorium on CMS’ direct supervision requirements on CAHs and small rural hospitals.
Why?

• In an environment of continuing shortages of health care professionals, particularly in rural areas, the direct supervision requirement will be difficult to implement for hospitals and CAHs, will reduce access and is clinically unnecessary. It will require hospitals to engage more physicians and NPPs for direct supervisory coverage without a clear clinical need and create patient access problems if hospitals are forced to discontinue or limit the hours of certain outpatient services.

• CMS’s view that this policy has applied to outpatient therapeutic services furnished since 2001 opens up the entire hospital community to misplaced enforcement scrutiny, including potential recoupments and whistleblowers who can claim that a hospital did not have appropriate direct physician supervision arrangements in place in some or all of its affected departments dating back to 2001.

• Direct supervision is not a requirement of the Medicare hospital CoPs and, in fact, the rules contradict the CoPs for CAHs. One CAH CoP requires a physician or NPP to be available by phone, but not necessarily physically present on the CAH campus. In order to ensure access to hospital emergency care in these otherwise underserved areas, another CAH CoP has long required only that a physician or NPP be able to arrive within 30 minutes of a request from the staff in the facility. Therefore, CAHs may meet the CoPs yet be non-compliant with direct supervision regulations.

Key Facts

Hospital outpatient therapeutic services have always been provided by licensed, skilled professionals under the overall direction of a physician and with the assurance of rapid assistance from a team of caregivers, including a physician, should an unforeseen event occur. While hospitals recognize the need for direct supervision for certain outpatient services that pose high risk or are very complex, CMS’s policy generally applies to even the lowest risk services.

The HOP Panel. The HOP Panel is an independent review body that considers stakeholder testimony and advises CMS regarding whether it is appropriate to change the level of supervision for individual hospital outpatient therapeutic services – from direct to either general or personal supervision – so as to ensure an appropriate level of quality and safety for the delivery of patient care.

The current definitions for the three levels of supervision that are relevant to the HOP Panel are:

• **Direct supervision** means that the physician or NPP must be immediately available to furnish assistance and direction throughout the performance of the procedure. The physician or NPP is not required to be present in the room when the procedure is performed.

• **General supervision** means the procedure is furnished under the physician’s or NPP’s overall direction and control, but the physician’s or NPP’s presence is not required during the performance of the procedure.

• **Personal supervision** means a physician or NPP must be in the room during the procedure.

CMS and its contractors have been permitted to enforce the direct supervision policy in all hospitals and CAHs since Jan. 1, 2017. The AHA continues to urge Congress to provide relief from this policy, and hospitals with an interest in this issue are strongly encouraged to consider providing testimony before the HOP Panel at its future meetings.