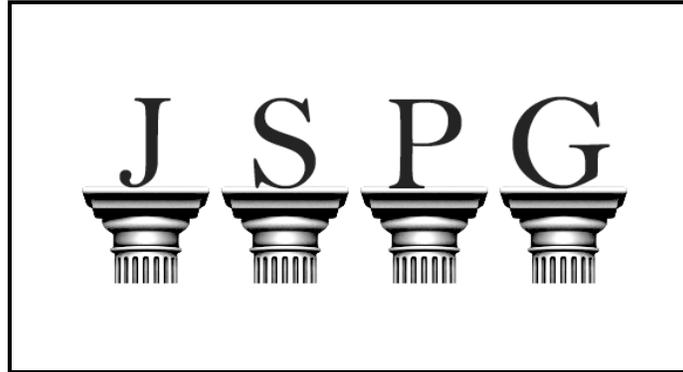


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POLICY ANALYSIS:

ADDRESSING THE CARDIAC PROVIDER SHORTAGE:

RECOMMENDATION FOR INCREASING ACCESS TO CARDIAC DEVICE

CARE

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Executive Summary

Each year in the United States, more than 285,000 new cardiac pacemakers and defibrillators are implanted in patients with heart rhythm problems or congestive heart failure. For each of these devices, regular outpatient monitoring is required to ensure that the hardware is functioning appropriately, as well as evaluate data that the device records about the patient's heart rates, heart rhythms, and activity levels. Cardiac device monitoring is highly technical, requiring subspecialized training for physicians, physician assistants, nonphysician providers (NPP) including nurse practitioners, and auxiliary health providers including registered nurses and technicians. At present, the Centers for Medicare and Medicaid Services (CMS), the U.S. federal agency that administers Medicare and Medicaid, categorizes cardiac device monitoring as a diagnostic service, which requires physician supervision. Although NPPs may directly perform and bill for diagnostic services within their scope of practice by specialty and state regulation, NPPs may not supervise diagnostic services performed by auxiliary providers. The United States is presently facing a shortage of cardiovascular physicians. At the same time, the older population is burgeoning, along with increasing prevalence of cardiovascular disease requiring implanted devices. This growing supply-demand mismatch impacts patient access to chronic cardiac device care, particularly with the limits placed on NPP supervisory services. In order to meet patient needs for cardiac device care, CMS should change its policy to allow qualified NPPs to supervise auxiliary providers for diagnostic services for cardiac devices. Additionally, cardiac and NPP advocacy organizations should form an advocacy coalition to promote policy change.

Chronic Care Services for Cardiac Implanted Electrical Devices

Case Vignette

It is 2018. Mr. Brown, a recently-retired computer programmer, has just had a minor surgical procedure to implant a pacemaker for his abnormally slow heart rate. As he recovers in his hospital room, the physician assistant arrives to review information about the pacemaker and schedule his follow-up office visit. The physician assistant explains that twice a year, he will come to the office to have his pacemaker checked to ensure that the battery and electrodes are functioning normally, as well as monitor his arrhythmias. During these visits, Mr. Brown's vital signs will be measured and medications are reviewed. He will sit in a chair, while a technician uses a specialized computer to communicate with his pacemaker. The technician will retrieve information about the pacemaker's battery power, along with information about any episodes of abnormal heart rhythms that Mr. Brown may have experienced since his last pacemaker test. During the testing, the technician will temporarily raise and lower the pacing rate, ensuring adequate function of the electrodes.

Mr. Brown tells the physician assistant that he remembers taking his mother to pacemaker checks a decade earlier. However, he notes, her checks were done every 3 months, not every 6 months. Mr. Brown asks if the technology has changed substantially since then. The physician replies that the core technology remains the same. However, a physician must be present in the office in order for the technician to perform the pacemaker check. Because of an increase in cardiology patients, and a national shortage of cardiologists, the physician must spend more time in the hospital and less time in the office. Therefore, the clinic has limited hours, and can only see patients at 6 month intervals for routine pacemaker checks.

