

On September 14, 2011, the Medicaid Redesign Team's Basic Benefit Review ("BBR") Work Group held its second scheduled meeting at the NYS Department of Health (DOH) Metropolitan Area Regional Office, located at 90 Church Street, in New York City. Copies of the materials disseminated, along with the PowerPoint for the meeting, are attached.

Both Co-Chairs of the Work Group, Frank Branchini, the President and CEO of EmblemHealth, and Commissioner Nirav R. Shah, were unable to attend, though Commissioner Shah did join the second half of the meeting via conference call. Dr. William Gillespie, the Chief Medical Officer for EmblemHealth, filled in for Mr. Branchini. Foster Gesten, MD, the Medical Director of the Office of Health Insurance Programs at the New York State Department of Health (DOH), led the meeting.

Dr. Gesten began the meeting at 10:45 a.m. with a brief round of introductions, since their first meeting was conducted via webinar. Only four members of the public were in attendance.

I. Introduction and Review of Agenda

Dr. Gesten reviewed their mission, which is, that New York Medicaid will have evidence informed benefit package which promotes high quality, efficient, and effective services that improve health and health care outcomes for its members. He indicated that following their last meeting, DOH staff sent around a template report for what the general pieces of this would look like, and that their primary goal was to make specific recommendations, like those done by the MRT, that would shape benefit design going forward. This would include creating a framework for prioritizing benefits and determining when and which benefits should be covered, and would also require consideration of current Medicaid benefits, coverage criteria, and copayment issues as they apply in fee for service and managed care for specific suggestions regarding ways to develop and promote evidence informed, cost effective health care services within the parameter of "budget neutrality" for the Medicaid program.

II. Brief Review of Distributed Materials

Greg Allen, the Director of Financial Planning and Policy at DOH, noted that members received "a flurry" of material over the past few days, including information on spend amounts for different services. Mr. Allen highlighted that of the \$48 billion DOH spent on services FY 2010, \$13.8 billion was spent on optional services, \$4.5 billion of which was spent on prescription drugs.

In reviewing the chart on spend (attached), Basit Chaudhry, M.D., PhD, a Senior Researcher for Healthcare Analytics, IBM Research, asked what "personal care" services included? Mr. Allen responded that this category included individual assistance, such as activities of daily living, which include shopping assistance, all the way up to more advanced assistance like home health care aid. He further noted that this is a coverage category that has gotten a lot of attention over the past two years,

since it constitutes the second highest total in spend of all the services. Dr. Chaudhry requested if they could provide a specific breakdown of the expenditures so they can provide dollars per claim for mandated services and optional services. Greg Allen noted that they would be putting these materials online.

Cost Sharing and Deductibles

There was a continued discussion from last meeting on the role co-pays, incentives, and deductibles should play in the Medicaid program. Peter Newell, the Director of the United Hospital Fund's Health Insurance Project, indicated that "60 seconds will not end the debate that has been going on for 60 years on utilization and cost sharing". Regarding deductibles, he indicated that while they result in lower premiums and may dissuade utilization, they are very ill suited for Medicaid populations "for obvious reasons." As for the general proposition of cost sharing, Mr. Newell noted that "the jury is still out" on its overall utility, noting that evidence has shown it can deter bad care as well as good care, which is almost always felt disproportionately by the chronically ill.

III. Presentation/Discussion of "Principles"

Rare Diseases

Elisabeth Benjamin, the Vice President of Health Initiatives for the Community Service Society, noted that individuals with rare diseases often have difficulty accessing the benefits they need because the treatments they require regularly do not make it through clinical guidelines. She indicated that the draft principles make sense in general, but should state that a route will be established, like external revenue, for situations where the treatment of a rare disease is either not consistent with the evidence, or for good reason, a patient and physician want to deviate from the plan. She also noted there may be situations where a series of doctors differ in their treatment assessment, providing further need for individualized determinations.

Foster Gesten responded that her points were well-taken, but that there are processes in place right now, whether by policy or statute, that deal with individuals with rare conditions, though they have not yet been woven into the process for benefit design. Dr. Gesten asked generally whether such a specific statement even belonged in the principles section. Ms. Benjamin responded that there needs to be due process built into the principles to provide that there will be recourse for patients who disagree with coverage determinations.

