



AMERICAN TELEMEDICINE ASSOCIATION

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April 25, 2011

Donald M. Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW.
Washington, DC 20201

Reference: File code CMS-1345-P

Dear Dr. Berwick:

The ACO shall define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies.

Patient Protection and Affordable Care Act, Public Law 111-148

...a patient who can have face-to-face video chats with her doctor

President Obama's State of the Union, January 25, 2011

An ACO will be innovative in the service of the three-part aim of better care for individuals, better health for populations, and lower growth in expenditures. It will draw upon the best, most advanced models of care, using modern technologies, including telehealth and electronic health records, and other tools to continually reinvent care in the modern age.

CMS Notice of Proposed Rulemaking, 76 FR 19533, (April 7, 2011)

ATA applauds this vision for Accountable Care Organizations (ACOs) as expressed both by Congress and CMS and supports the importance of incorporating modern technologies and telehealth. Unfortunately, despite Congressional intent and the enthusiasm of the Agency, the proposed ACO regulations will not enable this vision because the ACOs will still be subject to formidable statutory restrictions for telehealth services under Medicare Parts A and B as authorized under Social Security Act section 1834(m). Congress expressly gives the HHS Secretary the authority to waive this restriction under section 1899(f) but unfortunately this was not included in the proposed rulemaking.

ATA strongly urges the Secretary to waive this restriction. Otherwise, the ACOs will fail to fulfill Congressional and Agency intent.

Summary

Telehealth should be an integral part of how ACOs provide healthcare. The benefits of telehealth for Medicare beneficiaries and the Medicare program include:

- Reduction of in-person overuse, such as in emergency rooms and preventable inpatient admissions
- Triaging for faster, appropriate specialist care
- Improvement patient outcomes and quality
- Increase provider productivity
- Relief for provider shortages
- Reduction in disparities to patient access
- Decrease unnecessary variations in care
- Sustain federal investment in EHR/HIE, broadband, and telehealth infrastructure
- Beneficiary preference, such as convenience and satisfaction

To achieve these benefits, there are five parts of Medicare section 1834(m) that need to be waived as they contain major, arbitrary barriers to Accountable Care Organizations:

1. Section 1834(m)(4)(C)(i)(II) needs to be waived to permit health service by video conferencing for the 35 million Medicare beneficiaries who happen to live in one of the 1092 metropolitan counties.
2. The last sentence of section 1834(m)(1) needs to be waived to permit store-and-forward services (such as transmission of medical images) for the 43 million beneficiaries who live outside of Alaska and Hawaii.
3. Section 1834(m)(4)(F)(i) needs to be waived to permit the best judgment of physicians and other practitioners about the medical needs and other circumstances of all Medicare beneficiaries.
4. Section 1834(m)(4)(C)(ii) needs to be waived to permit telehealth services originating from a beneficiary's home, a hospice and anywhere else from which a beneficiary seeks service (without regard to an originating site fee).
5. Section 1834(m)(4)(E) needs to be waived to permit any beneficiary to get the otherwise covered Medicare services of physical therapy, occupational therapy, speech-language pathology, audiology and some other practitioners.

Given the ACOs financial limits and incentives, there is no reason for Medicare's usual utilization controls on telehealth.

Despite the laudatory statements, in the legislation and proposed rulemaking, the failure to waive these 5 specific Medicare requirements will effectively prohibit the ACOs from coordinating care *“such as through the use of telehealth, remote patient monitoring, and other such enabling technologies.”*

Recommendations

1. To permit health service by video conferencing for the 35 million Medicare beneficiaries who happen to live in one of the 1092 metropolitan counties, section 1834(m)(4)(C)(i)(II) needs to be waived.

Since many ACOs will initially be based at large urban health systems, a waiver of the prohibition on telehealth for beneficiaries in metropolitan areas is critical.

Every state has at least one Standard Metropolitan Statistical Area (SMSA). In the U.S., there are 363 SMSAs -- from Carson City, Nevada SMSA with about 55,000 and up. Arizona, California, Connecticut, Florida, Maryland, Massachusetts, New Jersey, New York and Rhode Island each have 90% or more of their Medicare beneficiaries living in a metropolitan area.