Background

Every year in the United States, more than 100,000 new implantable cardioverter-defibrillators and more than 188,000 new pacemakers, collectively termed cardiac implantable electronic devices (CIED), are implanted in patients in order to prevent morbidity and mortality related to abnormally fast or slow heart rhythms and symptomatic heart failure (Birnie et al., 2006; Patel & Koplan, 2009). Each CIED requires chronic expert evaluation at three to 12 month intervals for the life of the patient (Medicare National Coverage Determinations Manual, 2008b). This translates to an estimated 3,307,500 device evaluations each year with specialist cardiac device providers (extrapolated from Wilkoff et al., 2008), including in-person diagnostic testing appointments in the outpatient clinic or hospital and remote monitoring using telemedicine technology.

Expert consensus identifies four main goals of CIED care: optimize patient safety and quality of life, document appropriate CIED function, document arrhythmia and other cardiac disease parameters, and communicate with patients and relevant health care providers (Wilkoff et al., 2008). Multiple modalities for chronic CIED follow-up care exist, including in-person monitoring to be performed by specialty-trained physicians or nonphysician providers at a recommended interval of three to 12 months (Wilkoff et al.). Expert consensus notes that while local practices may vary in the delivery of chronic CIED follow-up services, “it must be remembered that the physician in the CIED follow-up clinic whose name is used to sign off on any orders is ultimately responsible for all aspects of that encounter of the patient’s CIED management” (Wilkoff et al., p. 916).

Provider Definitions

CMS bases its provider categories on those defined by the Social Security Act (SSA; 1965, 1989). Although experts allude to specialty training for providers at all levels related to CIED follow-up care, there is no specific guidance or policy requirement for formal certification for CIED specialization for physicians or nonphysician professionals (Wilkoff et al., 2008).

Physician

Social Security defines a physician as a medical doctor or doctor of osteopathy “legally authorized to practice medicine and surgery by the State in which he performs such function or action” (SSA, 1965). This definition is the one referenced by CMS for billing and supervision rules. The expert consensus statement for follow-up care of CIEDs refers to the “CIED physician” as “the physician in the CIED follow-up clinic whose name is used to sign off on any orders [and] is ultimately responsible for all aspects of that encounter of the patient’s CIED management” (Wilkoff et al., 2008, p. 916). This consensus statement does not refer to any SSA or CMS definition of physician to clarify that label.

Nonphysician Providers (NPPs)

NPPs recognized by CMS who may be involved with CIED follow-up include nurse practitioners, physician assistants, and clinical nurse specialists. NPPs “have their own benefit categories and may provide services without direct physician supervision and bill directly for these services” (Medicare Benefit Policy Manual, 2009b). In addition to therapeutic, or “physician” services, diagnostic tests performed directly by a nurse practitioner or clinical nurse specialist are not subject to physician supervision (42 C.F.R. § 410.32(b)(2)(v)). All NPP

services, whether therapeutic or diagnostic, are subject to scope of practice as defined by individual State legislatures (42 C.F.R. § 410.32(b)(2)(v); 42 C.F.R. § 410.75(c)(1)).

Auxiliary Personnel

CMS defines auxiliary personnel as “any individual who is acting under the supervision of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner)” (42 C.F.R. § 410.26(a)(1)). Auxiliary personnel are, therefore, distinct from the “provider” or NPP category. Auxiliary personnel relevant to CIED diagnostic testing include registered nurses and technologists who are trained to perform CIED follow-up services.

Clinically employed allied professional (CEAP)

The expert consensus document regarding monitoring of CIEDs in North America and Europe does not incorporate nonphysician provider definitions in line with SSA or CMS (Wilkoff et al., 2008). Rather, this document identifies “clinically employed allied professionals” (CEAPs) as “the diverse group of nurses, physician assistants, technologists, technicians, and engineers who are dedicated to promoting excellence in the care of patients with CIEDs” (Wilkoff et al., p. 908). The document specifies that the CEAP “works in collaboration with and/or under the direct supervision of a CIED physician and is not employed by a CIED manufacturer” (Wilkoff et al., p. 908). Although this consensus statement does not hold direct regulatory weight, policy makers account for such professional organization positions when crafting regulations.

