From the President The Window of Opportunity to Save Independent Medical Practice Is Closing

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The medical profession is moving away from its ancient traditions and ethics. We are losing our professional autonomy—our ability to treat our patients to the best of our abilities and according to our best judgment. And we are losing even the ability to define ourselves as a profession. We are increasingly subservient to administrators, politicians, lawyers, and non-elected bureaucrats, all of whom presume to tell us how to practice, how to document, how to educate and certify ourselves, and of course, how much we can earn.

We find ourselves at a crossroads. We will either reclaim control, or we will cease to exist as a profession. Time is short, but I believe we still have a chance to get our profession back.

It Started with Medicare

The Medicare system has been a major catalyst in the destruction of our profession. The recent Medicare Access and CHIP Reauthorization Act (MACRA) brings this into clear focus.

Costs within the Medicare system started to rise as soon as the program was instituted in 1966. This should have come as no surprise. Millions of seniors were handed an entitlement to medical services, which of course increased the demand for these services. Physicians were allowed to charge their "usual, customary, and reasonable" rates, and they did so.

Concern over rising costs led to various responses from the Health Care Financing Administration (HCFA, bureaucratic precursor of the Centers for Medicare and Medicaid Services, CMS), to rein in spending. These mostly took the form of price controls on physicians' services.

On its face, this is stupid policy, as payments to doctors were between 10 percent and 12 percent of total program spending. Cuts in this sector couldn't reasonably be expected to produce much in the way of savings. But doctors are such easy targets!

In 1984, HCFA began a fee freeze on Medicare payments to doctors. This was extended through 1986. Total Medicare spending increased dramatically during this period. Why? Doctors, to compensate for the reduced fees, increased the volume of services provided. This churned the system and led to less time per patient encounter. With this comes loss of quality and excessive reliance on testing, consultations, and hospitalizations, all of which drive up total costs.¹

In 1992, HCFA moved away from paying doctors based on their charges to the Resource-Based Relative Value System, a Marxist construct that assigned dollar amounts to the myriad services provided by doctors. Balance billing of all Medicare patients (regardless of their income) was severely restricted.

Nonparticipating physicians could only charge a bit more than the Medicare "maximum allowable charge." Since they were also penalized with a lower "allowable" rate, this increased the physician Medicare participation rate. The net result was another big pay cut to physicians, which was again followed by a major increase in total Medicare spending.

In the Balanced Budget Act of 1997, the Clinton-Gingrich Sustainable Growth Rate (SGR) formula was implemented. The idea was to base Medicare physician fees on total program performance the prior year. If total Medicare spending went above a certain target, payments to physicians would be cut, or frozen, in the current year.

But pay cuts to doctors predictably cause total spending to increase. Rob Lowes, writing in *Medscape*, reports that Medicare Payment Advisory Commission (MedPAC) data from 2002 to 2012 show Medicare spending on physician services per beneficiary increased by 72 percent. A 9-percent increase in rates during this period was dwarfed by the growth in volume of physician services, including lab tests (91 percent increase), imaging (79 percent increase), and other procedures (up 68 percent). As it is, the net effect of pay cuts and freezes has been to force many physicians out of private practice, and into hospital systems. During the same 10-year period, Medicare fee-for-service rates increased 9 percent, while the cost of operating a practice increased 27 percent.² Over this time frame, the proportion of doctors in private practice declined from two-thirds to one-third.

If SGR doctor pay cuts had been allowed to take place, payments would by now be well below Medicaid levels, and many physicians would have been forced out of Medicare participation completely. The SGR is truly idiotic. That is why almost every year since it became law, Congress has passed "doc fix" legislation to block the programmed cuts, and to provide an occasional update placebo.

Jumping the SGR Hurdle—into Something Worse

This year, perhaps tiring of the annual Kabuki dance, or perhaps not wanting to "let a crisis go to waste," the House put together a piece of sausage known as H.R. 2, and passed it without anyone having had a chance to read it, and without meaningful debate. The Senate recessed then passed it quickly after re-convening.

MACRA is a disaster for doctors and patients. It institutionalizes some of the worst aspects of "ObamaCare." The SGR is gone, but it is replaced with the same old price controls, with trivial updates that will be pulled back unless we jump through "payment for outcome" hoops. It furthers the destruction of private medical practice through a frontal assault on fee-for-service payment.

