Responses to PTAC PRT Questions Batch 1

Overarching Questions:

1. The proposal states, "In this initial phase, we are focused on the work of general surgeons and other surgical specialties. However, we expect the model to expand over time to include both acute and chronic medical conditions as well." Pleased confirm whether or not the model you have submitted for review and comment by PTAC is limited to a proposed model for surgical episodes, or if you are requesting PTAC review of a model for other acute and chronic condition episodes. If you are requesting review for non-surgical episodes, please indicate how non-surgical physicians and specialty societies have been involved in the development of the proposal and whether they have indicated interest and willingness to utilize the model if it is made available.

The ACS-Brandeis model is patient-centric and can be implemented by all payers, respecting the clinical work of all providers. We proposed phased implementation for practical reasons, including the finite bandwidth of the development team to this point, and the process envisioned for other medical specialties to review and refine episode specifications pertaining to their respective clinical domains.

Our initial submission makes available approximately 120 episodes. These include procedures typically performed by general surgeons, along with their common indications (conditions for which the procedures are done), and common sequelae (conditions that can arise in the context of those procedures). The initial set of 120 episodes also includes other procedures typically performed by surgical subspecialists, along with their indications and sequelae, and several other condition episodes that were developed and vetted in conjunction with EGM itself. EGM is a comprehensive system that recognizes every diagnosis and procedure code appearing in claims data, and includes metadata to interpret their meaning with respect to well over a thousand clinical concepts. The reviewing and refining process is intended to ensure validity and clinical acceptance regarding how individual services are represented in the episode system.

We have invited and received inputs from various specialties – including the American Society of Anesthesiologists and the Society of Hospital Medicine in terms of the metadata files used in the EGM logic. Our goals, with CMS' endorsement, would be to include more of the delivery system in these initial episodes and to expand the foundational work that has occurred in the many other episodes covering Parts A & B expenditures (see attached episode list). The episodes are designed for immediate movement to an implementation effort (with the continued input and support of the specialty societies involved) in a CMS program or as a pilot. We recognize that clinicians who participate in the clinical services within an episode may phase-in over time as qualified participants in an advanced APM. This means that a surgical episode may allow for formal participation of surgeons, anesthesia and hospitalists in the initial phase. Other clinical disciplines, such as PCPs, radiology and pathology may require more work before they are willing to consider their risk-based role in this model.

In 2016 we held a series of open webinars totaling more than 10 hours in presentations and Q&A, and more than a hundred participants. The purpose of the webinars was to propose options for the model, explain various components, seek comments and suggestions, and educate a growing community of clinical and policy experts who may support the implementation of this

model as an advanced APM. In addition to those plenary sessions, members of the ACS-Brandeis APM development team held other targeted meetings such as clinical review webinars, aimed at explaining the clinical logic and answering common questions from clinicians, and individual meetings with participating societies. We maintain a distribution list for the project with representatives from at least 30 organizations, although again, widespread or sustained outreach has not been possible to this point.1 We appreciate the public meetings and distribution of materials carried out by PTAC.

With all that in mind, we request that PTAC review the proposal from the perspective of procedural as well as condition episodes. As indicated in the proposal, there are 54 procedural episodes, 29 acute conditions, and 38 chronic conditions ready for review and implementation. Together, the episodes describe at least $174 billion in Medicare spending per year. We propose that implementation can proceed in stages mostly for practical reasons, and as a way to build up experience and confidence towards the longer run goal of systemic change.

2. How do you believe your proposed payment model differs from the resource-based payment adjustments under MIPS that will be based on the CMS Episode Grouper?

We agree that the CMS episode grouper is capable of providing the clinical logic and episode construction logic to support MIPS, as well as ACS-Brandeis and possibly other APMs. MIPS is a large and complex program that would be well-served by the expansive coverage and consistent logic available in EGM, as well as its ability to apportion costs among concurrent and clinically-related (e.g., nested) episodes without double-counting dollars or savings. Thus, in terms of measuring costs and savings at the episode level, our proposal needn't be different in principle from MIPS, and in fact there is virtue in having consistency of methods across the programs.

EGM operates by sorting claims data chronologically by beneficiary, identifying episodes of care during the observation period, assigning relevant services and costs, and linking episodes that are related clinically. The software forms groups of 5,000 beneficiaries at a time, and processes the groups using as many computer processors as are available, in parallel or in a cloud computing environment. Hence, even extremely large data files (e.g., the Medicare population for a year) are divided into chunks of 5,000 for the core grouper activities, and then saved in unified output files that include the original claims and all of the information necessary to analyze episodes of care. A major implication is that CMS could run national data files through EGM, and then use portions or all of the "grouped claims" for single or multiple policy purposes, such as the ACS-Brandeis model, MIPS, and reconciling accounts across APMS. This would provide CMS with an efficient mechanism for automating the "big data" tasks along with consistency and coherency across programs benefiting from the clinical logic.

However, MIPS and Advanced APMs are not intended to be identical programs. Our proposal differs from MIPS in several important respects. First, if all APM entities improve quality and

[1] AAFPRS, AAMC, AANS, AAO, AAOHNS, AAOS, ACOG, ACOS, ACP, ACS, AMA, AGA, APSA, APTA, ASA, ASBS, ASCRS, ASPS, ASTS, AUA, Bariatrics, FAH, LUGPA, NASS, Premier, SAGES, SGO, SHM, STS, and SVS.

resource use then they all gain. The more they improve the more they gain, both individually and collectively. MIPS, in contrast, is a zero-sum game.

Second, the proposed APM measures cost and savings at the level of the APM entity, not at the level of a TIN or TIN/NPI. Our model calls for voluntary risk arrangements and opportunities that are on a larger scale than MIPS clinicians, whether measured by individual NPI or TIN, and reinforces this with multiple attribution, which acknowledges a role for each clinician who provides services to an episode. Also, the risk arrangements may include hospitals and other institutions in addition to clinicians. This will allow for better alignment of resource measurement with the organizational level at which changes and investments are needed to create improvement.

Third, in MIPS resource use is just one of four domains of measurement. Two of the other three are process domains. The proposed APM focuses on the two outcome domains, resource use and quality. Furthermore, our model acknowledges the interaction of cost and quality. In contrast, MIPS so far has treated quality and resource use as distinct, non-interacting domains.

Fourth, although more development will be required, our model calls for synergistic merging of cost and clinical information so that the latter can inform cost expectations, and allow for quantification of differential clinical outcomes in relation to incremental cost.

3. How is this proposed APM different from CMS' Bundled Payments for Care Improvement (BPCI) initiative?

Although the ACS/Brandeis APM includes episodes or bundles of care, it is a much more comprehensive, patient-centered model than BPCI. Fundamental differences between the two models include the following:

Episode construction. Episodes in EGM are triggered by ICD9/10 diagnosis or procedure codes rather than MS-DRG, which is a label and payment category pertaining to hospital reimbursement and is determined after discharge. Triggering an episode on a limited set of MS-DRGs tethers the definition of an episode to an inpatient admission, which is problematic in terms of messaging and efficiency. CMS has promoted innovations such as observation stays or ambulatory alternatives to inpatient admissions. Meanwhile, providers cannot know which patients will actually be assigned to a bundle because the MS-DRG is not known until after discharge. Bad patient trajectories, such as ICU admission, major complications, and related MS-DRGs can disqualify a patient from the bundle that would have pertained in BPCI if untoward events had not occurred. Please see the attached public comment letter from HCI3 to CMS regarding limitations of triggering based on MS-DRG, and the substantial comparative advantages to basing a model on EGM.