Policy Significance to Practice

Diagnostic Services

Diagnostic services are defined generally in CMS rules as “diagnostic x-ray, diagnostic laboratory, and other diagnostic tests” (Medicare Benefit Policy Manual, 2009c). Supervision levels are determined according to current procedural terminology code, published quarterly in the Medicare Physician Fee Schedule Relative Value File (CMS, 2010). Pacemaker interrogation services are defined as diagnostic services, according to diagnostic capacity of devices at the time of the rule incorporation in 1984. The pacemaker evaluation rules were last reevaluated in 2003 (Medicare National Coverage Determinations Manual, 2008b). Implantable cardioverter-defibrillator services were last reviewed in 2008, and are defined in the context of pacemaker services (Medicare National Coverage Determinations Manual, 2008a). These rule evaluations, however, pertained primarily to the frequency of follow-up without any consideration of reclassifying the type of service from diagnostic to therapeutic.

Since 1998, individual diagnostic services have been subject to various levels of physician supervision (Medicare Benefit Policy Manual, 2009c; Vukmer, 1998). In-person follow-up services for CIEDs requires direct physician supervision of auxiliary personnel (CMS, 2010) with the physician immediately available in the office suite, though not necessarily in the same room (Medicare Benefit Policy Manual, 2009c).

This physician-centered approach to chronic care reflects Centers for Medicare and Medicaid Services (CMS) rules that identify physicians as the only eligible supervisors of diagnostic tests performed by auxiliary personnel (42 CFR 410.32 (b)(3)). NPPs, including nurse practitioners

and physician assistants, are designated as independent providers of diagnostic services, and it was long understood by industry professionals that NPPs could directly supervise diagnostic services if they were in the same room as the service being performed (Calnan, 2009). However, CMS clarified that this understanding was erroneous (Medicare Benefit Policy Manual, 2009c). In fact, CMS regulations prohibit NPPs from supervising diagnostic tests in all cases, regardless of level of supervision (42 CFR 410.32 (b)(1)).

Workforce studies related to cardiovascular care predict that the prevalence of cardiovascular disease will continue to rise over the next two decades (Rodgers et al., 2009), including abnormal heart rhythms and heart failure conditions that require CIED implantation. Compounding this problem, the supply of cardiovascular physician specialists is not expected to rise similarly to meet emerging demands (Rodgers et al.). Some policy analysts have recommended expanding the use of NPPs to help meet care demands (Bonow & Smith, 2004; Hirshfeld & Fye, 2004; Kereiakes & Willerson, 2004; Rodgers et al., 2009). Experts also note that there is a similar dearth of specialty-trained NPPs in cardiology due in part to a national shortage of nursing faculty, limiting the number of new nurse practitioners to enter the workforce (Bonow & Smith; Hirshfeld & Fye; Rogers et al.). Therefore, even the health care system used all available NPPs with an optimized cardiovascular care team approach, there will still be an expected shortage of cardiovascular physicians on the order of 7,000 to 17,000 full-time equivalents by 2022 (Rodgers et al.).

This overall provider shortage, coupled with CMS policy that limits non-physician providers to only provide direct CIED follow-up services, but not supervise auxiliary providers, results in an

overall limitation of access to outpatient CIED care for patients. For example, in a single-specialty electrophysiology practice in a suburban setting, CMS policy results in a total 15 hours per 40 hour work week that auxiliary providers can perform outpatient CIED testing – the limited time during the week when a physician is in the office suite rather than in the hospital. If the policy allowed for NPP supervision of auxiliary personnel to perform CIED follow-up care, CIED follow-up services by auxiliary personnel would expand to nearly 40 hours in a typical week when either a physician or NPP was present in the outpatient office, more than doubling patient access to care for cardiovascular technology.