Patient Safety & Appropriateness

Joseph Stankaitis, MD, MPH, the Medical Director for Excellus/Monroe Health Plan, wanted to see something address patient safety and appropriateness for conditions such as angioplasty, where much of the literature suggests there is more harm than benefit. Dr. Gesten responded that the language included now regarding "criteria for

conditions for benefit coverage and appropriateness of criteria” was intended to address this point.

Evidence

There was a lengthy discussion of what constitutes appropriate evidence for creating benefit review criteria. One member of the Work Group asked if they should create two sets of operating guidelines regarding evidence used for benefit determinations; one containing high level principles, and the other denoting specifically what criteria would be used to determine whether there is sufficient evidence of effectiveness of a particular benefit or treatment. Dr. Gesten then opened the question up to the group, asking if they thought they needed a greater level of specificity in the principles of what counts as sufficient evidence.

Dr. William Gillespie, the Chief Medical Officer of EmblemHealth, explained that there are three forms of evidence that are regarded as reliable. The most reliable is evidence derived from peer review studies. The second most reliable is evidence derived by a panel of experts, while the minimum standard that still qualifies as being “evidence based” is “acceptable standards of care in the community.” He noted that the last form of evidence is the one most often relied upon in actual practice. In response to Dr. Gesten’s specific question, Dr. Gillespie opined that they should keep the principles simple to serve as a guiding framework. Other members seemed to agree.

Another member of the Work Group indicated that he was uncomfortable with one of the sentences that seemed to call for coverage of a benefit if there is “evidence that it is better than nothing for the population’s health.” He said this sentence meant to him that, if there is some procedure that gives a patient a 2% or 5% chance of survival and is very expensive, that the State would cover all such procedures.

Dr. Gillespie commented that the principles appeared structurally correct and appropriate, and that in his opinion, the Work Group should move on from here.

IV. Overview from OSHU Opportunities

Research Processes

Next, there was a presentation by Mark Gibson, who provided an overview of the research processes States use in determining what benefits to cover in their own government-funded insurance programs.

Mr. Gibson started with an overview of the research process, which includes the following five steps:

- Defining the question
- Searching the literature
- Appraising the literature

Synthesizing the evidence

Peer review

The starting point under the first step, "defining the question", begins with clarifying the key issues, abbreviated by the acronym "PICO Plus": Population, Intervention, Comparator, Outcome, and "Plus", which stands for policy context and analysis and cost effectiveness. While all of these must be clearly defined, Mr. Gibson noted anecdotally that States uniformly give the greatest emphasis to successful health outcomes that a patient can recognize and experience as opposed to a lab metric that it has a particular impact on health (e.g., cholesterol readings, glucose levels in diabetics).

Mr. Gibson noted that in many cases, States are using systematic reviews as a foundation point for their policy decisions, and in these reviews, all the "major databases" are generally searched. Potentially relevant research and evidence, once gathered, is then fact-checked using individual researchers who review sources and bibliographies to ensure that they have not missed anything that could be relevant to the State's decision making. Mr. Gibson emphasized that this systematic review is lengthy and expensive, as it typically takes one to two years to complete and costs around \$250,000.

Alternative options include using existing studies and updating them, or reaching out to Federal organizations for sponsorship or grant aid. Other cost effective options include limiting research to a set of core sources, such as researching a particular database like the Conklin Collaboration, which includes registries of trials and systematic reviews. Mr. Gibson noted that as costs are cut and the research becomes less exhaustive, the evidence becomes less reliable. Once research has been completed, the sources must be appraised to assign weight to the material retrieved. Evidence is typically weighted in the following order:

- Meta-analysis of randomized controlled trials
- Systematic review of RCTs
- Individual RCT(s)
- Observational studies (diagnostic accuracy)
 - Cross-sectional, cohort, case-control
- Basic science research and clinical experience
 - Guidelines

Next, Mr. Gibson discussed how evidence is then synthesized by comparing results and then graded, with the highest quality evidence being a series of randomized trials, the next best quality being a single trial or a randomized trial with minor flaws, and the lowest quality being the opinion of an expert in the field. High quality evidence "is a touchdown" he noted, since it can demonstrate from the systematic standpoint of a clinical intervention what does and does not work.

