

Health Policy Opinion

First, Do No Harm by Adopting Evidence-Based Policy Initiatives: The Overselling of ICD-10 by Congress with High Expectations

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As we just entered 2015, the health care system continues to undergo massive change with uncertainties among patients, payers, and providers. Among the major issues U.S. physicians and practices face are the seemingly endless cycle of impending sustainable growth rate (SGR) cuts and deadlines for International Classification of Diseases, Tenth Revision (ICD-10) implementation. In addition, physicians and practices face significant policy and marketplace changes, with hospitals, the insurance industry and information technology (IT) dominating the marketplace, often to the detriment of independent physician practices.

As October 1 nears, once again Congress appears to be implementing another unfunded mandate that is not rigorously based on the evidence (1-3). ICD-10 implementation is based on a liberal interpretation of an inconspicuous provision in Title II (4) of the Health Insurance Portability and Accountability Act (HIPAA) regulating health care transactions, national identifiers, and health care fraud and abuse (5). Based on this, a January 2009 final ruling by the Department of Health and Human Services (HHS) decided that classification of diseases ICD-9 diagnosis and procedure codes must convert from using ICD-9 to ICD-10 on October 1, 2013 (4).

CONTROVERSIES

The controversy over ICD-10 arose immediately HHS announced in January 2009 the implementation date of October 1, 2013 (5). This liberal interpretation of the law led to significant criticism. In fact, the introduction of ICD-10 was described as trying to tie the 2 developing silos (6). When HIPAA Administrative Simplification Compliance Act was signed, no one in the industry could predict that the transactional requirements would be to such a granular level with horrendous expansion of diagnosis codes. Consequently, all covered entities have been severely burdened with 2 compliance requirements (HIPAA 5010 and ICD-10), enablement of which is a mandatory requirement (6). These requirements were described as stringent and a moving target. Further, HIPAA rules have constantly been redefined. The estimated return on investment was in the range of \$700 million to \$7.7 billion just for implementing ICD, with ability to reduce fraud and abuse in Medicare and Medicaid. Extensive efforts have been made by multiple organizations, including the American Medical Association (AMA) and the American Society of Interventional Pain Physicians (ASIPP), to block the conversion. Implementation dates have been extended on 2 occasions, to October 1, 2014, and subsequently to October 1, 2015 (7-11). While medicine is a field focused on patient care and healing, revenues do need to be generated in sufficient quantities to provide appropriate quality care and to meet overhead with qualified staff and functional technology. The Resource-Based Rela-

tive Value Scale (RBRVS) nominally provides reimburse at the cost of providing a service. The common practice of reimbursing below the RBRVS leads to the interesting question of how one provide care for less than the cost of providing it. Health care is seeing an explosive and expensive growth of IT requirements with electronic health record (EHR) incentive programs, which is partially responsible for an increased rate of consolidation among hospitals and health systems driving smaller, independent medical practices into larger systems or into retirement (12-15).

Congress is willing to implement ICD-10 at a time when Centers for Medicare and Medicaid Services (CMS) has yet to prove that it can handle ICD-10 (16-18). We note that CMS has been touting their success with ICD-10 end-to-end testing with only successful submission of 81% of ICD-10 claims (18).

FIRST, DO NO HARM

The primary responsibility in health care is *primum non nocere*, meaning "first, do no harm." The phrase is also sometimes presented as *primum nil nocere*, abstain from doing harm. *Primum non nocere* has been used since at least 1847; the concept goes back to Hippocrates. Our policymakers should follow the same principles of first do no harm and demand evidence-based philosophy. The implementation of ICD-10 is not based on evidence to improve any aspects of health care and has not been proven to be harmless. The evidence-based philosophy and concept of first do no harm must be applied at each and every step of health care regulations. The strongest proponents of ICD-10 are the health technology sector even though many of the existing products fail to meet appropriate criteria with a 65% dissatisfaction rate of provider community (12,13). These programs often lack intraoperability (19-21). The insurance industry may paradoxically benefit from payment delays and denials. The hospital association appears to support ICD-10 to facilitate consolidations. In that context, it is noteworthy that the escalating IT requirements are a factor that is often cited in small practice consolidation. Proponents also continue to cite the use of the ICD-10 to assess quality of care, make benefit coverage decisions, and to determine physician and hospital payment.