Moreover, allowing for NPP supervision of diagnostic services would allow for more robust CIED services to be delivered to patients in rural areas for whom transportation to a metropolitan center is a struggle. These rural clinical services are frequently curtailed due to limited physician time that must be focused on performing invasive diagnostic and therapeutic procedures in tertiary medical centers, rendering extensive rural travel infeasible. For example, the CIED patient care demands in one rural Ohio clinic have exceeded the capacity of the single nurse practitioner that travels from the urban medical center to provide local care. Presently, CMS rules have limited the practice's ability to provide auxiliary personnel assistance for CIED follow-up services, so patients in the rural community currently have an extensive wait for local CIED services (P. Kohanski, personal communication, April 19, 2010).

Therapeutic Services

It should be noted that therapeutic services by Medicare Part B are defined in CMS rules as “physician services,” including “diagnosis, therapy, surgery, consultations, and home, office, and

institutional calls” (42 C.F.R. § 410.2(a)). Outpatient therapeutic services are differentiated between hospital outpatient and nonhospital settings. Supervision of therapeutic services in nonhospital settings has traditionally included NPP supervision of auxiliary personnel since NPPs were defined as a provider category in 1989 (SSA). NPP supervision of auxiliary personnel was extended to hospital outpatient settings in 2009, partially in response to concern from professional associations (American Hospital Association, 2009; Sink, 2010). This policy change demonstrates the impact of coordinated professional society involvement to impact policy change based on demonstrated clinical concerns. However, supervision of diagnostic services was not included in this policy shift.

Remote Monitoring Services

Remote monitoring services are considered separately from in-person therapeutic and diagnostic services. There is no physician-specific supervision requirement for telemedicine services, as remote monitoring services are subject to telehealth rules and are not in-office diagnostic procedures (42 C.F.R. § 410.78(b)). The supervision concept does not apply to remote monitoring of CIEDs (Medicare Benefit Policy Manual, 2009c). Therefore, remote monitoring of CIEDs can be supervised by NPPs including nurse practitioners, clinical nurse specialists, and physician assistants (42 C.F.R. § 410.78(b)(2)(ii-iv)). Increased use of remote monitoring services could significantly bolster access to basic CIED monitoring technologies. However, remote monitoring does not allow for direct measurements or adjustments to be made to the device to accommodate changes in the patient or hardware performance. Moreover, remote monitoring services may be limited for patients who do not have a stable telecommunication “land line” available.

Stakeholders

Healthcare Providers

Nonphysician providers including nurse practitioners, physician assistants, and clinical nurse specialists are impacted by this policy as it relates to chronic CIED follow-up care. In the larger policy context considering diagnostic services in other specialty areas, other NPPs including nurse anesthetists, nurse-midwives, and clinical psychologists are potentially impacted by this policy.

Physicians are stakeholders in this policy issue from two perspectives. First, physician shortages in many primary care and specialty settings, including cardiovascular care, create unreasonable burdens for physician presence in hospital and office settings in order to supervise diagnostic services at levels according to CMS guidelines (Rodgers et al., 2009). Therefore, restrictions on NPP supervision may be considered an undesirable burden. Moreover, cardiology offices that employ NPPs may not be able to use them to their full potential due to regulatory limits on their ability to supervise auxiliary staff for routine CIED diagnostic services. This results in economic disadvantages for practices, as well as limiting access to CIED services for patients.

Conversely, physicians may be concerned about ceding physician-specific activities to NPPs because it may decrease their income and credentials. The American Medical Association (AMA) has raised this concern in several policy statements related to therapeutic and diagnostic services (AMA, 2000; AMA, 2006).

Auxiliary care personnel, including nurses and technologists, are also stakeholders in this policy, as limitations on supervision may limit the time during which they can perform diagnostic services in their workplace setting. Such limits may translate to limits on possible hours of employment, and may thus impact their earning potential.