Many metropolitan beneficiaries face major barriers to getting needed health services, such as living in a health shortage area and transportation challenges. Particularly noteworthy are the almost 6 million disabled Medicare beneficiaries.

Stroke care is a good example of an urban health shortage alleviated by telemedicine. Stroke is the leading cause of serious long-term disability. It is critical to get an ischemic stroke diagnosis within 3-4 hours to start clot-busting treatment. In 2002, 77% of U.S. counties did not have a hospital with neurological services. With problems of in-person access to scarce stroke specialists, only 3-5% of eligible stroke patients receive clot-busting treatment. In 2004, more than 940,000 Medicare beneficiaries were treated for stroke. Medicare spent a total of \$12.3 billion treating them, accounting for about 4% of total Medicare expenditures.

High-quality resolution video conferencing is fast becoming common from smart phones and other small, relatively inexpensive consumer devices. ACOs should be able to use these, as appropriate, as well as other fast-evolving technologies for more efficient health care delivery.

2. To permit store-and-forward services (such as transmission of medical images) for the 43 million beneficiaries who live outside of Alaska and Hawaii, the last sentence of section 1834(m)(1) needs to be waived.

A major way of delivering health care by telecommunications technologies involves storing patient information, such as medical images, at one medical site and forwarding it to another medical site for consultation with a specialist or other medical purpose. Medicare law restricts “store and forward” services to “any Federal telemedicine demonstration program conducted in Alaska or Hawaii.”

Medicare already covers many similar services, not as “telehealth,” but as “physician services.” CMS’s policy on “physician services” includes the following: “A service may be considered to be a physician’s service where the physician either examines the patient in person or is able to visualize some aspect of the patient’s condition without the interposition of a third person’s judgment. Direct visualization would be possible by means of x-rays, electrocardiogram and electroencephalogram tapes, tissue samples, etc.” (CMS Medicare Benefit Policy Manual

Chapter 15 – Covered Medical and Other Health Services,” “30 - Physician Services, (Rev. 1, 10-01-03), B3-2020, B3-4142.).

Physicians have been using remote digital imaging for both of these services for many years and their use has been fully integrated into federal programs serving veterans, the military, Native Americans and even federal prisoners. All have had multiple scientifically-validated studies showing clinical efficacy and cost-effectiveness. All have approved and validated practice guidelines.

Important store-and-forward uses for Medicare beneficiaries include telecardiology, diabetic retinopathy, wound management and other teledermatological services.

Under Medicaid, 10 states already have some form of coverage and reimbursement for store-and-forward services.

3. To permit the best judgment of physicians and other practitioners about the medical needs and other circumstances of all Medicare beneficiaries, section 1834(m)(4)(F)(i) needs to be waived.

Medicare’s coverage for Part B services is only available for a restricted list of specific services as defined by CMS using CPT/HCPCS codes. This needs to be changed for several reasons.

The current restriction conflicts with a growing number of state laws. Over 106 million Americans (more than twice the number of Medicare beneficiaries) are in one of the 12 states that require all other health benefit plans to pay for covered services provided via telehealth – without further specification. About half of these states have had such a requirement in effect for over 10 years – without any complication, harm or overutilization. At least 6 more states are proposing such legislation this year. Patients served by ACOs should be allowed to benefit from the same telehealth coverage.

Current restrictions limit potential patient benefits. There are services that Medicare should cover when provided by telehealth. In recent years, ATA has made a case for, and CMS has rejected, coverage for the following codes:

- 96040, medical genetics and genetics counseling services
- 96118-96119, neuropsychological testing
- 97802-97804, medical nutrition therapy
- 99091, collection and interpretation of physiologic data and 99090, analysis of clinical data stored in computers
- 99231-99233, subsequent hospital care
- 99238-9923, hospital discharge services
- 99291-2, critical care and evaluation
- 99307-99310, subsequent nursing facility care per day
- 99315-99316, nursing facility discharge services
- 99318, other nursing facility services
- 99334-7, domiciliary or rest home evaluation and management

99406-7, smoking and tobacco use cessation counseling
99444, on-line internet assessment and management by physician and 98969 by non-physician
G0108-01909 diabetes outpatient self-management training services

The current restriction is contrary with the idea of an ACO. Under the operation of the current delivery system, CMS has reserved the right to make its own determination for each specific medical service that could be delivered by telemedicine. This highly structured approach is contrary to the philosophy and specific construction of the ACOs, where appropriate patient services and delivery approaches are delegated to the organization, which is then accountable for the patient's outcomes.

