Joseph L. Dorsey, MD
Former Corporate Medical Director, Harvard Pilgrim Health Care and Medical Director for Inpatient Programs, Harvard Vanguard Medical Associates

Remarks on Value-Based Payment and Coverage For Medical Technologies
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Who Cares, (i.e., who are the stakeholders and why do they care)?

1. **Society** (i.e. private and public payers, and their employees or beneficiaries) who see inexorable cost increases and international outcome measures portraying relatively poor value for their dollars

With increasing attention to the need for universal coverage, thereby eliminating our position as the only industrialized Nation in the World without it in one form or another, enhanced access to care is likely to lead to even higher rates of use of health services and costs. "Breaking the bank" is a major fear in states like Massachusetts right now.

2. **Health Plans**
   a. Often caught in the middle
   b. Expected to control costs but never allowed to "just say no"
   c. Employers and employees want cost containment on a population basis, but not when their employees complain about a request for care being rejected, and not when it comes to care for themselves or their family members

Relevant Examples from my own personal and professional experience

In my years as corporate medical director at Harvard Pilgrim Health Care (yes HPHC, the NCQA designated #1 Plan in the Nation on both HEDIS and patient satisfaction measures, just 4-5 years after coming out of receivership), my responsibility was to seek value (Quality/Cost), not just to save money. I lived through some tough failures and some remarkable successes.

I. FAILURES:

1. **Reduced Maternity LOS Programs**. The DRG's for normal vaginal delivery (#1) and C-section (#4) are in the top 5 reasons for hospital admission in virtually every commercial and Medicaid program.

At Harvard Community Health Plan, we ran a very successful program, but did not have the data to prove it. Also, the financial savings turned out to be less than expected because our hospitals "front end loaded" their per diem charges to us. The proof of quality and patient satisfaction came after "drive through deliveries" became the term of derision for our work, and reduced maternity LOS programs were legislated out of existence. (See Madden et al. 2002 NEJM article in list of references.)

2. **Capitation in general**. The public, and especially, the media, did not trust us to "do the right thing" (i.e., produce value) by restraining unnecessary expenditures through selected utilization control programs, and many less than well-organized groups of physicians lost money. The former leader of one such entity has had a change of heart now that he is an Aetna corporate officer. (See Cassel and Brennan in list of references.)

3. Occasional errors in judgment re requested benefit exceptions did occur and soured some of our employer groups and members.

II. SUCCESES:

1. **Approval of Lovenox for Outpatient Treatment of DVT**. An expensive drug but able to eliminate most of the 5-7 day admissions for DVT. Steve Pearson, in the audience today, developed the clinical guidelines to be sure we did it safely and managed the program for us.

2. **Diabetes Disease Management Initiative.** Judith Frampton, N.P., demonstrated through a careful and thoughtful literature review that the rank order of cost effective interventions for most diabetic patients is:
   a. One ASA daily- cost is close to zero and the reduction of macrovascular complications, very common in diabetic populations, is large
   b. Blood Pressure control. Assuming use of effective less costly agents and an ACEI or ARB to protect the kidneys
   c. LDL<100-at the time. It was thought that the goal should be to get <130 so this was surprising to me. The cost of statins to get to this level was significant, but the back end reductions in macrovascular complications were far greater below <100 than <130, so it was worth the added costs to strive for LDL levels <100.
   d. In addition, smoking cessation programs, when successful, have a high payoff. Likewise, regular exercise and weight control. We have come in more recent years to espouse A1c levels below 7.0 whenever possible.

3. **Coverage for experimental chemotherapy for patients who have failed standard regimens.** This was a tough one because all of the physician leaders in health plans believed that the costs of care associated with experimental chemo should be borne by the sponsoring research agency, usually the NCI, or should require prior approval.