Institutions

Hospitals are stakeholders in this policy issue, particularly as diagnostic services are considered in hospital outpatient settings. For hospital outpatient settings whether on an inpatient campus or in a remote location, physician staffing might pose significant limitations on the hospital's ability to provide diagnostic services (American Hospital Association, 2009; Association of American Medical Colleges, et al., 2009). Expanding NPP supervising authority for CIEDs may improve hospitals' ability to deliver CIED services to inpatient and outpatient populations.

Skilled nursing facilities, with limited physician presence, may also be stakeholders in this issue, as physician presence in the skilled nursing facility is typically limited. Therefore, access to CIED care supervised by NPPs may be improved for this fragile patient population with reduced capacity to travel to a physician office.

Payers

Payers in health care typically include the government (i.e. Medicare, Medicaid, TRICARE), private insurance companies, and individual patients. Cardiovascular care, including CIED services, is significantly delivered to individuals receiving Medicare. Transferring CIED services to NPP supervision could save Medicare and Medicaid money because NPPs are

reimbursed at 85% of the physician reimbursement rate. Although an expansion of CIED service availability in the short-term may increase charges for CIED follow-up evaluations, an increasing shift to NPP-supervised CIED evaluations may improve timely access to care and thus prevent costly expenditures for emergency department evaluations and hospital inpatient stays. Although the impact of 85% payment rates may not translate to all public and private payers, a potential decline in emergency care and inpatient charges would impact all payers throughout the healthcare system.

Patients

Patients are also stakeholders, as access to clinical CIED follow-up services may be limited due to physician time limitations for supervision. Patients may experience delays in CIED testing for symptom evaluation for new or chronic conditions, preventing timely recognition of acute problems that, untreated, may require emergency department or inpatient hospital care. Patients may also experience travel burdens due to possible geographic limitations for CIED follow-up services due to physician scheduling. In addition, limited physician schedules may force patients to undergo in-person CIED follow-up testing at times that might adversely impact patients' employment, and thus societal productivity.

Professional Organizations

Likely Supportive

Professional organizations representing cardiovascular specialists in particular, and provider groups in general are significant stakeholders in this policy issue. The American College of Cardiology has an active legislative advocacy presence at the federal level, and has been a leader

in identifying emerging workforce gaps in cardiovascular care (Foot, Lewis, Pearson, & Beller, 2000; Hirshfeld & Fye, 2004). The American College of Cardiology has roundly advocated expansion of NPP practice as an integral part of the cardiovascular care team (Hirshfeld & Fye; Rodgers et al., 2009). In 2003, therefore, the American College of Cardiology reorganized its membership to include a nonphysician provider category whose members serve on nearly every committee and working group throughout the organization. Based on its history of workforce scholarship and NPP advocacy, the American College of Cardiology would be a leader in promoting a change in policy to allow for NPP supervision of CIED services by auxiliary staff.

Heart Rhythm Society has similarly incorporated NPPs into its membership and leadership structure. Compared to the American College of Cardiology, however, Heart Rhythm Society has been less robust in publication and advocacy related to workforce challenges. While Heart Rhythm Society acknowledges the critical role of allied professionals, including NPPs, in patient care processes, expert consensus publications continue to communicate a structure with the physician ultimately responsible for all patient encounters (Wilkoff et al., 2008). Heart Rhythm Society is widely recognized as the professional leader related to CIED follow-up services. Therefore, any effort to achieve policy change in this arena would require strong support from this organization.

The American College of Nurse Practitioners advocates for “provider-neutral language” in federal legislation and regulation (American College of Nurse Practitioners [ACNP], 2009). The American College of Nurse Practitioners has identified a policy priority to ensure that nurse practitioners are included in policy development panels and other committees at the federal level

for legislative and regulatory policy efforts (ACNP). The American College of Nurse Practitioners would be a supportive advocate for policy change, though it may not be a direct leader in the effort related to specific CIED services as a relatively small proportion of the nurse practitioner community ultimately provides CIED services.