The ACS-Brandeis grouper allows for multiple simultaneous episodes per beneficiary, and assigns all services according to clinical relevance. The model is based on a comprehensive taxonomy with hundreds of episodes, allowing each service to find its best assignments based on timing and clinical relevance. This is in contrast to the BPCI exclusion lists, which are based on the assumption that everything is in the episode unless actively excluded.

Risk protections. The ACS-Brandeis model can use several types of risk adjustment to calculate an expected cost for each patient for each episode, including specific comorbidities, attributes of the episode such as surgical technique, indication and anatomy, and timing (concurrent medical events versus recent or further in the past). In contrast, BPCI adjusts the target price, or even excludes patients, based on the eventual MS-DRG. Both models trim the costs of outlier cases. BPCI employs statistical adjustments that blend a site's actual cost with the average cost of all sites based on sample size and variance.

Team-based care. The ACS-Brandeis model is focused on the patient, and the clinical team, but not on the setting of care. The model assigns a role to every clinician involved in the care of a given patient for a given episode. This information can be used to support care redesign and gainsharing in ways that go well beyond inpatient or institutional care.

In addition, the ACS-Brandeis model can be scaled to cover the majority of clinical work for a clinician, group practice, or delivery system and is not limited to one episode at a time. This difference is important because it provides the financial incentive and organizational impetus to invest in system-wide care redesign.

4. What types of surgeries or conditions would be most appropriate for testing or implementing the model?

The developers have prioritized implementation based on several factors, including but not limited to, the state of development of episodes within the EGM, preferences of specialties participating in clinical review, which episodes are most likely to make it possible for physicians of a given specialty to qualify as Advanced APM participants, and episodes likely to have larger variation in outcomes or cost. Our focus begins with patient-centered Clinical Affinity Groups (CAGs) such as cardiac care, musculo-skeletal care, oncologic care, chronic conditions population management, etc. If implemented, CMS may choose to prioritize episodes within a CAG using several criteria:

- Ease of implementation
- Promote early adoption
- High variation
- High volume/high cost
- Performance measurement discernibility in low cost variation

The EGM contains a number of fully developed episodes that could be rapidly implemented and a greater number of partially developed episodes which could be implemented within a reasonable time period. (Please see the attached list of episodes in development along with those that are fully developed. The fully developed episodes could be implemented immediately pending approval from the participating specialties involved.)

5. How do you envision the episode grouper definitions and parameters being updated over time? Will that be done by CMS, by ACS, or through some other mechanism?

The ACS-Brandeis APM is based on the software and clinical logic of the Episode Grouper for Medicare (EGM). The EGM grouper definitions and clinical logic are designed to be updatable whenever clinical practice changes. Updating will be necessary to keep up with advances in clinical knowledge, with technologic advances, and with the coding changes that such advances mandate. The EGM, as a public domain program owned and developed by CMS, will need support and infrastructure for continuous updating to maintain currency.

The Brandeis team has developed a process and software management tools to create, modify, and vet episode rules and specifications with clinical experts, including members of medical specialty societies, practicing physicians and other interested stakeholders. The process begins with a series of tables that show trigger codes, trigger rules, relevant services and diagnoses, sequelae and, for procedure episodes, indications. For refined episodes, these lists have generally gone through multiple rounds of vetting. For episodes undergoing more basic refinement, these lists are generated from associations in claims data. Either type of list can be reviewed by a group of clinicians, with comments coming back to a central group for review and final action (accept or reject the proposed change). With support, these methods and tools can be sustained and implemented to keep the episode specifications and APM algorithms up-to-date.

One theme in our proposed APM is that CMS ensure a widespread but consistent diffusion of the underlying technologies, including the EGM software itself, as well as the clinical metadata used to specify episodes. We call this the "single-grouper" solution, and it is intended to create a consistent national standard for defining clinical concepts and episodes, determining how to assign services and costs to those episodes, and communicating important clinical associations such as indications for procedures and related sequelae. Without such discipline, there is great potential for redundancy and miscommunication whereby N payers work in conjunction with M provider groups to produce N × M idiosyncratic and misaligned "groupers" that thwart aggregation and valid comparisons.

Whether the technologies are implemented as a single-grouper solution across payers, or if CMS simply supports the model as an advanced APM, the technologies will need to be updated and maintained over time. CMS owns the software and will need to make any necessary updates and specify the version used at any point. If CMS makes the software available to other payers or entities, they will need to keep track of new releases, and which version they are using for a particular purpose. Similarly, each application requires a proper and current version of the clinical metadata. We wish for a situation in which the software and metadata are licensed or at least protected by copyright so that everyone can have confidence in the contents of each designated version, and any results used for performance measurement or payment. We wish to guard against various payers or providers making idiosyncratic changes to the contents without at least stipulating nonconformance with the prevailing standard versions.

The current model is built as a business construct using the EGM developed for CMS by Brandeis. The ACS-Brandeis construct of a business model is built on this work product which represents Clinical Affinity Groups that participate in episodes, and built into clusters of episodes for contracts to a third party such as through an APM entity or payer. All copies of the clinical metadata and measurement algorithms for this APM currently reside at Brandeis. Further, ACS has created a phases-of-care quality overlay with dyads of measures that are patient-centric, CAG-centric measures with shared accountability. The IP aspect of these elements of the proposal are currently under internal review with regard to their proprietary nature. Our intent is

for this model to be freely licensed as an APM for all payers and is not subject to change without review and approval by the ACS.

ACS is furthering its efforts in the phases-of-care measures and patient-reported outcome measures (PROMs) for MIPS. Our efforts seek a common measurement environment for MIPS, APMs and all payers so that the measurement focus is directed toward optimal care and not solely linked to a payment program. Again, it is our intent to freely license these efforts for their public use. However, development costs and maintenance costs for performance measurement require resources. To the extent payers do not support these development and maintenance expenses, we would expect licensing agreements that support a going concern in these programs.

6. Will physician participation in the model require the use of proprietary intellectual software/decision support tools?

Physician participation in the model as an advanced APM entity would not require their use of any proprietary tools. The model holds the promise of illuminating service utilization and spending patterns uniquely so that entities can understand their cost structure within and across episodes, and respecting the work of all clinicians participating in patient-centered care. Thus, it behooves CMS and other payers to generate actionable information on behalf of participating entities and providers, or to provide those entities with original data for analysis for that purpose. We presume that any tools that CMS uses to implement the model would be put into the public domain or made available to participating entities.

Questions about Risk Adjustment:

1. The risk adjustment system seems to be driven by its ability to predict current spending, rather than to ensure higher budgets for patients with hither needs? Have you considered using a clinical category system instead?

The purpose of the model's risk adjustment is to determine an expected cost, or budget, that appropriately reflects patient need. It does so by 'predicting' current spending based on patient risk factors and the assumption of 'average' efficiency. So the ability to predict current spending is how it ensures higher budgets for patients with higher needs, not an alternative. While not ideal, current spending is the most practical available measure of patient need in terms of a cost budget. We are aware of no evidence that the estimate of patients' relative need would be different if only the cost of 'appropriate' services were used.

The risk factors of the model's risk adjustment system are co-existing clinical categories, applied in a multivariate model. We considered an alternative of mutually exclusive clinical categories such as MS-DRGs or RUGs but concluded that such an approach was unwieldy and impractical for the proposed model.