In response to some questions from members on the issue of medical judgment v. reliance on evidence, Dr. Gesten noted that, for folks making medical policy decisions,

evidence is essential, but not always sufficient, since judgment is always required. The point of the presentation was to provide a way to begin thinking about research, though admittedly, research does not always dictate policy or provide a crystalline answer every time. However, the reality is that high quality studies can and often do differ from each other, so evidence is necessary and sufficient because well-designed studies often arrive at different conclusions.

Members then discussed the issue of external v. internal validity. Mr. Gibson defined internal validity as, if in the best possible circumstances something works or not, while external validity means the study can be generalized into the real world. Dr. Chaudhry noted that in prioritizing evidence, there needs to be some kind of criteria that assures external validity. Otherwise, even if the internal validity is high, it is not going to be useful.

How to Use the Evidence

The next part of the presentation provided a series of examples of how States have used evidence to modify benefit determinations:

Missouri: Implemented prior authorization for certain interventions like hi-tech imaging following research of when it is appropriate to do CT scans around the head and thorax. Missouri was able to flatten their trend line and bring those utilizations down to a steady state.

Oklahoma: The Oklahoma legislature sought to pass a bill that its Medicaid program provide coverage for terbutaline pumps for pre-term labor; the Oklahoma Department of Health utilized evidence to show that there were significant risks and no evidence of benefit, and was able to prevent it from becoming a mandated service.

Washington: Instituted a robust health technology assessment process and direct use through state statute, whereby whenever a new request is brought to Medicaid cover a benefit, the requesting party must supply evidence that it actually works; this is what they use as a baseline for further reviewing the intervention.

Minnesota: Rather than using prior authorization for hi-tech imaging, they use an evidenced based decision support process through stakeholders to develop community centers of care to create support systems for managed care plans.

Overview of Examples

The purpose of this section was to provide examples of coverage decisions that have helped reduce costs for procedures with little or no demonstrated effectiveness. These benefits are either subject to prior authorization, automatic coverage limitations, or, are simply classified as “never events” under their State plans, because they are benefits that should never be covered. Examples of never events include proton beam radiation and real-time glucose monitoring for diabetes type 1 and 2. The other prior authorization and coverage limitation recommendations were:

Intradiscal steroid injection for chronic lower back pain (coverage limitation/prior authorization recommended)

Elective Delivery: Induction of Labor less than 39 Weeks (coverage limitation)
Elective Delivery: Cesarean Section less than 39 Weeks (coverage limitation)
Self-Monitoring of Blood Glucose for Type 2 Diabetes (coverage limitation)
Arthroscopic Surgery of the Knee for Osteoarthritis
Coronary Computed Tomographic Angiography
Insulin pumps (prior authorization recommended)
Vagus Nerve Stimulators for Depression (coverage limitation).
Functional Electrical Stimulators for Spinal Cord and Head Injury, Cerebral Palsy, and
Upper Motor Neuron Diseases (never event)
Terbutaline in Preterm Labor (coverage limitation)

One member of the Work Group commented that they should use a different term than “never event” to connote benefits that should not be covered, because the term is already used to refer to provider preventable medical errors that occur in hospitals and other facilities. Mr. Gibson noted the comment and agreed.

At the conclusion of the presentation, Dr. Gesten noted that the purpose of this presentation was to show the members what private payers and States examine in making benefit determinations. He further noted that some of the examples could be used as a springboard for prioritizing benefits this Work Group would review. Elisabeth Benjamin asked Dr. Gesten if they could asterisk the benefits NY already covers.

Some members asked about the scope of their work, and in particular, if they would be defining evidence-based criteria, creating a hierarchy of evidence, or deciding what benefits the State would actually be covering.

Greg Allen answered that the purpose of their meeting was to produce two things. First, a product to do on-going assessment of the benefit against evidence. Second, to create a set of concrete benefit recommendations they can submit to the full MRT.