Similarly, the American Academy of Physician Assistants would be a supportive advocate in the policy change arena. Like nurse practitioners, physician assistants are designated as NPPs of diagnostic services. However, physician assistants are not independent NPPs of physician services, and require general physician supervision of all activities, including diagnostic services (42 C.F.R. § 410.32(b)(3)). Physician assistants necessarily practice in the context of a “physician-PA team” (American Academy of Physician Assistants, n.d.) and do not seek provider neutral language like nurse practitioners (ACNP, 2009). Therefore, the American Academy of Physician Assistants is less likely to be an advocacy leader for this issue.

Professional organizations representing relevant auxiliary personnel include the American Nurses Association (2008) and Society of Invasive Cardiovascular Professionals (2002). These constituencies are impacted by policies limiting NPP supervision of diagnostic services, as a potential expansion of NPP diagnostic supervision could increase potential full time equivalent roles for auxiliary personnel in institutions providing chronic CIED follow-up services that might not otherwise have full-time physician supervision capacities. These organizations would be additive voices to support expansion of NPP supervisory services. In particular, the American Nurses Association has a long history of supporting advanced practice nursing practice as well as

nursing practice (APRN Consensus Work Group & National Council of State Boards of Nursing APRN Advisory Committee, 2008).

The International Board of Heart Rhythm Examiners is the credentialing body for cardiovascular device specialists (International Board of Heart Rhythm Examiners, 2010). Although there currently exists no specific policy to guide qualification for performing or supervising CIED follow-up services, the designation of “qualified” is delineated in the existing policy. At present, this is the sole credentialing organization for nonphysician device specialists. Physician device specialists may be credentialed by the International Board of Heart Rhythm Examiners or seek board certification in electrophysiology by the American Board of Internal Medicine (n.d.).

Patient advocacy organizations such as the Sudden Cardiac Arrest Association (n.d.) and AARP (formerly the American Association of Retired Persons; AARP Foundation, 2009) comprise a significant proportion of patients with CIEDs. These organizations would be important patient stakeholder advocates in a policy change effort to improve access to CIED follow-up care by implementing a paradigm of NPP supervision.

Likely Opposed

The American Medical Association, in contrast, has a history of opposing non-physician supervision of health care services in all cases (AMA, 2000), including diagnostic services (AMA, 2006), citing concerns about quality. Based on this history of advocacy and policy positions, the AMA is likely to oppose any expansion of NPP activities as supervisors of

diagnostic services. As a leading advocate for physician services, the AMA consistently promotes direct physician oversight of all health care services.

Recommendations for Reform

The current literature around access to care for CIED follow-up services centers on advances in remote monitoring technology, and has been studied primarily in Europe, where increasing need for patient services and declining physician and auxiliary staff supply are similar to the United States (Mladovsky & Leone, 2010). Although remote monitoring is a valuable technology that poses distinct workload advantages for NPP and auxiliary providers, remote monitoring currently does not allow for device reprogramming to accommodate changes in patient health or CIED hardware function.

Two distinct approaches may be taken to achieve a policy shift to allow NPPs to supervise in-person CIED follow-up services performed by auxiliary personnel and therefore increase patient access to in-person CIED care. One approach is to expand NPP services to include diagnostic supervision; the other is to redefine in-person CIED follow-up services.

Expansion of NPP Services

Supervision requirements for CIED follow-up services may be amended to include NPPs as supervisors of these diagnostic services. This has already been done for outpatient therapeutic services in nonhospital and hospital settings as a result of changes to CMS policy supported by advocacy efforts from state and national patient and hospital associations. In addition, CMS has established a process for review of stakeholder requests for decreased physician supervisory

requirements for specific outpatient therapeutic services (CMS Office of Public Affairs, 2011). These policy changes have alleviated burdens of limited physician staffing for hospitals, particularly critical access hospitals in rural and underserved areas. Therefore, current CMS guidelines hold precedent for NPP supervising of auxiliary personnel (Medicare Benefit Policy Manual, 2009a; Patel & Rushefsky, 2006).