2. Have you considered re-estimating the risk adjustment regression coefficients after deleting the services where you think savings opportunities exist, so that they better predict appropriate spending rather than current spending?

No. This idea seems to presume that reducing cost is just a matter of identifying and removing specific services (identifiable by CPT code) that are always unnecessary, or that claims data has sufficient information to support algorithmic identification of when each service is appropriate and when not. We don't think this is correct, and it seems impractical in any event.

The question may also imply that budgets (independent of risk-adjustment) should be set to reflect an estimate of what is 'appropriate' rather than simply what is. Aside from practicality, we think it better to base the APM's budgets on current average costs, including inefficiencies that may be identified and removed as providers engage in care redesign. The difference between their actual cost, including those efficiencies they are able to engineer, versus the original predicted cost constitutes the estimate of savings for that episode. As part of information feedback, we have considered publishing guidance that includes differential predicted costs associated with different scenarios. For example, the expected cost for a procedure may be significantly higher in the presence of certain identified comorbidities. Similarly, the expected cost for a procedure may be significantly higher if a more expensive setting of care, or surgical technique is selected by the provider for a given patient. The guidance would inform providers about how the expected costs can vary, informing their decisions affecting eventual cost and quality outcomes.

3. How will you ensure that risk adjustment is based on accurate and current comorbidities vs. what appears on claims forms?

An initial phase risk adjustment will necessarily rely on information from claims. Our concern with this is not the accuracy or currency of claims, but rather their completeness.

Because the proposed model is retrospective, claims information will be 'current' with respect to the episode-periods. We propose not to include information from within the period as a matter of policy, not because of information constraint. To the extent that claims are inaccurate or not current, it will be incumbent on providers to ensure or learn to include accurate and current comorbidities in the claims that they submit, and the proposed model would give them incentive to do so.

Addressing the important concern of information completeness will require incorporating new sources of information. The proposal anticipates future development to incorporate more complete clinical information from registries and/or EHR systems into episode formation and risk adjustment.

4. How will patient functional status be assessed and incorporated into risk adjustment?

The work of developing additional data sources with more informational value than claims should include any measures of functional status deemed to be appropriate and necessary by the clinicians who specify the contents of such registries and EHR systems. As with any risk factor, they should be found predictive and supportive of the desired incentive structure.

Once appropriate data are available, patient functional status could be incorporated as additional risk factor(s) in the proposed model. The episode based measure framework is ideal for testing high value, goal-based process measures which could incorporate functional status and goals for improvement. Such goal-based process measures are also ideal for inclusion in the episode based measure framework as a linked measure to dyads of related PROMs. For example, functional improvement as a goal can be linked to a PROM which assesses the level of achievement on a Likert scale.

Questions about providers:

1. Are providers grouped in a defined episode inclusive of those not participating in the risk arrangement?

Yes, some clinicians participating in the care of the patient for a given episode may not be participating in the risk arrangement. Those who do not elect to participate in this APM may continue to provide care for their patient and participate in MIPS or other APMs. The ACS-Brandeis model does not restrict beneficiaries' freedom to choose among providers or preclude providers from seeing their patients.

Importantly, the logic and calculations of value are patient-centered, and are not weakened or contorted in order to accommodate residual silos, or to preclude shared accountability across risk environments (e.g., clinicians in two separate APM entities seeing some of the same patients). All clinicians participating in the care of the patient affect the eventual cost and quality, and from a professional perspective are part of the clinical team. The performance standards do not carve out or ignore the contributions of any clinicians to the results for the patient.

The ACS-Brandeis model does not attempt to judge the contributions of individual clinicians to the results for a patient. Evaluations of quality, cost outcomes, and value are determined statistically over patient cohorts (analogous to a "flood lamp") using the patient's team-based care as the unit of analysis (a "spotlight"); whereas no conclusions can be drawn simply from the individual clinician's role (a "laser beam") apart from the patient-centered and team-based contexts.

Which is not to say that status quo conditions are optimal. Empirical evidence suggests there are many more clinicians participating in patient care, and many more services and costs than may be optimal. Strengthening the clinical teams is a part of the work of the APM entity to help improve and ensure high value.

2. What happens if a PCP is not formally part of the team? How will any shared savings or shared losses associated with the PCP be dealt with?

The fiscal attribution logic in the ACS-Brandeis model includes a role for the Primary provider(s) who see the patient over time. Their contributions to the actual results for a patient are real and important. Their contributions are counted formally as their "shares" in those results. Each clinician's shares rightfully belong to them in the evaluation of their contributions to cost and quality outcomes for their patients.

The ACS-Brandeis model does not appropriate those shares, positive or negative, and redirect them through attribution to other clinicians. In an episode, if physicians in a particular service area do not contract with the APM entity to accept risk, regardless of whether it is a PCP, Anesthesia or other specialty, that percent of the risk is retained by CMS and can be attributed appropriately to other auspices. When clinicians are participating in care for the same patients and episodes, then their proportional contributions should follow them into consistent evaluations of value, either as part of their affiliated APM entities, or as part of their MIPS CPS.

3. What happens if a particular specialist doesn't want to participate?

The ACS-Brandeis model was developed to respect and attract specialists into formal CAGs and team-based care guided by an understandable and fair value proposition. MACRA does not force physicians into APMs, let alone into a specific APM or entity. A particular specialist may prefer to remain in MIPS, or to participate in a different APM entity. The model fully expects not all specialists will participate in all episodes and all service areas, at least at first. Over time, we would hope that with more exposure to the model, more specialists would find value in the risk arrangement and join as a participant in an A-APM. An episode might call for a PCP, a surgeon, a radiologist, anesthesiologist and more. If only the surgeon participates, then only 40% of the risk in that episode would actively apply to that entity.

A more nuanced answer would consider three aspects of the question. First, as in our answer to the prior question (#2), the financial shares attributed to the specialist as a Principal provider would be handled properly as with the Primary provider; i.e., as part of the evaluation of that provider under the auspices of his or her affiliated APM entity, or under MIPS. Second and similarly, a particular specialist may prefer to operate under different auspices (another entity or MIPS), and the model allows for that.

Third, the premise that “a particular specialist doesn’t want to participate” could convey a negative connotation, namely that he or she does not want to participate in value-based care, or secondarily to participate in efforts to achieve benchmark quality and cost outcomes. This scenario emphasizes the need for all clinicians participating in team-based care to work on behalf of the patient to achieve high value, and this includes trying to convene optimal teams, and influencing all team members to strive together for the best outcomes. This also emphasizes a premise of the ACS-Brandeis model, namely that even clinicians who prefer to hunker in silos will be held to the same standards deemed appropriate for the profession. A corollary is that such clinicians should emerge from the silos and contribute to defining and achieving appropriate standards. The ACS-Brandeis model allows physicians to choose their organizations of practice, and still separately participate actively and effectively in team-based care.

4. Who determines a particular clinician’s role in a given episode?

Fundamentally, the various providers along with the patient jointly determine the clinicians’ roles. In the ACS-Brandeis model, clinical logic is implemented through algorithms that infer

and assign the various roles for clinicians, and corresponding percentages of risk. Clinicians' roles can change according to the needs of the patient.