Timing should also be an important consideration to cover services. Telemedicine reduces delays in access to care and lessens the consequences for beneficiaries of delayed access; ranging from anxiety to death.

CMS should not preclude beneficiary choice. As evidenced by the decision-making in this annual CMS process, there seems to be an idealized and outdated mindset about the quality and convenience of in-person service as well as a view that technology can only diminish, not enhance, service. Patient satisfaction with the use of telemedicine has consistently been very high – especially after the initial experience.

The first section of Medicare law (§1801) states: “Nothing in this title shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided...” Unfortunately, the application of the standards for the addition of codes interferes with appropriate physician medical judgment and beneficiary circumstances in a way that conflicts with this rule.

4. To permit telehealth services originating from a beneficiary's home, a hospice and anywhere else from which a beneficiary seeks service (without regard to an originating site fee), section 1834(m)(4)(C)(ii) needs to be waived.

Medicare rules preclude some otherwise-covered sites from being used to originate a telehealth service, such as hospices, independent kidney dialysis facilities, and even federally funded Indian Health Service facilities.

The original purpose for designating telehealth originating sites in the Social Security Act section 1834(m) was to enable priority health facilities to receive compensation for related staff time and operating costs through a separate “facility fee.” Although not supported by statute, the specification of originating sites is now used to restrict beneficiary access to needed services that can be provided by video conferencing. We contend that a Medicare beneficiary should be covered for telehealth-provided services – even if their location is not specifically reimbursed.

A prime example is a Medicare home health patient who, by the eligibility definition, is *homebound*. This unfortunate inconsistency is compounded by the new requirements for recertification of the patient's need for home health under Patient Protection and Affordable Care

Act section 6407 that explicitly recognizes telehealth as a means to do so. Other PPACA provisions that are made unnecessarily burdensome are recertifications for hospice care (section 3132) and durable medical equipment (section 6407) and for annual comprehensive medication review or the targeted medication enrollment (section 10328).

Also, due to CMS programs that support personal care services, patients who normally would be in a skilled nursing facility are able to be located in less skilled environments. Examples include community based residential facilities and licensed assisted living centers. Persons residing in such facilities have the same transportation, disability, and medical needs as persons in skilled nursing facilities. For example, Medicare populations in these facilities have chronic conditions, need routine on-going primary and specialty care and are the victims of sudden changes in conditions that are experienced by persons in skilled nursing facilities. However, they are not eligible to serve as originating sites for telehealth under current rules.

5. To permit any beneficiary to get the otherwise covered Medicare services of physical therapy, occupational therapy, speech-language pathology, audiology and some other practitioners, section 1834(m)(4)(E) needs to be waived.

Medicare law bars some providers from delivering telehealth services -- even as they are otherwise permitted under Medicare. Notably, physical therapists, occupational therapists and speech-language pathologists, are barred from delivering telehealth services.

This change, along with #4, would allow for home-based telerehabilitation, an important service for beneficiaries from whom *going* to therapy is a major barrier. Beneficiaries, including people who have had a stroke, traumatic brain injury, or hip replacement, would immediately benefit from this change.

Conclusion

The ACO model is an important opportunity to make Medicare health care delivery more innovative and higher performing. Telehealth is a key set of tools that has been widely acknowledged as an integral part of helping ACOs make a difference. Congress stipulated in the ACO statute that “The ACO shall define processes to ... coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies.”

The HHS Secretary has the power to waive Medicare statutory provisions “as may be necessary to carry out” the accountable care organization provisions. While the Secretary proposes to exercise that authority to waive some Medicare provisions, such as physician self-referral and anti-kickback protections no similar waiver has been included for telehealth.

ATA requests and recommends that the Secretary waive the restriction-riddled Medicare telehealth statute as necessary so an ACO "patient can have face-to-face video chats with her doctor" -- regardless of where she is.