Thus far, we posit that proponents of ICD-10 have failed to show any evidence of benefits of ICD-10 (8-10). Indeed some of the countries which have adopted ICD-10 continue to use ICD-9. Further, there has been much written about ICD-10 lessons to be learned from other

countries (21,22). It is also interesting to note that the cost of coders is twice in the United States compared to England and other countries and coding is not intensive in these countries because of national health care systems (22). Further, documentation issues and issues related to fraud and abuse are extremely intense in the United States compared to other countries. The descriptions provided from other countries are in line with the fears expressed by the American provider community which showed that on average, 81 courses were taught for almost 2,500 participants in all states of Australia and New Zealand, involving face to face workshops with coders and train the trainer sessions in contrast to easy portrayal of adapting to ICD-10 in the United States by the supporters (21). An impact assessment by Australian National Center for Classification in Health found that the approximate cost to cover employment of additional coders, training, backlogging materials amounted to approximately \$10.5 million, for a country with 7.3% of population of the United States in 2013 with a national health care and extremely simplified coding with less stringent documentation requirements. It took 3 to 6 months to adjust for coding in Australia (21). This also falls in line with the saga of EHRs wherein UK hospitals seem to be learning from the United States (23). The UK-US government memorandum of understanding on health IT signed was described as the first sign that the UK will finally develop a sustainable strategy to promote the adaption of hospital EHRs. This is dependent on inadequate systems developed in the United States which have turned out to be a disaster for practices with a carrot and stick policy (12). In a 2010 manuscript, Robertson et al (24) described the implementation and adaption of nationwide EHRs in secondary care in England as requiring considerable attention, financial investment, and support for a long, complex, and iterative process requiring flexibility and adaptability. On the same token, the U.S. health care industry has been warned not to repeat the UK's EHRs failure. Now it appears that the United States, as well as UK, have worked for over 6 years and recognized the failures with UK embarking an investment of \$18 billion in health IT in 2005, with the U.S. embarking on \$30 billion investment in 2008 and after 6 years with a signing a memorandum of understanding between both countries (23,25). The pro ICD camp does have money, controls the electronic media, and has the support of the administration (26-37). Nonetheless we continue to believe that the implementation of ICD-10 should be delayed until sufficient evidence has been accumulated

demonstrating its necessity, as well as describing its adverse consequences.

Evidence-Based Policies

Contrary to the established policies of the previous 2 administrations and the Congress, implementation of ICD-10 does not follow any evidence-based policies. The expectations are unproven and vague, whereas risks and disadvantages are real. Haskins (38,39), from the Coalition for Evidence-Based Policy, documents that evidence-based social policy initiatives are the most important initiatives in the history of federal attempts to use evidence to improve social programs. Haskins, a Brookings Institution senior fellow who was the lead House Republican staffer for 1996 welfare overhaul and later advised President George W. Bush on welfare policy, articulated the principle that “the government should fund only social welfare programs that work” and describes the recently-enacted evidence-based initiatives in which “the Obama administration, building on work by the Bush administration, has insisted that money . . . go primarily to programs with rigorous evidence of success, as measured by scientifically designed evaluation” (40). Further, Haskins has described that despite decades of efforts and trillions of dollars in spending, rigorous evaluations typically find that around 75% of programs or practices that are intended to help people do better at school at work have little or no effect.