The ability to infer and assign roles is facilitated by the careful articulation of episodes by the EGM. For example, a physician could enter a case to diagnose or treat sepsis that is a sequela to a prior condition, such as pneumonia. That physician could have a substantial role in the sepsis episode but no role in the prior pneumonia episode, meaning no individual responsibility for the onset of that individual case of sepsis. Having said that, if physicians who routinely deal with pneumonia and sepsis cases work under the common auspices of an ACS-Brandeis model CAG, then they will work together to identify opportunities through shared accountability and common interest generally to prevent the onset of sepsis in pneumonia cases.

We recognize that MACRA and CMS will call upon clinicians to self-report their roles in the context of episodes. Once implemented, and for quite some time, using algorithms that infer roles in conjunction with primary data may lead to optimal assignment of roles. In either case, the articulation of episodes by the EGM provides the context for interpreting the roles assigned to individual clinicians.

5. What specific specialties or practices have indicated willingness to participate in the model?

Surgical specialties, Anesthesia, and Hospitalists have all expressed interest. Our efforts have also invited PCPs and a few medical specialties. See also our answer to the first question in this document.

6. What is the minimum composition of a Clinical Affinity Group needed for the model to be successful?

We have posited CAGs to represent the multidisciplinary contributions needed to critique and to redesign care, including appropriate guidelines, and supporting technologies and service capacity. The composition of a CAG is conditional on the subject of interest. In some respects, these begin with the larger specialties whose members participate in care for a particular condition or type of episode. For example, cardiology as a clinical profession and specialty, along with others, meaningfully defines appropriate care for patients with cardiovascular conditions. Such blueprints need to be adapted and implemented to local circumstances. That speaks to the great potential for regional collaboratives to help engineer coherent delivery and referral systems in local areas. Even further, implementation must occur at the patient level, involving the rosters of professionals and numerous settings of care available to patients residing in particular locations. That is the role of the APM entity.

Thus, at the entity level the minimum composition of a CAG is reasonable representations of the multidisciplinary contributors to the care needed to succeed given the context of an episode. If the criterion for success involves quality and cost outcomes for procedural episodes, then a minimum composition might include the surgeons, medical specialists, and anesthesiologists. More generally, the idea here is to connect the major elements of the team in a context of innovation and shared accountability for the sake of optimal quality and cost. In the ACS-

Brandeis model, the mindset of shared accountability and meaningful innovation is not constrained to new "silos" created by entities, especially if CMS and other payers extend measurement of the shared accountability to the clinicians' respective organizations of practice, APM entities, or MIPS.

7. Is there a minimum threshold as to how many/which physicians need to be involved in the Alternative Payment Entity in order for the payment model to work?

This is a central question for all APMs. Can anyone expect consistently positive and substantial results if most of the "team" isn't motivated or able to help? That was a death knell to the SGR. That also can be a limiting factor for population-based models with undifferentiated "networks," and possibly for facility-based models that attempt to lasso professionals into helping the cause.

Motivation is a complicated concept. For the most part, the ACS-Brandeis model follows the premise that clinical professionals benefit from motivation to participate in systemic solutions, and not from nominal or pecuniary "rewards" for idiosyncratic solutions or individual heroics. As Daniel Pink argues, there is a mismatch between the science of motivation and common extrinsic motivators (e.g., see http://www.ted.com/talks/dan_pink_on_motivation). The ACS-Brandeis model appeals to clinicians' intrinsic motivation for autonomy, mastery, and purpose; in contrast to micromanagement consisting of carrots and sticks. Accordingly, the work of the CAGs and APM is to make the rules simple for clinicians by clarifying professional standards and best practices, and implementing corresponding systems of support.

The minimum threshold question pertains to the critical mass required to amass sufficient numbers of cases, shared savings, and participating clinicians to enable and sustain the adoption and implementation of all the ingredients necessary for excellent care. That is a business question related to ROI. If a "million-dollar robot" or other capital investment is a cost-effective move, how large must a business be to enable and justify the move?

The ACS-Brandeis model combines the potential coverage of a population-based model with the specificity of bundle-specific ROI questions. For QPs by and large, their clinical work is included in the APM by definition via the episode clusters. Hence, their threshold of participation and interest is intrinsic to the model. And by joining into shared accountability under the auspices of an entity, the idea would be to achieve critical mass regarding care redesign, subject to adequate scale and commensurate returns sufficient to cover fixed costs associated with implementing the new clinical vision for care.

Questions about targeted patients:

1. Does the patient have complete choice as to which physicians will be involved in their care, where they will receive post-acute care, etc.? What does the phrase "we do not expect that patients will be able to opt out" (page 18 of proposal) mean?

Although the ACS-Brandeis model may eventually expand to include provider contracts with Medicare Advantage plans, the proposal is intended to start with original Medicare. As such,

there are no limits intended on beneficiaries' freedom to choose providers. By and large, beneficiaries' choices probably first involve Primary providers managing their care over time, and Principal providers managing particular conditions over time. Those providers likely will help beneficiaries choose episodic providers in many cases, i.e., surgeons and possibly the Principal/Episodic providers during acute condition episodes.

In situations where beneficiaries choose clinicians who are participating in the APM entity, we do not expect that those patients will be able to opt out of the team-based protocols intended to improve value, or possibly even patient-reported outcome measures that may be intrinsic to evaluating performance. In other words, if the patient's providers have opted for the APM, then the patient's experience will reflect life in the APM, and not MIPS.

2. If patients will not "be able to opt out of individual bundled care arrangements of the providers from whom they seek care" does this mean that they must limit their chosen providers to those who voluntarily are part of the bundle?

No, the ACS-Brandeis model does not create a closed network of providers for beneficiaries. For example, if a beneficiary's PCP is part of the ACS-Brandeis model and functions as a Primary provider, that does not result in a closed network of potential specialists or surgeons.

Questions about the Quality/Appropriateness:

1. What kinds of quality improvements do you expect to achieve, and how will those improvements be achieved?

This proposal aims to improve quality by effecting positive change in team-based care processes. The model will focus provider attention on the drivers of excess cost during the episode period. We believe that this will lead to innovative efforts to address not only low-value resource utilization but also quality-related events such as unplanned readmission or reintervention, wound complications, hospital-acquired infections and other HACs. Indeed, in automatically capturing all plausible clinical sequelae and attributing them to the Clinical Affinity Group (CAG) or team of providers involved in care delivery, the model builds in an incentive to avoid complications that is far more sensitive than any single measure or group of measures. Effective countermeasures to each of these complications vary by practice size/type and patient characteristics. Improvements are ultimately expected on several possible axes including; patient safety, complication-free quality, functionality and quality of life (as reported by the patient), efficacy, and resource efficiency.

The model is not, and should not be, prescriptive with regard to how each provider or group approaches these efforts, as best practices are constantly evolving and there is no desire to constrain this process by mandating compliance with particular care practices. In other words, rather than trying to delineate the "ideal bundle" in each episode we have instead sought to set the stage and incentives for providing efficient, high quality care.

APM entities and eligible clinicians are incentivized through the quality measurement framework, which reserves the highest potential financial rewards for those who achieve high performance in process and outcome measures and PROMs measured at the specific episode level. We also intend to reduce inappropriate resource use without losing ground on quality of care by linking a shared accountability model for quality to payment, making it more difficult to share in savings or avoid penalties if quality is not maintained or increased.