To quote my friend and colleague, Dr. Kristin Held, the H.R. 2 "fixes" doctors in the veterinary sense: "The Doc Fix [MACRA] neuters the profession of medicine and transforms us from healers to heelers getting paid by doing exactly what the HHS secretary says."³

Section 101 (e) of H.R. 2 promotes Alternative Payment

Models. It creates more bureaucracy, setting up the Physician-Focused Payment Model Technical Advisory Committee, which by November 2016 "shall establish criteria for physician payment models, including specialist physicians (Sec.101 (e) (2)) and establish incentive payments for participating in such models (z)." Money will no longer be paid to physicians, only to Eligible Alternative Payment Entities (i.e., Accountable Care Organizations, medical "homes").

A Merit-Based Incentive Program will replace the current EHR Meaningful Use and Physician Quality Reporting System penalties. Physicians will be given a Composite Performance Score, which will be posted publicly on the Physician Compare site on the CMS website, and is based on "quality," resource use (i.e., cost), "clinical practice improvement," and "meaningful use" of the electronic health record (i.e., reporting clinical data).

Physicians with a top performance score may be "rewarded" with a 0.5 percent annual fee update. Pop the champagne! Medicare Advantage plans somehow managed to get a 1.5 percent annual update. It seems that lobbying pays.

So we have arrived at a place I have been warning about for years—we are to be told explicitly how to practice medicine by central planning bureaucrats who are already (with the help of the American Medical Association, the American College of Physicians, and the American Board of Internal Medicine) creating treatment algorithms based on existing clinical practice guidelines, to be enforced (at first) by financial penalties and rewards.

"Payment for performance," based on "quality," or "outcomes," is a dangerous concept that is flawed in every way. It assumes doctors need financial prodding to "perform." That is patently absurd, and insulting. We are one of the highest performing groups in the nation; that's how we got to be doctors!

It also assumes that "quality care" can be defined and accurately measured. To prove how difficult this is, I will ask you to come up with your own definition of quality, as Robert Pirsig did to his philosophy students in the monumental *Zen and the Art of Motorcycle Maintenance*.

No one could do it, and he devoted the rest of the book to the question. "I think there is such a thing as Quality, but that as soon as you try to define it, something goes haywire. You can't do it."

Of course, he is not satisfied by this non-definition, and pushes further to an epiphany:

Quality couldn't be independently related with either the subject or the object but could be found only in the relationship of the two with each other. It is the point at which subject and object meet. Quality is not a thing. It is an event. It is the event at which the subject becomes aware of the object.⁴

The quality, for example, is in the interaction between a craftsman and his work. A good interaction produces an excellent result. This could just as easily be describing a doctor performing an evaluation of a patient:

Quality in healthcare occurs at the cutting edge between subject and object, the patient-doctor interaction. Anything that enhances this relationship improves Quality; anything that interferes with it destroys Quality. If the interaction between patient and physician is positive, craftsman-like, serene, and secure, this will afford the physician the best possible chance of figuring out exactly what is wrong with the patient. The patient will feel the caring, and that, in fact, begins the healing process.⁵

Obviously, all of the "Quality Improvement Initiatives" impair quality of care because they all detract from the patientphysician relationship in different ways. But we are forced to participate in these meaningless exercises, to the detriment of patient care.

Payment for Performance (P4P) relies heavily on "clinical practice guidelines," which are consensus statements of panels of "experts." These "experts" have extensive financial conflicts of interest with industries that all too often fund the guideline process. They are cloaked in "evidence-based medicine (EBM)," which, when examined closely, rarely rises above the level of junk science. Yet, even guideline authors include the disclaimer that their product should not dictate practice, which should remain the domain of the individual clinician. Unfortunately, P4P does just that, and creates a "one-size-fits-all" model of patient care that is hailed as "standardized care." It will certainly be harmful to many patients who do not fit the mold. P4P is how pharmaceutical companies hope to enrich themselves through ObamaCare and MACRA.

Since the principal determinant of patient outcome is the pre-existing level of co-morbidity, P4P or payment for outcomes will eventually lead to physician avoidance of the very ill patients. Thus will doctors, and the Accountable Care Organizations they will be working for, institute rationing.

There are many examples of how EBM and guidelines are corrupted to promote specific treatments. Note the eternally shrinking target levels for low-density lipoprotein (LDL) in the Adult Treatment Panel (ATP) guidelines that have led to absurd numbers of healthy individuals and low-risk patients taking statins for life. Note also the financial conflicts of the panel members.⁶

The EBM studies on which many guidelines are based take a tiny absolute risk reduction, and through recruitment of huge numbers of subjects, transform this into a statistically significant and impressive sounding relative risk reduction.

Dialysis: a Case Study in EBM and P4P

The economic course of dialysis in the U.S. is a case study in the malign effects of price controls, EBM, and guidelines.

