2016 TECHNICAL REVIEW PANEL
ON THE MEDICARE TRUSTEES REPORT
Minutes of the Meeting Day December 20th, 2016

The Technical Review Panel met on December 20th at 9:00 a.m. in Room 738G of the Hubert Humphrey Building in Washington, D.C. In attendance were the following panel members and presenters:

- Ellen Meara (Professor, The Dartmouth Institute for Health Policy and Clinical Practice), co-chair
- Michael Thompson (President & CEO Elect, National Business Coalition on Health), co-chair
- Kate Bundorf (Associate Professor, Stanford School of Medicine)
- Melinda Buntin (Professor and Chair, Department of Health Policy at Vanderbilt University School of Medicine)
- Austin Frakt (Health Economist at Department of Veteran Affairs and Boston University)
- Mark Pauly (Professor, Wharton School of the University of Pennsylvania)
- Geoffrey Sandler (Senior Actuary, Health Policy at Aetna)
- Greger Vigen (Independent Health Actuary)
- Dale Yamamoto (Founder and President, Red Quill)
- Don Oellerich (Deputy Chief Economist, Assistant Secretary for Planning and Evaluation at the Department of Health and Human Services)
- Paul Spitalnic (Center for Medicare & Medicaid Services (CMS), Office of the Actuary (OACT))
- Sean Keehan (CMS, OACT)
- John Shatto (CMS, OACT)
- Clare McFarland (CMS, OACT)
- Stephen Heffler (CMS, OACT)
- Murray Aitken (IMS/Quintiles)

Presentation Issues and Executive Summary—Michael Thompson

Michael Thompson began the panel meeting with a discussion of the executive summary for the Trustees Report. An executive summary could be an opportunity to concisely provide a status of the programs and describe key findings of the report. The summary could also differentiate between demographic issues and the inflationary pressures that contribute to excess cost growth. It could include items on each part of Medicare, the alternate projection, sensitivity analyses, and other related topics with a focus on the present. The summary could also place key data points and graphs that are currently buried deep in the report onto the front few pages. The key takeaway from the summary should be trend, particularly as it relates to whether spending is rising faster than gross domestic product (GDP). A panel member posed the question of whether the Trustees report is intended to highlight some of what might be policy issues or rather to provide a current snapshot of program status. Paul Spitalnic agreed that the intent of the introduction is to highlight key takeaways and that it may be valuable to revisit the content of the introduction or consider a new executive summary.

Panel members had other suggestions for content of an executive summary. A panel member said that the summary could be a suitable location for an item on excess tax burden. The summary could discuss what cost trends mean for the marginal tax rate, including payroll and income taxes, either using an average or various points in the income distribution. Another panel member noted that in other contexts, a complex report has been synthesized to a one-page document with a summary of key points intended for a congressional audience and that perhaps the panel could include something similar. A panelist noted that the Social Security Trustees Report has a one-page introduction followed by an overview section with a highlights subsection of about five pages. The panelists noted that all the relevant material is in the introduction currently, but that it needs to be more accessible. A panel member said that it might be better to have a one pager summarizing key findings concisely.

Paul Spitalnic agreed with these points, saying that the introduction should have the key points that the reader needs to know. He noted that the biggest changes in Medicare projections have been due to legislative changes.

Update on Medicare Advantage (MA) Spillovers—Austin Frakt

Austin Frakt started the panel discussion on Medicare Advantage (MA) spillover with an overview of the issue. Numerous studies have shown that as MA enrollment and penetration grows, traditional Medicare experiences slowdown in utilization, spending, and intensity. MA imposes managed care techniques, changes in referral patterns, lower intensity of capital investment, narrow networks, and other changes that tend to spill over into other markets. The issue for consideration is whether this effect is sufficiently reflected in projections. Austin Frakt noted that consideration of spillover less of an issue for the short-run model because the short-run model mainly reflects recent trends, but it is less clear how this is incorporated in the factors model.

MA spillover can affect Part A expenditures and actual expenditures manifested in claims. In regards to the long-term factors model the only explicit effect is in the average coinsurance rate. In some respects, spillover represents itself implicitly; for example, in the coefficient for annual GDP per capita and the residual, which incorporate reductions due to spillover. The elasticity of income and residual in the model are trended downwards on basis of historical patterns but there is no explicit notice of spillover. Austin Frakt recommended the report more address how factors such as managed care, public policy, and endogenous institutional factors are incorporated into the model through trended coefficients.