What constitutes high quality care may differ for each episode and involve the Donabedian aspects of structure, process and outcome. We have added PROMs and would envision appropriateness measures in future years. Furthermore, for surgical procedures, we have divided the process measures into high-value and low-value groups. The high-value process measures typically represent patient engagement such as establishing the goals of care. These high-value process measures are well-suited for pairing with PROMs, which assess the patient's satisfaction with achieving their care goals.

An example of a high-value process measure linked to a PROM might be a process measure for goals related to a surgical procedure or 2 months of tobacco cessation prior to an operation. The processes involve engaging the patient, the PCP, the anesthesiologist and the surgeon in the care plan/goals. The associated PROM would measure to what level the goals were achieved, the patient's ability to amend the goals, and the team-centered approach toward goal achievement.

These quality goals may vary by the episode. The goals are defined specific to the patient and the specific episode. The measures applied include the current CMS specialty specific measures in MIPS and the initial Surgical Phases of Care measure set previously submitted to CMS. ACS is soliciting more additions to the general surgical measure set for inclusion by working with Anesthesia, Hospitalists and other specialties who wish to engage in shared accountability.

2. Why is there no minimum standard of quality to be met?

The proposal does include a minimum quality standard which we believe is consistent with minimum requirements for other CMS payment models. The initial minimum reflects participation rather than level of performance and is intended to allow for the setting of quality performance benchmarks, consistent with CMS' historical approach at the launch of new payment models. The EPM rule selects as few as 2 measures and CAHPS for some episodes. In our model, the minimum quality standard in the initial benchmark setting phase is that participants report a minimum of 2 quality measures including at least one outcome measure. Participation at this level is sufficient to achieve "acceptable" quality and therefore be eligible to share in savings. However, in the acceptable quality tier it is either more difficult to achieve savings or the share of savings provided to the entity is reduced (depending on the payment model). Achieving higher quality tiers (at first through participation and reporting but later through performance), requires greater participation, including reporting a greater number of

measures including PROMs and makes it less difficult to achieve savings targets or increases the share of savings received. The highest quality tier attempts to bridge the gap between participation and performance. To achieve this tier, a significant number of episode-specific measures (such as the surgical phases of care measures for surgical procedures) must be reported and performance in at least one of these measures must be in the top decile. To achieve this level of performance will require a full team effort.

3. The model proposes to measure quality in a manner that "spans all specialties" (page 5). Why are there no procedure-specific outcome measures? Is there no expectation of patient interest in procedure-specific outcomes; e.g., improved mobility / function after an orthopedic procedure?

The delivery of high quality care that results in optimal outcomes requires a team of providers focused on this goal and, in fact, this is what is referred to by the notion of quality measurement that "spans all specialties" on page 5 of the proposal.

The developers agree that patient goals and interests are important to the delivery of high quality health care. We incorporate high-value process measures and validate the level of goal achievement as an outcome using PROMs. We also strongly believe that quality should be measured as closely to the episode of care delivered as possible, be that a procedure or a chronic or acute condition. In our model, achieving the "excellent" quality tier requires measurement tied to the specific episode, including PROMs.

Procedure-specific outcome measures are achievable and should be tailored to the episode. The proposal provides a framework which can be tailored to each episode, but which is also flexible to allow as many providers to participate as possible. Measuring goals of care spans all patients, all episodes and all clinicians; and at the same time, the goals can and should fit the individual episode and patient. For example, in a chronic cancer care episode, the goals may vary depending on the stage of the cancer and the patient's wishes. The high-value process measures for cancer related goals reflects "patient goals" measures which span all specialties and at the same time could fit the episode and the patient very specifically.

As another example, a condition episode for musculoskeletal conditions related to osteoarthritis may reflect goals to avoid early surgical care while maintaining patient functional goals for pain, lifestyle and employment. If the condition episode progresses to a surgical procedure, such as elective joint replacement, the outcomes measures should fit the patient for the procedure episode. Some patients replace joints for improved function, others for pain management, other patients seek both. The proposed measurement framework allows for high-value process measures, including patient goals, correlated with matched PROMs.

The model does not seek to limit innovation in measure development. ACS has provided an example of episode-specific measure sets in the form of the Surgical Phases of Care. The model development team has already been approached by other societies who are interested in exploring development of similar measure sets for the most common procedural episodes provided by their members. Since episodes cover a period of time, (generally 90 days for a

procedural episode,) we believe most patients would have phases of care to consider specific for each episode, although the phases of care may vary by the type of care provided. Surgery, for example, has five phases. Other procedure or condition episodes may have 2-4 phases such as an acute phase, a subacute phase, a recovery phase and a stable chronic phase. We have specific measures for the general surgical measures and include outcomes measures in the phases of care measure sets: SSI, readmissions and PROMs. We have pledged to assist all the other surgical disciplines in using the phases of care approach and providing selective measures for their episodes.

4. The model references (in Appendix A) the use of three adverse outcome measures: 30–day unplanned hospital readmission, surgical site infection, and unplanned reoperation rate within 30 days. What is the incidence rate of these adverse events and what is the minimum patient size necessary for these measures to have discriminatory power across providers?

The proposal is not reliant on the performance characteristics of any particular measure. The measures in Appendix A are intended to serve as an example of the type of measurement expected in the Episode-Based Quality Category, initial implementation could even be transitional without measurement risk, allowing refinement of measurement over time. The important concepts of this proposal are not reliant on an existing measure.

The adverse events and minimum patient sizes necessary for discriminating among providers are problematic for almost every surgical procedure because of the lack of statistical power in small numbers. It is for this reason we have previously advised CMS that outcomes based measurement alone will not allow for accurate and meaningful discrimination between surgical care teams with an adequate C-statistic and sensible confidence intervals.

For example, for a colectomy episode to measure mortality rates as a discerning outcome, the volume of resections required for an individual surgeon to perform would be nearly 2000 a year. Similarly, and also for colectomy, which is a procedure with considerable surgical site infections (SSI), measuring a discernible level of SSI to distinguish one surgical team from another even with risk adjustment, would require a surgeon to maintain a volume of over 250 cases per year. Neither of these are reasonable case volumes.

The situation worsens for conditions where mortality, SSI and readmissions are even less common (the statistical problem of small numbers). For this reason, we have developed the EBMF with shared accountability model with phases of care, high performance, goal-based process measures linked to PROMs. This work is in its early stages but will proceed with CMS' assistance as part of a QCDR within the MIPS program.

The proposal developers do however greatly value these outcomes measures as a means of informing local improvement cycles and focusing efforts to define the high-value process measures. We encourage their use in the APM and recommend their inclusion in the weighting used to establish the quality tiers.

5. Why are there no patient - reported outcome measures? The proposal includes the acronym "PROMs" on pages 5 and 6, but no patient-reported outcome measures are included in the Appendix A. (We further note that S-CAHPS measures patient experiences during care, but not outcomes.)

As noted above, the PROMs are part of an overall measure matrix in the phases of care. A number of PROMs are in development for the MIPS program and could be included in the proposed model. The development of these PROMs is resource intensive. Without support from the payer community, their development is tied to the limits of the clinician community developing them. The ACS is collaborating with the World Health Organization's efforts in PROMs and continues to develop these invaluable instruments.

The ACS maintains that CAHPS surveys are of limited value, particularly in informing the early experience with episodes or bundle-based payments. The CAHPS selected for use in existing CMS programs are typically hospital based. The hospital-based CAHPS are surveys of the entire scope of care in a hospital. These samples are not representative of the episode of care. Thus, our approach has been to consider more focused episode-based patient experience with PROMs.