Elisabeth Benjamin expressed that she was disappointed with the process because she believed that they (the Work Group) were the ones who were supposed to decide what benefits would be covered, but now, it sounded as if the decision was going to be made by some other entity (the MRT). Dr. Gesten responded that he did not think it was off the table, but nevertheless, that it was not “the list” that they wanted this group to deliberate on, but rather, the process for how they would make benefit determinations in the future.

Greg Allen followed this up by reminding everyone of the importance of their task. Referencing the Commissioner’s words from the prior meeting, he explained that with the growth in medical expenses and additional eligibles coming down the line, if they are not successful here, it will mean the need for across the board cuts, “which really damages the fabric of care.”

Dr. Stankaitis asked if DOH will be backing up the MMC plans if, for example, they decide to prior authorize certain procedures, noting that in many instances, the MMC

plan is left to determine its own criteria. Dr. Gesten responded that it should not just be the MMC plan's problem. Since we are dealing with a tax payer supported program, it is the State's problem and everyone's problem. He added, "maybe we should have a conversation on how we do prior authorization with principles and concepts, since no question, this is going to include the plans".

Members continued with general questions. One member asked about the new cap on therapeutic activity, and the rationale for imposing the cap? Mr. Allen responded that this was actually a great example of why this group's work was so important, since without this kind of "evidenced-based tool box" they are working to create here, they had to resort to instituting an arbitrary cap like the 20 use cap since they had no tools but did not want to cut the entire benefit.

V. Drill Down: Examples

While eliminating or reducing costly benefits with limited effectiveness is naturally a chief concern, there was also a discussion on how to increase utilization for effective, but underutilized benefits, like tobacco cessation. One of the slides presented demonstrated that in 2009, only 13% of smokers accessed this benefit. The question posed by DOH was, is there a benefit design issue that needs to be addressed? For example, does a reverse copay make sense to provide the necessary incentivization? Dr. Gesten noted that NY recently received a grant from CMS which may allow it to test various incentives. He further noted that there is also currently collaboration among various plans, as well as the American Cancer Society and the New York City Health Department, discussing ways to better market the benefit.

Paloma Izquierdo-Hernandez, the President and CEO of Urban Health Plan, Inc., noted that one problem that clearly stands out is that the benefit has to be provided by a physician, nurse, or a physician assistant, "who are often too busy and do it very fast and do not spend a lot of time on it". She recommended that they provide training and create certification standards for "tobacco cessation specialists".

Ira B. Lamster, DDS, MMSc, the Dean of Columbia University College of Dental Medicine, noted that there is a scope of practice issue here. Dentists could certainly do it, but it would have to be worked out between the Department of Education and the Department of Health.

VI. Costs of Inappropriate/Uncertain Coronary Angioplasty for Medicaid Patients in New York State

Dr. Edward Hannan provided an overview of percutaneous coronary intervention (PCI) (a/k/a, angioplasty). PCI involves threading a catheter to the coronary arteries, inflating a balloon to widen the narrowed artery, and usually inserting a stent to hold the plaque against the artery wall. While PCI is very effective for evolving heart attacks, its value is less certain for patients with milder heart disease. Dr. Hannan further explained that PCI has been increasingly used to treat complex coronary artery disease, although its appropriateness and efficacy continues to be called into question by recent evidence,

particularly when compared to other treatment options. In fact, a lot of evidence has suggested that patients have significantly more adverse coronary events following PCI than CABG, which has historically been the procedure of choice to treat heart disease.

Dr. Hannan next discussed the appropriateness criteria for PCI and CABG Surgery, noting that CABG has been found to have been appropriate 90% of the time, while for Medicaid patients that underwent PCI from 7/1/09 through 12/31/10, 1,003 patients out of 3,785 could not be rated, and of the remainder, 37% were appropriate, 51% were uncertain, and 12% were inappropriate. This is problematic considering the national cost of PCI is approximately \$20,000 per procedure.