A panel member suggested that perhaps the recommendation could be extended to consideration of ways to explicitly incorporate spillover effects and tie them more explicitly to attributes of plans or enrollment. Austin Frakt agreed, and asked the panel whether this is a good investment of time and resources given the challenge of implementing these ideas and lack of information on explicit coefficients. He also suggested explicitly modeling public-side policies and the spillover the public side may have.

Another panel member noted that managed care generally rather than MA specifically may be important; and that practice patterns change across the board especially with tighter care management and coordination. A panelist suggested looking at spillover on a total market basis

and tracking days per thousand in the HMO and non-HMO side. Another panelist added that when private HMOs spread Medicare hospitalization rates decrease and that Medicare drug plans may get spillover from their non-part D business. In reaction to this discussion, Paul Spitalnic summarized the discussion noting that what is done currently seems reasonable, that this could be more adequately described in the report, and that there could be a recommendation to continue studying ways to more explicitly address the effects of spillovers.

Paul Spitalnic said that the spillovers attributable to MA plans may be slowing due to less expansion in the program. Austin Frakt mentioned that there are two forms of spillover, including the expansion of MA itself and innovations within MA plans themselves. A panel member added that expense spillover can reduce pressure on the sustainability of the program.

Part D and Pharmaceutical Assumptions—Dale Yamamoto

Dale Yamamoto shared some questions to frame the discussion of prescription drugs. He said that everything being done right now on Part D projections is reasonable and defensible. He then turned to his write-up, in which he describes the history of Part D since its inception, relevant developments that have occurred since this time, and an overview of basic assumptions being used. Paul Spitalnic reviewed OACT's approach to Part D spending. The agency analyzes all drugs, rolls them up into different classes, and analyzes how the classes change over time and notes which are going off patent. This is a bottom-up approach that was developed as a result of a recommendation from the last panel. In contrast, the national health expenditure (NHE) side is a more top-down look at aggregate spending.

Dale Yamamoto's piece includes historical Part D spending data and tables on per capita growth projections, historic monthly bid amounts, historical spending trends, coinsurances, and trend by plan type. Dale Yamamoto also noted differences in trend between commercial and Medicare and drug spending versus non-drug spending. The biggest recent development is the growth in specialty drugs, which has contributed to growth in reinsurance.

Dale Yamamoto observed several other trends. Generally, the Medicare population spends more on prescription drugs than the non-Medicare one. The claimant coinsurance on the commercial side is going down. There is a wide difference between reinsurance and direct subsidies for Medicare drug plans. There is also higher trend for reinsurance versus the direct benefit component of Part D plans. Paul Spitalnic noted that OACT does not have an explicit changing rebate percentage nor is this tied to utilization changes. However, rebate levels have increased in part due to Part D incentives for rebates over cost reductions.

Murray Aitken—Long-Run Pharmaceutical Spending

Murray Aitken is executive director of the Quintiles IMS Institute. The role of the institute is to undertake research that draws upon data and analytical capabilities from within the Quintiles IMS company. For this presentation, Murray Aitken drew material from two reports including Outlook to 2021, which is global in scope, and a report released in April that is a lookback at 2015 with respect to drug spending, utilization, and patient out of pocket costs in the United States.

Quintiles' findings concern all prescription drugs regardless of payment type, distribution, or whether they were branded, generics, or biologics. Quintiles analyzes the totality of all medicines requiring a prescription and uses invoice prices from wholesalers to customers. These medicines can be distributed in retail pharmacies, hospitals, clinics, and other settings. Quintiles uses the price that is recorded as a net sale by the manufacturer; that is, the invoice price net rebates, negotiations with intermediaries, subsidies to patients through co-pay coupons, price concessions, and other adjustments.

According to Murray Aitken's slides, per capita ten-year annual growth rate for total spending on medicines on a global scale is 1.5%. There are five major segments of market growth: (1) new branded drugs (on the market for less than 24 months), (2) branded drugs that have lost exclusivity, which are expensive due to loss of patent protection, (3) remaining or incumbent brands, which do not tend to grow in spending, (4) impact of price increases on existing incumbent brands, and (5) price and volume growth for generics.