6. How would you assure clinical appropriateness of services performed under the model, including the decision to perform surgery and that there isn't an increase in the number of procedures for low-risk patients (page 19 suggests there is a protection, but it isn't defined)?

The proposal is not intended to resolve the challenge of clinical appropriateness measures for surgical care. We acknowledge such measures are needed and the quality framework is designed to rapidly assimilate those measures once they are reliable, valid and implementable. Appropriateness measures are some of the most important and sophisticated measures. The Rand Appropriateness of care measure methodology has made it possible to develop appropriateness measures for diagnostic imaging. However, it is much more complicated to develop such measures in instances where procedural appropriateness and clinical decision support are required. The resources to develop and ultimately implement such measures in surgery have not been forthcoming so their availability remains limited. We strongly support federal funding for development of appropriateness clinical decision support tools. These tools should exist within clinician-patient workflows to promote their natural use in the field. In the ACS-Brandeis A-APM, our use of high-value, clinical goal-based process measures tied to short, post-op PROMs serves as a proxy for appropriateness.

To illustrate the challenge, herniorrhaphy is an appropriate operation to consider in the face of an asymptomatic hernia. The patient preferences, goals, and conditions influence the appropriateness of this procedure in a given patient's care. Theoretically, this could be represented in the form of an appropriateness index, if one were developed and tested for validity. To continue the illustration, imagine an 18 y/o construction worker who is in perfect health except for an inguinal hernia. In this instance, it is broadly accepted that this is patient is an excellent candidate for herniorrhaphy and the procedure would therefore be considered appropriate. Conversely, consider the same condition in a sedentary, diabetic patient with severe

COPD and ischemic heart disease. This is a very different perspective on the appropriateness of a surgical repair. Many would consider surgical care in this patient less appropriate. If the same individual has a symptomatic hernia with sign of incarceration, the level of appropriateness changes. All of these efforts call for clinical judgment applied to the algorithm of care and shared decision-making with the patient and his or her family.

There are appropriateness measures emerging in diagnostics such as appropriateness of advanced imagining based on comparative effectiveness. Other appropriateness measures relate to opioid use in post-op and elderly patients. These emerging measures are easily accommodated within our quality framework and should be added when fully developed and available.

7. Will quality measures be differentiated based upon specific specialty performance in a defined episode?

Quality measurement in the model should ideally be tied closely to the episode of care. The underlying concept of clinical affinity groups reflects the complexity of the practice of medicine and its team-based nature. and reflects team-based care more than individual efforts. In the initial transition phase, available measures may reflect attributions more commonly associated with one specialty over another, however, patient care is team-based and quality measurement should reflect this fact. We will continue adding measures from participating clinical disciplines involved in the episode. These additional measures would add to the efforts for shared accountability from other providers participating in each episode.

To illustrate the model's team-based approach, measuring SSI in a surgical case depends on the urgency of the care, the preparedness of the patient (nutrition, chronic disease management, etc.), the anesthesia, the surgical judgment and technique, and the post-op care protocols. Well-controlled diabetics undergoing a surgical procedure demand pre-op, intra-op and post-op management of their diabetes if SSI reductions are to be optimized. SSI therefore serves as a measure of shared accountability for team-based care and reducing its incidence will require engaging everyone in all aspects of patient care. The status quo of silos of measures to draw distinctions among individuals rather than to measure patients has been of limited efficacy. The ultimate goal of our model is a more patient-centric, shared accountability approach for quality.

8. The "Transition" phase standard is merely to report measures, not perform well on them, except highest decile; when will the "more mature phase" occur and how does quality measurement work then?

The developers recognize the importance of ongoing efforts to tie a greater percent of Medicare payments to the quality of care provided as seen in both MACRA and the earlier HHS targets. It is our intent to move from reporting to performance as soon as possible. From the developers' prior experience with quality measure development, we have learned that it can realistically take two years or more to acquire enough data on a measure for it to be meaningfully used to distinguish between the quality of care being delivered by different providers.

The proposal's initial focus reporting serves the dual goals of easing participation into the A-APM and allowing time to collect a baseline of data. We feel that this implementation strategy is consistent with the approach taken by CMS in the implementation of other models. That is, CMS has previously launched programs with participation standards and progressed to performance standards over time (For example, moving from PQRI to PQRS to the MIPS Quality component).

9. Why will you only report measures on 50% of patients? Why not 100%?

In PQRS, the first year of MIPS quality reporting and other current CMS payment models, the measure submission threshold has been set at 50%. The proposal has set our reporting threshold at the same level in order to avoid reduced participation due to disproportional reporting burden. The developers believe that quality measurement and reporting are important and believe that it could be encouraged through this model. For example, in future years, reporting on a higher percent of patients could provide credit in your quality score and make it more likely to achieve the good or excellent quality tiers for example.

10. What will be done to ensure that high-risk patients aren't precluded from receiving procedures?

As noted, appropriate stratification an any number of axes is feasible in this model, consistent with the concept of fracture stratification within CJR. The model design is intended to accommodate high-risk patients through its risk adjustment mechanism. In fact, the patient-specific risk adjustment and target price setting of the ACS-Brandeis model means that potential savings may actually be greater for these patients. Each patient is risk-adjusted for the episode based on their comorbidities versus similar patients with the same comorbid conditions and the same episode. If coupled with outlier policies or stop-loss provisions, the model could actually incentivize providers to take on higher-risk patients. Re-insurance at the APM-Entity to cover against extraordinary losses is another potential way to address concerns over high-risk patients. Medicare Advantage Plans have experience in these vehicles and could act as an APM-entity.

Additionally, constant attention to the validity of risk adjustment, including future validation of claims-generated projections using registry data, data on social determinants of health, and other factors will further guard against unintended exclusion of high risk patients.

11. How would the process of taking "samples" of "gaps in care" work?

Whether delayed or avoided care is, in fact, inappropriate will be determined by whether the outcomes of the care pathway for the patient are better or worse than for patients treated in another pathway. It may be that delayed and/or avoided care is in fact the best care for a patient. The trigger for looking for inappropriately delayed or avoided care would be worse outcomes. When worse outcomes are identified for one or more types of episodes cared for by an APM entity, then further investigation into the care pathways used can be triggered as a tool to identify

the problem or problems. The EGM's completeness and precision with respect to assigning clinically relevant services to episodes can facilitate examination of possible gaps in care.

12. How would the model accommodate introduction of new technologies and evidence?

Medicine is continually evolving, with the constant development of new knowledge and new procedures for providing care. The ACS-Brandeis Advanced APM proposal is based upon the EGM, which can be continually updated to reflect current coding practices and to include current procedural approaches. For example, the procedural details associated with the surgical care of the patient with ischemic peripheral vascular disease are evolving on an almost daily basis. New techniques for revascularization of the leg are being developed constantly. The EGM will require regular updates of the clinical data and logic for both the condition episodes associated with peripheral vascular disease and the procedural episodes associated with the diagnosis and treatment of that condition. However, beyond those considerations, our APM proposal is agnostic to what specifically is done to care for a patient. As long as a care pathway results in good clinical outcomes, and at low cost, the APM methodology will reward the providers involved – regardless of what route is taken to get there.