An exception for supervision of diagnostic services already exists for clinical psychologists (42 C.F.R. § 410.32(b)(2)(iii)(B)). Clinical psychologists function with clinical doctorate preparation and are defined as NPPs similar to nurse practitioners (42 C.F.R. § 410.32(a)(2)). To date, there have not been direct comparisons between the quality of care for CIED follow-up for physician and NPP providers, nor has any direct concern been raised about the comparative quality of care related to NPP supervision of CIED follow-up. However, other studies of primary and chronic care specialty services have demonstrated that NPP care is equal to physician care (Horrock, Anderson, & Salisbury, 2002; Wilson et al., 2005).

Qualification for NPP supervision may be proposed to include certification as a cardiac device specialist (CCDS, [IBHRE, 2010]) in addition to meeting relevant State and professional regulations. Similarly, assurance of qualification may extend to CCDS for auxiliary personnel. Cardiovascular professional and advocacy groups could advise CMS regarding appropriate certification criteria to qualify CCDS-certified NPPs to supervise CIED diagnostic services provided by auxiliary personnel who also hold CCDS certification. This certification confers a designation of competence in basic care and monitoring of a CIED. Certification is present required to perform CIED care in some institutions, but there is no national standard for

certification at present. This means that physicians without any background or certification in CIED care and management can presently supervise auxiliary personnel, whereas NPPs with CIED certification cannot. Qualifying nonphysician and auxiliary providers with CCDS certification would help to demonstrate basic levels of competence for performing CIED diagnostic services. It should be noted, however, that quality outcomes data do not exist to compare CIED diagnostic services provided by individuals who do or do not hold CCDS certification.

A policy shift specific to CIED diagnostic services would set a precedent for future expansion of NPP supervisory services for other diagnostic testing modalities by applying an incremental approach to achieving change (Patel & Rushefsky, 2006). Specifically, outcomes data from pilot programs of NPP-supervised CIED diagnostic services could be used to demonstrate clinical noninferiority and cost-effectiveness compared to physician-supervised services, expanding work in this area from the primary care paradigm (Horrocks et al., 2002). It would be valuable to convene transdisciplinary teams including physicians, NPPs, auxiliary providers, and patients to design pilot programs for diagnostic services supervision to ensure appropriate stakeholder engagement. Such data could provide quantitative support to NPP supervision expansion, and may bolster the effort to achieve policy change (Dickson & Flynn, 2009).

This change would align provider supervision rules across therapeutic and diagnostic services, bringing supervision rules for diagnostic services in line with those for therapeutic services that already allow for NPP supervision. This would reduce complexity in arranging outpatient services using expert NPP supervision of specialty-trained auxiliary staff. Such simplification

could result in cost savings across health care provider organizations, and may offer an additional advocacy point, particularly in the current era of uncontrolled health care spending.

Reclassification of CIED Services

Alternatively, CMS could reevaluate CIED follow-up services to acknowledge the extensive nature of therapeutic care that is managed through device evaluation, beyond simple diagnostic testing. For example, in addition to testing for battery life and lead integrity, in-person CIED evaluation also includes extensive evaluation of patient physiologic parameters including heart rates, activity levels, and arrhythmia incidents. Moreover, in-person evaluation allows patients to express their symptoms (e.g. fatigue, heart racing, dizziness) more directly than remote monitoring technologies presently allow. These subjective and objective findings may prompt reprogramming of one or more settings on the device to increase the therapeutic value to the patient.

The distinctive nature of CIED services is delineated in existing CMS rules by differentiation from diagnostic laboratory and x-ray tests, therefore acknowledging a substantive difference between CIED evaluation and radiographic imaging or blood testing. Despite this distinction, all of these diagnostic services are subject to the same supervisory rules (42 C.F.R. § 410.10(n)). If in-person CIED evaluation were reclassified as a therapeutic service, as opposed to its present classification as a diagnostic service, NPP supervision of auxiliary staff would be allowed as with existing therapeutic professional services (42 C.F.R. § 410.75(c)(1)). In order for this policy shift to occur, the therapeutic components of the service would need to be delineated. As with existing rules for NPP supervision of therapeutic services, provider qualification to perform

the service would be necessary. As discussed above, CCDS certification for NPPs and auxiliary providers would be a useful tool to demonstrate this qualification. Although this policy change solution would potentially address the access issue related to CIED services, it would not be more generalizable to other diagnostic services, as would a reclassification of provider-types granted supervising authority.