When in 1972 Congress voted to expand Medicare to cover dialysis, payments were generous—around \$140 per treatment. Over time, inflation eroded the value to about \$14 per treatment. To remain profitable, dialysis units shortened treatment times ("high efficiency dialysis," which was a disaster for patients though EBM suggested otherwise), and made margins selling injectable drugs such as Epogen, iron, and vitamin D analogues. Profits were driven by volume, and algorithms promoted by the industry led to extremely aggressive dosing of these agents to achieve numerical targets. The targets were defined in the Dialysis Outcomes Quality Initiative (DOQI) and Kidney Disease Quality Outcomes Initiative (KDOQI) practice guidelines.⁷ The National Kidney Foundation created this guideline group with a very large and open-ended grant from Amgen, the manufacturer of Epogen. The anemia guidelines were based strictly on observational studies showing a link between poor outcomes and hemoglobin levels below 11 g/dl. In 1998, a prospective study of dialysis patients treated to normalize the hematocrit showed possible harm, but was widely ignored.⁸ The guidelines held sway, and dosages and sales of Epogen (and dialysis unit profits) soared. The guidance was amplified by CMS including the hemoglobin target of 11–12 g/dl as a "clinical performance measure."

It all came crashing down in November 2006 with publication of two key prospective studies in the *New England Journal of Medicine* showing poor outcomes at higher targeted levels of hemoglobin in anemic patients with chronic kidney disease (CKD).^{9,10} The uproar eventually led Congress to expand the dialysis payment "bundle" to include injectable drugs such as Epogen. Because they knew this would lead to less drug use, they included a P4P penalty for patients with average hemoglobin levels less than 10 or greater than 12 g/ dl. Patients were being inappropriately transfused to bring their hemoglobin above the lower number! When another study was published showing that even this lower limit was inappropriate,¹¹ CMS (to its credit) removed this from the P4P. The transfusion rate returned to baseline.

In my view, the reason for the discrepancy between the observational and prospective treatment studies is that the assessment of anemia in kidney patients is flawed by volume status. The hemoglobin level is typically measured pre-dialysis, when patients are maximally volume expanded. At the end of treatment, levels typically climb by 1.5 g/dl.¹²

What We Must Do

By 2021, the Medicare incentive plan is to be expanded to include private insurance. This is the "Combination All-Payer and Medicare Payment Threshold Option." Health and Human Services Secretary Sylvia Burwell said as much in a recent public appearance. It is starting to resemble a complete federal takeover of medicine, isn't it?

Physician participation in Medicare is not mandatory. Or is it? Section 507(4) of MACRA requires a valid NPI (National Provider Identifier) number on pharmacy claims and gives the HHS secretary power to determine whose NPI is valid. If we do not have a valid NPI, our patients will not be able to obtain coverage for medications we prescribe or labs and/or imaging studies we order—and may not be able to obtain them even if willing to pay. In other words, we will not be able to practice medicine.

So, we are at a critical juncture. We can continue to allow Medicare and the corporate payers to control our lives, limit our fees, force us to disclose confidential information, prescribe based on pseudo-scientific constructs, and to suffer the indignities of continuous re-certification in our specialties.

Or we can break free. We can declare independence. We can opt out of Medicare. We can cancel our abusive insurance contracts. We can continue to be available to all of our patients, at a mutually agreeable price. We can give them the time and attention they deserve. We can become healers once again.

Time is short. The window of opportunity to reaffirm independent medical practice may be slammed shut with little warning. It is essential to get to a critical mass of independent, opted-out physicians before this happens. AAPS has been fighting to preserve independent, Hippocratic medicine since 1943. We are suffering setbacks, but we are still in the fight. We are in need of reinforcements. All physicians who believe independent medical practice is worth defending need to join us in this fight. Our commonality of purpose unites us across all ideological perspectives. We are all brothers and sisters in an ancient and noble profession. It falls to our generation to preserve our traditions and autonomy for future generations.

The medical profession, because we care for individual patients, is an essential bulwark against totalitarianism. Remember that Hitler first co-opted and controlled the doctors before implementing the Final Solution. Doctors who owe allegiance to the state will have difficulty standing up against policies that abuse the individual, or human dignity and life. We already hear the drumbeat for physician-assisted suicide, to be followed by euthanasia. Doctors should not be involved in killing patients. It is a long and slippery slope down from there.

If we stand united, we can take back our profession. This will involve mass opting out of Medicare, and will require considerable courage. I am inspired by the courage of the founders of our Republic who risked everything for freedom. Many paid with their lives. We should be able to take the necessary steps now to preserve our professional freedom and to keep it safe for future generations.

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