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September 26, 2016

Andy Slavitt, Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: CMS-5519-P: Medicare Program: Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model

Dear Acting Administrator Slavitt:

The Health Care Incentives Improvement Institute (HCI^3) is a nonprofit organization with deep experience in improving health care quality and value with evidence-based incentive programs, and a fair and powerful model for payment reform. We have drawn on that experience and expertise in formulating our comments on CMS's proposed rule (CMS-5519-P) creating new Episode Payment Models and a new Incentive Payment Model, and revising the Comprehensive Care for Joint Replacement Model.

First, we commend CMS for recognizing and remedying some of the weaknesses in the earlier proposed rule (CMS–5517–P) that defined Advanced Alternative Payment Models. As we noted in our comment letter responding to that proposal, the Comprehensive Care for Joint Replacement model and Bundled Payment for Care Improvement initiative merit recognition—with some modifications—as Advanced Alternative Payment Models under CMS's Quality Payment Program.

We are pleased to see that the new proposed rule, in Section V, subsection O, recognizes CJR's risk levels and outcome measures as meeting Advanced APM criteria, and that it modifies CJR to require Certified Electronic Health Record Technology, also in accordance with Advanced APM criteria. In addition, we are encouraged that the proposal anticipates "building on the BPCI initiative...to implement a new voluntary bundled payment model for CY 2018 where the model(s) would be designed to meet the criteria to be an Advanced APM" (Section III, subsection A).

At the same time, we continue to have serious concerns about other elements of the CJR and BPCI designs, concerns that prevent us from supporting the Episode Payment Models (EPMs) outlined in the proposed rule.

The rule's revisions of BPCI and CJR do not alter those models' reliance on Medical Severity Diagnosis-Related Groups (MS-DRGs), and indeed the rule builds the new EPMs upon MS-DRGs. Making MS-DRGs the basis for identifying episodes and for calculating episode budgets is counterproductive for a number of reasons, some of which CMS acknowledges in the text of the proposed rule:

- The MS-DRG is assigned to a patient's case upon discharge, and it may not be predictable during a patient's treatment prior to discharge. This can make it difficult for providers to implement care redesigns targeted to a patient population identified by MS-DRGs
- The MS-DRGs assigned to a patient's stay are often inaccurate or otherwise inappropriate for the patient's diagnosis, making the classification an inappropriate basis for episode triggers, budgets, quality measurement and adjusting for underlying patient illnesses
- Greater-severity diagnoses under the DRG system carry larger payments, potentially rewarding hospitals when patients develop complications during their hospitalization; payment models should *discourage* rather than reward complications
- MS-DRGs are specific to hospital stays, and therefore are not applicable to outpatient care

In addition, the new EPMs replicate other critical flaws of Medicare bundled payment programs namely:

- Only facilities and not clinicians—who are central to the task of raising care quality and improving affordability—are allowed to initiate and control the episode, making it difficult to engage clinicians in care reengineering
- The models do not include provisions to adjust for patient characteristics, including severity of illness, outside of the imperfect adjustments made by MS-DRGs (detailed above). In particular we're troubled that the proposed rule specifies the need to severity adjust for quality measurement, but includes no methods for doing so in episode budgeting

Given that BPCI and CJR models already are operating, and considering CMS's alterations to allow those models to potentially qualify as Advanced APMs, we support continuing those programs with the rule's proposed changes.

However, based on our analysis of the proposed rule and its shortcomings, it is our strong recommendation that CMS not implement the new EPMs with MS-DRGs. Instead, we suggest that the agency expand on its existing Episode Grouper for Medicare (EGM) methodology, an approach to value-based payment that avoids many of the serious shortcomings of the EPMs, and use it instead. Our detailed appendix to this letter describes, in depth, this possibility, and also answers the proposed rule's requests for comments on how to implement event- and condition-based episode payments.

Sincerely,

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Appendix to HCI[3] Comment Letter on Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model (CMS-5519-P)

OVERVIEW

Recently, the Center for Medicare and Medicaid Services (CMS) released its proposed rule for Advancing Care Coordination Through Episode Payment Models (EPM) pursuant to section 1115A of the Social Security Act. In addition to seeking comments on the methods and processes for implementing a new set of mandated EPMs that are described in the rule, in section III, subsection 3. b. of the proposed rule—"Potential Future Condition-Specific Episode Payment Models"—CMS seeks comment on ways "condition-specific episode payment models may provide for a transition from hospital-led EPMs to physician-led accountability for episode quality and costs," particularly in the context of acute myocardial infarction (AMI) and coronary artery bypass graft (CABG) models that include Medicare beneficiaries with coronary artery disease (CAD). In section III, subsection 3. c. of the proposed rule, CMS also seeks comments on "Potential Future Event-Based Episode Payment Models for Procedures and Medical Conditions", with a specific regard to:

> "…procedure-related clinical conditions for which the site-of-service can be inpatient or outpatient (for example, elective PCI for non-AMI beneficiaries) or hospitalization for medical conditions for which the ultimate MS-DRG assigned is less clear at the beginning of an episode (for example, hospitalization for respiratory symptoms which may lead to discharge CMS-5519-P 80 from heart failure, pneumonia, or other MS-DRGs based on reporting of ICD-CM diagnosis codes on hospital claims)."

Our analyses and recommendations respond to these requests, and we include technical details on how CMS could implement a physician-focused, event-based EPM.

Shortcomings in currently proposed EPMs for AMI, CABG, and surgical hip/femur fracture treatment

1. **Lack of comprehensive adjustment for patient characteristics and severity of illness**. Consistent with CMS/CMMI's prior and current EPMs, the current rule does not include provisions to adjust for patient characteristics or severity of illness outside of the crude and imperfect adjustments offered by Diagnosis-Related Groups (DRGs). The proposed rule makes several references (e.g., section III, subsection f. 2.) to using certain audit and review functions to ensure that EPM participants don't cherry pick patients. This approach is an acknowledgment that the current EPM designs do not include intrinsic adjustment for patient severity, and require administrative inspection and control mechanisms to prevent participants from avoiding high-cost patients.

2. **Lack of diversity in EPM initiator role**. Much like the Comprehensive Joint Replacement model, and different from the Bundled Payment for Care Improvement

program, this proposed rule limits the role of EPM initiator and primary financial risk bearer to the acute care facility in which the episode is initiated. The rule, in particular in section III, subsections 3. b. and 3. c., acknowledges the significant limitations of such a policy and asks for comments and suggestions on how to design EPMs that would enable a far greater role for physicians. The proposed rule acknowledges the limits of having acute care facilities as sole initiators, and we underscore the significance of that issue.

3. **Lack of incentives to reduce complications**. In addition to the baked-in incentives of DRGs that reward hospitals and physicians for complications that occur during the patient's hospitalization, the introduction of an AMI EPM creates an incentive for physicians and hospitals to admit patients for a complication in the management of coronary artery disease (CAD). While the proposed rule suggests that the introduction of the AMI EPM acts as an engagement of physicians in the management of CAD, the opposite is true. AMIs are potentially avoidable complications stemming from imperfect management of CAD. A substantial body of research has shown that optimal management of CAD can significantly lower the incidence of AMI. By introducing this EPM, CMS is creating an incentive for patients who are marginally symptomatic of AMI to be admitted for an AMI, thus triggering a new episode and payment. This incentive is completely contrary to the overall goals of EPMs, which is to lower the incidence of complications. In its rule, CMS acknowledges the importance of creating condition-based EPMs instead of event-based EPMs. Not only do we recommend adopting condition-based EPMs (described in detail, below) we strongly recommend halting this event-based EPM that is, in itself, a complication from the lack of optimal management of a condition.