Dr. Hannan then ran through three recommended appropriateness criteria to reduce the amount of inappropriate PCI procedures that occur and the savings that would be generated from each, assuming a baseline projection of \$20,000 per procedure:

if all inappropriate cases were eliminated or not reimburse: **\$4,320,000**

if all inappropriate cases and all cases without non-invasive diagnostic tests/without adequate documentation of disease from diagnostic tests were eliminated or not reimbursed: **\$17,693,000**

if all inappropriate cases, all cases without non-invasive diagnostic tests/without adequate documentation of disease from diagnostic tests, and all cases for which angioplasty had uncertain value were eliminated or not reimbursed: **\$36,667,000**

Thus, by instituting some required additional testing and safeguards, the State can cut down on its expenditures while simultaneously dissuading a costly and potentially dubious procedure.

After this presentation, Dr. Gesten and Greg Allen discussed the Medicaid fee For Service Radiology Program, which essentially implemented a prior authorization framework to limit what had become staggering growth in the utilization of radiology services. The limitation applies to non-emergency outpatient radiology only, and as of June-August 2011, utilization has decreased by one-third compared with a year ago. The DOH staff then opened the meeting up for comments.

Elisabeth Benjamin noted that if the State adopted one of Mr. Hannan's scenarios, there would be substantial hurdles to access because of all the requisite re-testing that would occur. She cautioned that the Work Group "carefully consider the externalities" of any such proposal.

Henry Chung, MD, the Vice President and Chief Medical Officer of CMO Care Management Company, Montefiore, commented that "adopting appropriate criteria, and integrating it into prior authorization, can be a very valuable thing". He noted that, often times, physicians will send stuff to Montefiore and hope they will deny it, so they can go back to their patients and say, "see, I told you this was inappropriate."

Dr. Eugene Heslin, representing the NYS Academy of Physicians, also noted that physicians need to consider how they practice medicine, because physicians tend to think their experiential knowledge is greater than what the actual evidence indicates. He also noted the difficulty of dealing with patients who will research or hear about a procedure and insist upon having it, and in the context of coronary artery surgery, those who will request PCI and then not make subsequent changes to their diet and lifestyle.

Some members then asked the DOH staff members, "what are the low hanging fruit they should go after? Dr. Gesten indicated that they had hoped the Work Group would identify these targets, joking, "there is no such thing as low hanging fruit when it comes to stopping something, because one person's waste is another's tuition payment". Dr. Gesten added that a major goal of this group is to identify some specific targets within the next month.

Ms. Hernandez asked if there was a way DOH could identify those really "out-of-whack expenses" so they can avoid cutting the whole benefit package. Dr. Gesten responded "yes and no"; while they can look at what is high and increasing, and identify where there is controversy around a particular benefit, or what other states are doing, and hope that there is some crosswalk there, a big part of their work is to develop a grid or matrix on what the low hanging fruit on benefit addition or subtraction are, and what the nomenclature around that would be.

Greg Allen commented that, when we think about how to use the third and fourth meetings, this question may be the one that get us to the final work product.

Ms. Hernandez suggested that they have the data drive their work, by looking at, for example, elective models for cesarean sections, and then compare NY's data against that of other states, this could direct them to the low hanging fruit.

Greg Allen noted that one thing that tends to be forgotten is that the spend for procedures is "not astronomical", and in general, the State ends up spending more on medicine than it does on surgery, and more on psychiatry and addictions than on evidenced-based and non-evidencebased procedures combined.

Dr. Stankaitis asked about the possibility of forming agreements with other States Medicaid Directors to accept each other's Medicaid rates in certain instances, noting that a lot of times, they have to send children out of state because they cannot find a provider to perform the procedure in state, and wind up paying a lot more money to the out-of-state provider because they do not accept NYS Medicaid. He noted, for example, that Cincinnati Children's Hospital performs cardiac procedures that no other provider performs in New York.

VII. Draft Proposal for Benefit Review Process

Dr. Gesten and Greg Allen quickly noted some draft proposals, which included

YMCA Diabetes Prevention Program
Pharmacist reimbursement for Tobacco Cessation
Nurse Family Partnership
Gender Reassignment
Counseling
Breastfeeding Consultants

They indicated that these would be flushed out and discussed in greater detail at the next meeting.