Multiple manuscripts have been published in the past illustrating lack of necessity and adverse consequences of ICD-10 (7-11). In addition, Health Affairs published a manuscript (10) which showed that ICD-10 conversion will be expensive, arduous, disruptive, and of limited direct clinical benefit. Further, extensive descriptions have been provided for lack of evidence of necessity to implement and adverse consequences of implementation. Thus, Congress postponed implementation deadline to October 1, 2015 (11). However, this decision has not gone unnoticed and has met with extensive lobbying from the health IT industry, now gaining support from other industries who will also potentially benefit from ICD-10 implementation (41). It appears that the proponents of ICD prefer SGR cuts instead of ICD-10 postponement. In addition, consequences of extensive costs of implementing ICD-10 on physician practices and impending cash crunch has been largely ignored (26-37,42-47).

The Clock Is Ticking

The environment in which health care providers

work is once again in a major flux. Further, we can look at the activities and progress since April 2014. The pro ICD-10 industry appears to be out-lobbying the opponents of the ICD-10 (1,2,26-37). CMS, which was ready to implement in October 2014, has issued notice of acknowledgement testing week with successful results from ICD-10 (16,18). However, unfortunately this testing was limited. Further, the acceptance rates ranged from 76% to 89%. This is contrast to the normal acceptance rate for Medicare claims of 95% to 98%. Considering that Medicare processes over 4 million claims per day, the change in the best case scenario of 10% and worst case scenario of 20%, will have an enormous impact on the system and payments to providers, with over 400,000 to 800,000 claims denied per day. CMS touted successful end-to-end testing in 2015 which is more extensive; however, with 81% acceptance (18). Further testing will occur in April and July 2015, only 2 months prior to implementation date. At a recent hearing in Congress with the majority of the stakeholders testifying representing implementation supporters, it appeared that Congress is supporting immediate implementation, yet again without any evidence (2,37). Unfortunately, the testimony was focused on how the health care technology community is ready for implementation. This testimony is far from being unbiased as health care IT community is naturally conflicted.

Proponents of Immediate Implementation of ICD-10

Supporters of ICD-10 implementation also have produced an extremely biased unscientific cost survey conducted by the Professional Association of Healthcare Office Management, the association for managers of physician practices without regard to actual expenses (29-32). This white paper showed that the implementation costs of a mere average of \$8,167 for practices with 6 or fewer providers and an average expenditures per provider of \$3,430. These estimations are quite low as this survey also shows that it only requires 45.5 hours per provider of ICD-10 related hours expended across all personnel types in the practice. The underlying assumptions of these extremely inexpensive implementation are that newly available educational and training materials, new resources from the vendor community, and the increasing adoption of EHRs by providers will help ease transition expenses and concerns (30,32). However, the experience in other countries indicates otherwise as shown above (21,22).

Ironically, with all the existing deficiencies of

EMRs, issues related to meaningful use, (12,13) with a 65% dissatisfaction rate, physicians and other health care providers are yet again suffering from high cost of mandatory transitioning (7). This time, the vendors of health care software want thousands of dollars to unlock the data so they can be shared. Once again, Congress steps in to provide relief with the fees thwarting the goals of the \$30 billion federal push to get providers to digitalize health records. Politico Pro (7) reports that exorbitant prices to transmit and receive data can amount to billions a year. Further, the EHR industry is increasingly reliant on this revenue. The cost of such activity may range from \$7,500 to \$40,000. According to Representative Burgess this is a market failure that should be resolved in the marketplace. He is proposing legislation to fix this issue. Again, the burning question remains if market forces would take care of it, why did the federal government get involved in EMRs with its onerous penalties and major bureaucracy, even before implementation of ICD-10.

In addition, the cost estimates produced by supporters of ICD-10 (29,30,32) are in contrast to the former implementation cost estimates from the comprehensive study by the AMA which ranged between \$56,639 and \$226,105 for small practices (42). The AMA released these results in February 2014 and the pro ICD-10 group released their results in February of 2015 (29,30,32). The difference is so substantial that the results are mutually exclusive. As shown earlier, these cost estimates are not close to the costs in the countries which have already partially implemented ICD-10 for over the last 10 years, which will increase substantially with inflation adjusted measures of the cost (21,22).