The American Cancer Society targeted Massachusetts to try to persuade the industry to change its position, frankly because they knew that the not-for-profit HMO medical directors and the Dana Farber Cancer Institute leadership had very positive working relationships. Dr David Nathan, then President and CEO of DFCI, described for us the clinical dilemma our prior authorization procedures placed in the way of the Oncologist in the room with an advanced stage patient and family when they'd offer an experimental regimen, but have to say there would be delay and uncertainty as they sought health plan

approval. They advised us that DFCI does offer such patients the option of hospice care if they preferred that to the known side effects of the experimental drugs.

We all agreed to their request for coverage and, to this day, believe it was "the right thing to do". Many health plans across the Nation followed suit.

4. Support Wellpoint's appeal to the FDA to move Claritin into OTC status. It seemed ridiculous to allow Benadryl, a much more soporific drug, to be OTC, while requiring a physician's prescription for the safer choice, Claritin. And yes, the price on all the oral antihistamine drugs dropped as a result.

5. Three-tier drug benefit. To this day, this remains the single most important step we took to enhance value.

Prior to 3-tier, we encouraged physicians in our network to adhere to our formulary. When a patient had been on an off-formulary agent in the same class for years without problems and they were asked, "Why are you switching me now?", physicians hated answering, "Because that's what your insurance company wants me to do".

After 3-tier, a patient on a 3rd tier drug is likely to initiate this conversation with their PCP, "Isn't there as good a choice in the second tier?", and, usually the answer is yes. What a different dynamic. It's the classic "everyone wins". The patient saves money; the physician feels good about not forcing the issue; the health plan saves money. Even the pharmaceutical industry gains something. To the extent that patients can better afford drugs in the second tier, and are more likely to be compliant, sales of some agents rise.

I would be remiss if I failed to mention the conversations that ensued between our purchasing staff and pharmaceutical company representatives with a drug in the third tier about what their price would need to come down to in order to get the drug into the 2nd tier. This is the market at work!

Current "Hot Topic": The Massachusetts Coalition for the Prevention of Medical Errors has identified "Outpatient Anticoagulation Management" as its #1 Patient Safety Initiative.

Warfarin is an effective but dangerous drug. Complications arise from:

- “Undertreatment”. Only about 50% of patients with paroxysmal or chronic atrial fibrillation, the largest group of candidates for Warfarin treatment, are on the drug. They are at risk for a thrombotic stroke

- “Overtreatment”. Intracranial hemorrhage is the dreaded complication and carries a 50% mortality rate (See Singer article). Nursing home patients-close to 10% are on Warfarin (See Gurwitz reference.)

Management of such patients in an "Anticoagulation Monitoring and Management Service" reduces complications, enhances patient safety and assists prescribing physicians manage their patients on Warfarin. AMMS' have been shown to be cost effective because the upfront costs are more than offset by the reduced complications. From the viewpoint of quality, even if the savings were not proven for some population groups on long term treatment, it's still "the right thing to do".

For those of you from CMS and health plans, the "right thing to do" is to activate payment codes 39363 and 39364. I'll spare you the details but be glad to give you the why's and wherefore's upon request. Also, for selected patients, point-of-care or home INR monitoring has been shown to further reduce the rate of complications and be cost effective. Again, I'd be glad to get you the articles on request.

The Massachusetts Medical Society and the Massachusetts Association of Health Plans have joined the Massachusetts Coalition in advocating for these changes. Many of you have a sphere of influence that could be of help. If any of you represent the manufacturers of the home INR devices, it would be great if you could lower the front end costs as the manufacturers of home glucose monitors have done.

So, in brief, a few closing, “gratuitous” comments about what I'd like to see from the pharmaceutical industry to make the world a better place:

1. If you are going to continue to be the source of financial support for the FDA, please get them the funding they need to do post release tracking, not just to approve the new drugs in your pipelines;
2. Reduce marketing for "off label" indications;
3. Use more circumspection in DTC advertising. I know it works but physicians resent it;
4. Enable the FDA to find expert witnesses without conflicts of interest-practicing physicians and the American public want and deserve no less;
5. Keep coming to Boston-you are great for our workforce and our economy!

Thanks for listening.

References

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