Advocacy Strategies

Based on existing rules that allow for NPP supervision of auxiliary staff for therapeutic services, one could conduct a retrospective observational study comparing outcomes for incident-to services for NPPs and physicians to demonstrate noninferiority of NPP supervision services (Dickson & Flynn, 2009). Particularly with the advent of expanding use of clinical registries in electrophysiology as a means of tracking quality of care and outcomes across broad patient populations (ACC Foundation & HRS, 2010; HRS, 2010a), it may be reasonable to consider NPP supervision of CIED services as a pilot registry-type study for one year with tracking of adverse outcomes and costs.

Such outcomes data would provide evidence to support expansion of NPP supervision to diagnostic services in hospital and nonhospital settings. Outcomes data would also refute the AMA's recommendation to prevent expansion of services by NPPs "where clear-cut documentation of assured quality has not been carried out" (AMA, 2000).

A unified stakeholder message centered on access, quality, and cost (Stone, 2002) will be necessary to achieve real change. Primary targets of this message will be members and staffers

of the Senate Committee on finance and the House Committee on Energy and Commerce (Longest, 2006), as well as CMS officials. Using the example of the coalition to amend supervision rules to allow for NPP supervision for hospital outpatient therapeutic services (Association of American Medical Colleges et al., 2009), an effective policy change effort would require a similar coalition of provider and organizational stakeholders relevant to CIED follow-up care, as well as support from patient advocacy organizations. Classically, this type of coalition would be expected to drive the development of alternatives to existing policy, rather than shape the core policy agenda itself (Kingdon, 1995). For example, a coalition may inform solutions to identified policy imperatives, such as escalating costs and decreasing access to care, but would not initially identify cost and access as policy imperatives. Therefore, it will be important to increase a sense of urgency regarding access to quality care in the face of escalating costs in order to build an agenda for change (Kingdon).

NPP supervision of diagnostic services is not presently an advocacy target of the American College of Cardiology and the Heart Rhythm Society (ACC, 2010; HRS, 2010b). However, patient access to services related to projected dramatic cardiovascular workforce shortages in the event of an impending 21.3% Medicare cut has been a locus of concern and major advocacy arena for specialty organizations (ACC; HRS; U.S. Department of Health and Human Services, CMS, 2009). In the long term, regardless of Medicare reimbursement rate decisions, this established priority on patient access to care, coupled with the American College of Cardiology's expert recommendations for expanded use of NPP services, lays the groundwork for an advocacy effort to expand NPP supervision over diagnostic tests. The example of CIED care supervision could expand to impact a wider range of diagnostic services that could realize impact from a

change in NPP supervision rules. For example, appropriately qualified NPPs could supervise stress tests, echocardiograms, and other diagnostic services. This could help to alleviate provider shortages across the range of cardiovascular specialty services, while ensuring patient access to quality care by appropriately credentialed providers.

Conclusions

Cardiology workforce experts have repeatedly identified expanding the use of NPPs as a critical means to overcome the looming shortfall in cardiovascular care services. At present, CMS policy identifies qualified NPPs as direct providers of all diagnostic and therapeutic services within the individual's State-regulated scope of practice. However, NPPs are not designated to supervise the same diagnostic services if provided by an auxiliary staff member.

Expanding the CMS-defined supervision of auxiliary providers to NPPs for CIED follow-up services would allow for seamless expansion of NPP services to meet the expanding societal needs for cardiovascular care in an era of innovations in pacing and defibrillation technology to improve lives.

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