Costly Consequences of Unfunded Mandate

Private practices, many hospitals, state governments, and even CMS do not seem to be ready for implementation. In fact, the recent Government Accountability Office (GAO) report, which has been used by CMS to provide support of implementation from October 1, 2015, has ironically showed that 20 of 28 stakeholders contacted by them had serious concerns (17). Further, the results of a survey from the Physicians Foundation published in December 2014 (19) described that in addition to the accelerated medical consolidation, the extension of ICD-10 deadline was important for physicians as multiple onerous issues continue to face physician practices. They showed that impact of ICD-10 on physician medical practices is enor-

mous, with 50% of the survey respondents indicating that ICD-10 will cause severe administrative problems in their practices, with 75% of the respondents believing that ICD-10 will unnecessarily complicate coding (19). Further, the majority of the physicians felt that the implementation of ICD-10 will be highly disruptive for physicians and their medical practices, ultimately resulting in lost time with patients and affecting the patient care. Physicians also expressed concerns about cash flow disruptions. These findings are in contrast to the pro ICD implementation survey (29,30,32). In fact, the GAO had serious concerns about the CMS' outreach and education efforts, as well as the lack of adequate testing. The GAO report also stated that stakeholders recommended that CMS do more to engage covered entities through non-electronic methods and to make it its Medicare fee-for-service contingency plans public (17).

It also appears that as of November 2014, only 2 Medicaid programs had tested the system and another 24 are still updating their systems and not yet able to begin testing (1). It is worrisome that if the state government is not ready for the transition, it will be extremely difficult if not impossible for physicians to be ready and they will not be reimbursed for seeing Medicaid patients. The change to ICD-10 will affect all physicians with specific challenges for interventional pain physicians who are already facing numerous other issues and cuts with some extinguishing their practices (12-14,48,49). Many physicians are facing potential draconian cuts based on SGR, meaningful use, Physician Quality Reporting System (PQRS), value-based adjustment, electronic prescribing, and, finally, sequester cuts (12,13). The overall costs of HIPAA have been skyrocketing with underestimations by the administration and the Congress with estimations as high as costs of 8.5 billion a year for hospitals (50). In addition, the majority of hospitals with less than 100 to more than 500 beds felt that HIPAA compliance can be a significant barrier to providing patient care with electronic patient information restricting the use of electronic communications. Apropos the present discussion, the overall total cost of HIPAA was initially estimated to be around \$1 billion but actual costs continue to escalate. Ironically, the same pro ICD lobby also continued to bolster the advantages of EHRs, meaningful use, value-based payment systems, PQRS, despite challenges with these systems that can result in various issues with patient care (12,13).

SUMMARY

While it appears to be beneficial to apply a detailed disease classification system, the costs, cash flow disruptions, and increased investments with physician time incorporated into learning these processes, patient care might unfortunately suffer. This is essentially an unfunded mandate with much of the burden of transitioning to ICD-10 falling on health care providers, especially small independent practices. This will impact interventional pain management practices substantially. Further, as we have shown in previous manuscripts, the so-called advantages of multiple codes with specificity and granularity does not translate into reality where some specificity is actually lost for various codes. As Grimsley and O'Shea (1) have described in clinical practices, doctors do not treat codes, but they treat patients according to the individual clinical condition. A doctor will be losing valuable time and also will not be able to obtain meaningful information due to burdensome regulations of meaningful use, PQRS, value-based reimbursement, electronic prescribing, and now a major impact with change to ICD-10. Thus, very little benefit will be seen by practitioners, which cannot be said for the health care information industry. With overwhelming regulatory atmosphere created by numerous federal regulations and those including under the Affordable Care Act (15), there is no evidence

that ICD-10 is needed, there is no evidence that it will be effective, and, finally, there is preponderance of evidence of adverse consequences. Thus, Congress should be cautious in imposing further regulations on already strained independent practices with ongoing regulations and imposing yet another unfunded mandate on the medical profession.

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