Murray Aitken made reference to several trends pertaining to the aforementioned segments. There was moderation in 2014 and 2015 in growth due to patent expirations. Also, every year there are price decreases on average relative to pre-existing brand prices as well as increasingly high generic drug efficiency. At the same time, new brands contribute significantly to growth—up to $23 to 24 billion in recent years in large part due to hepatitis C, oncology, and, to an extent, diabetes drug net rebates and price concessions. There is a decline, however, in brand spending when molecules lose patent protection, as was the case for Lipitor in 2011.

Aitken then distinguished between invoice and net price growth. Quintiles compared the prices companies disclose in financial statements with net sales for major brands as well as volume shipped by manufacturers to volume dispensed through wholesalers. It compared price per unit to wholesale invoice prices. 70% of the branded total sales on invoice price basis skews toward larger publically traded companies since privately held manufacturers may not disclose. Invoice prices for brands peaked at 14% in 2014 then decreased to 12.4% in 2015. Net growth fell in recent years due to greater negotiating powers of intermediaries such as pharmacy benefit plans, the willingness of manufacturers to accept lower prices, and their desire to compete for formulary positions more aggressively. Higher rebates and co-pay vouchers adds to the discrepancies between invoice and net sale price, which totals $150 billion ($10 billion from offsets by manufacturer, the rest in rebates, including discounts from pharmacy benefit managers).

Going forward, in 2016 growth is projected to be 6 to 7% on an invoice price basis and 3 to 4% on a net price basis. From 2017-2021, invoice prices will grow at 6-9% as opposed to 4% on a net price basis. There may be some moderation as certain companies attempt to keep list price growth in the single digits. In 2018, there is an expectation of significant patent expirations. Also, biosimilars are increasingly becoming available, which could lower costs and inject more competition into the market. However, there is uncertainty as to the exact impact of biosimilars, especially since physicians may not consider them as safe or effective as more traditional drugs. In addition, there are a number of global medicines in late stage development, a number of which are orphan drugs. There is not an expectation, however, of a huge spending spike or another blockbuster drug such as Sovaldi.

Murray Aitken then turned to U.S. market growth. The U.S. market is different from other markets, including the European one, in the sense that growth in the former is concentrated more around price and for the latter is based mainly on volume increases. In regards to U.S. market trend, the Y2K factor led to a huge build up in inventory in 2000. There was a considerable slowdown in growth through 2012, followed by an uptick with additional branded drugs coming to the market. However, the desire not to acquire negative publicity and achieve better formulary placement combined with greater competition and blowback from physicians have caused there to be more moderate price increases. Also, there is more discussion regarding justifying prices using a value-based framework involving higher cost offsets. However, there are difficulties associated with developing outcomes-based contracts. There is uncertainty concerning the clarity of the outcome, the potential impact of comorbidities, the molecule profile, and the ability to isolate the effect of the drug.

Regarding broader trends, Murray Aitken said a significant issue is patient non-adherence to treatment. However, with data-based developments, progress has begun to be made on this problem. Another issue is bifurcation between patients who do very well and can be treated with low cost generic drugs and the smaller percentage of patients who only respond to expensive low volume drugs. There is also a shift in the site of care for dispensing drugs away from the office and toward outpatient clinics. Murray Aitken concluded by reiterating his desire to be helpful to the panel.

Panel Discussion of Uncertainty, Transition, and Next Steps

The panel returned to the previous discussion on drug spending. A panel member noted that there is a smaller chance of heroic measures at end stage but that over time, drug spending averages out, and that it may be problematic to consider recent historical trends permanent in forecasting. A panelists suggested having a different trend rate for the basic benefit portion of Part D versus reinsurance for both the extended short-term period and longer term. Paul Spitalnic said that OACT uses overall drug growth and a separate growth applied to the catastrophic side, which together balance each other out and reach equilibrium.

Stephen Heffler added that bottom-up drug growth, which ultimately transitions to NHE growth, becomes very speculative after three or four years. There is a range of opinions about what is in the pipeline, what is blockbuster, what will be big and small, and long-term trends need to be interpreted with caution. There is also a tremendous amount of uncertainty; few people expected the arrival and pricing of the hepatitis C drugs, for example. Paul Spitalnic noted that OACT uses the bottom-up approach for three years and transitions to NHE at year 6.

A panel member suggested that drug stock prices may be a good average predictor of the price of the treatments being produced and another member added that the stock price upside may not be as predictive as the downside. A panel member asked about the potential recommendation—in particular, whether the difference between the trend rate for standard benefit growth and reinsurance is different from what is included currently. A panel member asked if it is possible to know the brand versus generic split for the standard benefit versus reinsurance. Paul Spitalnic raised the point that what happened in the last five years is not likely to continue to occur in the next five years so it is hard to use past data to predict the future. Paul Spitalnic added that the majority of the Part D benefit goes to people using very expensive drugs,

a relatively small group, while the median spending per beneficiary has dropped. Therefore, growth has distributional effects and it is not even across all Part D beneficiaries which could affect the beneficiary decision to participate in Part D.

The panel subsequently turned to the topic of uncertainty. Paul Spitalnic noted that there are two key types of uncertainty. First is policy uncertainty and second is overall parameter assumption uncertainty, referring to the right way to demonstrate, estimate, and adequately describe a relevant trend. Sensitivity analysis pertains to a larger category of projection uncertainty or assumption uncertainty. Paul Spitalnic also asked the panel whether there are there better ways to describe assumption uncertainty beyond the high and low cost estimates.

A panel member noted that in the Trustees Report, a sensitivity analysis of +/− 1% is applied to costs relative to payroll, but explaining this further would be helpful. Another panel member suggested only using the high/low on health care cost growth, though health costs are rarely, if ever lower than economic growth. This panel member also said there should be a more explicit illustration of uncertainty on cost growth. A panelist suggested using a stochastic model based on cost trends, which could give a framework for cost trend projection. Another panelist noted discomfort using stochastic modeling to provide a range of uncertainties.

Ellen Meara returned the panel to the guest invited for the next meeting, Elizabeth Fowler. She can give the panel useful advice on the alternate projection. The panel can also ask her about political uncertainties relating to current law and CMS/CMMI activities/innovations.

Ellen Meara then returned the panel to its to-do list. In particular, there are several items on the list: (1) Spillovers, (2) Illustrative Alternative/Sustainability, (3) Uncertainty, (4) Alternative Payment Models (APMs), (5) Prescription Drugs, (6) Transitions, (7) Age issues (e.g., time to death, spending by age), (8) Executive Summary, (9) Access/Excess Burden, (10) Incorporating trends in health status, and (11) Intensity of Service Issues. Following up on this list, Michael Thompson said that the panel had a good discussion on the executive summary, which accompanies access and excess burden. He will continue to lead on this item while others help. Geoff Sandler volunteered to assist on the summary and Mark Pauly volunteered to continue on access and excess burden. Paul Spitalnic noted that it may not be possible to collapse access/excess burden into the executive summary but they could be components of sustainability.

On the illustrative alternative, Kate Bundorf will to continue to flesh out her findings and draft recommendations. Michael Thompson and Greger Vigen volunteered to help on the assumption aspects of this item. In regards to spillovers, Austin Frakt will write a revised draft of what the panel discussed and include APMs as a part of his piece—that is, how explicit should the report be in describing their effect. On prescription drugs, Ellen Meara advised the panel to listen to Elizabeth Fowler before formulating recommendations.

In regards to transitions, the panel has detail on how OACT constructs the blended alternative. Ellen Meara will work on that topic and draft a piece on the implications of blending short and long-term projections. Ellen Meara will also proceed on the topic of age and time to death. She will schedule a call with OACT to reconcile spending by age and how that fits in with time to death.

On site shifting and intensity of services the relevant question concerns whether the panel needs to do more or if this item can be tied to prescription drugs. A panelist noted that the panel should come back to this issue with specific information sources noting that it is not certain as to whether it is actionable. Also, there is a question as to whether the downward trend in inpatient utilization/spending deviates from recent historical experience enough to warrant modifications. Greger Vigen also volunteered to more closely analyze differential growth by part, as seen in Table 2D-1 on the Trustees Report.

For the other topics, Melinda Buntin volunteered to conduct further analysis as to whether uncertainty can be presented differently in the Trustees Report. A panel member posed the question of whether error bars on estimates of the elasticity for the factors model trended forward could be informative of uncertainty. Mark Pauly will continue working on sustainability, which incorporates the topics of access and excess burden. Melinda Buntin will contact her colleague Jon Schwabish who specializes in data visualization for policymakers to assist in this work.

There was no public comment for the meeting. Ellen Meara adjourned at 2:30 p.m. The next panel meeting will take place on February 7th and 8th.