Potential Solution to Shortcomings in the Proposed EPMs: Deploy Episode Grouper for Medicare (EGM) to Implement EPMs

Although HCI^3 has developed its own episode of care (EOC) analysis and payment software that could be used for Medicare EPMs, we note that CMS already possesses the basic tool it needs to do this. Our experience in this domain suggests to us that the Episode Grouper for Medicare (EGM)—the development of which HCI^3 has contributed to, and which, to date, has only been considered for resource-use measurement—could be modified to implement APMs designed around EPMs. Working directly with EGM or an enhanced version of EGM, CMS could correct the issues enumerated above—the problems with severity adjustment, the limits who can bear risk, and the inadequate incentives against complications—and also power a comprehensive set of event- and condition-based EPMs.

In our detailed comments below, we describe the Episode Grouper for Medicare, and lay out ways it, or an equivalent, could be leveraged to create an Advanced APM. Using such a tool for Advanced APMs could not only mitigate the issues we've identified with the proposed EPMs, but also address additional issues of importance to CMS.

TECHNICAL EXPLANATION OF A NON-DRG EPM MODEL AND IMPLEMENTATION

The Episode Grouper for Medicare (EGM)

The Affordable Care Act required the Centers for Medicare and Medicaid Services (CMS) to develop a public domain episode-of-care grouper to be used for feedback to physicians on resource use. In 2012, CMS awarded a contract to Brandeis University to develop the grouper over a four-year period in association with the American Medical Association-convened Physician Consortium for Performance Improvement (AMA-PCPI), the American Board of Medical Specialties Research and Education Foundation (ABMS REF), the Health Care Incentives Improvement Institute, Inc. (HCI^3), IPRO (the Medicare Quality

Improvement Organization for New York State), and Booz Allen Hamilton. The contract directed the Brandeis-led coalition to develop the grouper methodology and software.
We feel that the proposed rule's request for comment is highly relevant and an excellent avenue for building on CMS's experience with the existing Bundled Payments for Care Improvement (BPCI) and Comprehensive Care for Joint Replacement (CJR) models. An acute care bundle in the hospital setting is important, but so is managing chronic conditions in an outpatient setting (which often lead to acute inpatient episodes). In addition, contracting for condition episodes and procedure episodes separately is feasible and creates a different level of accountability, but it is even more desirable to consider contracting for the whole patient; that is, procedure episodes should be considered downstream events deeply tied to the effective management of condition episodes. The nested construction logic of the Episode Grouper for Medicare was designed with this in mind, as the recently released Health Care Payment Learning and Action Network's report *Accelerating and Aligning Clinical Episode Payment Models* emphasizes.[1]

How the Episode Grouper for Medicare (EGM) could facilitate EPMs

A high-level explanation of how the EGM works is provided below. It serves to illustrate three points: 1) CMS has at its disposal an episode-definition system already paid for by the taxpayers that does not rely on DRG, and 2) EGM could be re-purposed to pay for new condition-specific EPMs that do not rely on DRGs for constructing episodes of care and have the built-in incentives for higher quality and lower price, and 3) EGM has within its system a nested methodology to create and pay for event-based episodes for procedures and medical conditions that are site-agnostic.[2]

The following descriptions draw heavily from documentation generated by the Brandeis University EGM development team for CMS, and can be used to describe how CMS could implement condition-specific EPMs, as well as event-based EPMs with a focus on CAD, CABG, percutaneous coronary intervention (PCI) and AMI. The same methodology could be extended to other procedures such as pacemaker and defibrillator implantation, gall bladder surgery, hysterectomy, prostate surgery, as well as to medical conditions such as diverticulitis, inflammatory bowel disease and more, where physician-led opportunities would allow the models to be identified as Advanced APMs. Holding physicians and care teams accountable for the entire budget of such an APM would shift care from acute inpatient settings to a more proactive alternative outpatient, patient-centered, coordinated management.

In the following technical recommendations, we concentrate on cardiac examples (as the proposed rule suggests), but the methods can be applied to many conditions and procedures. Much of the enumerated commentary that follows is based on the HCP LAN recommendations for clinical episode payment models. We address these aspects essential for fair, effective, clinically sound EPMs:

1. Triggering an episode of care
2. Services in the episode definition
3. Beginning and ending episodes
4. Pricing episodes, including risk-adjustment
5. Sharing of responsibility for quality and spending between primary care providers, specialty physicians, and other health care professionals

[1] http://hcp-lan.org/workproducts/cep-whitepaper-final.pdf

[2] For a full description of EGM on the CMS website, please see: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Method-A-Technical.pdf

6. Incentivizing the engagement of physicians and other providers and suppliers in the episode care
7. Designating the accountable entity for the quality and cost of the episode, including the role of physician-led opportunities
8. Interfacing with other CMS models and programs responsible for population health and costs, such as ACOs and Primary Care Medical Homes (PCMHs)
9. Measuring quality and including quality performance and improvement in the payment methodology
10. Other considerations specific to identifying future models as Advanced APMs

1. Triggering an episode of care.
EGM examines claims data in chronological order by patient, and compares the information to specified criteria needed to trigger any given episode. Not only do the codes on the claims have to match the codes on the episode definition tables, but also the trigger rules have to be fulfilled for the episode to be triggered. For example, to trigger an episode for acute myocardial infarction (AMI), there must be one of the specified diagnosis trigger codes for that condition (e.g., acute myocardial infarction of anterolateral wall, initial episode of care) conforming to the trigger rule for that condition (i.e., trigger code in principal position on inpatient facility claim).

Condition-specific episodes are defined in terms of diagnosis codes, whereas treatment episodes are defined in terms of a combination of procedure codes and qualifying diagnosis codes. Trigger codes are used in conjunction with trigger rules to identify each instance of an episode. EGM supports a number of rules that reflect information available from different types of providers (e.g., hospital as well as physician claims) and how that information can be used to trigger an episode.

For example, a principal diagnosis of heart failure on a hospital claim can trigger acute (and chronic) heart failure episodes, whereas more than one professional evaluation and management services for heart failure can trigger a chronic heart failure episode. Triggering a chronic condition episode is not necessarily the same thing as identifying when the patient's illness began, or even when it became diagnosed for the first time. However, it is important to use the information when it becomes available, including the presence of an episode of care for the chronic condition.

EGM uses several levels of classification based on common anatomic locations or a clinical taxonomy that organizes diagnosis codes into the software's definition tables along with criteria for triggering episodes. Using CAD as an example, EGM will trigger CAD if any of the criteria listed below are observed:

- An inpatient hospital admission with a primary diagnosis of CAD

- A CABG, AMI, PCI, or coronary thrombolysis procedure with a primary or secondary diagnosis of CAD

- A cardiac catheterization, cardiac stress test, or cardiac enzyme test performed between one and 30 days prior to an evaluation and management (E&M) code with a primary or secondary diagnosis of CAD

- Two E&M services each with a primary or secondary diagnosis of CAD occurring between 30 and 450 days of one another

2. Services in the episode definition.
Over the past decade HCI[3] has worked intensively with clinical working groups to define the boundaries of episode definitions, one of which is determined by diagnosis codes that are relevant to the episode. In a similar way, available publications on the CMS website describing EGM state that all relevant services provided during the time-window of the episode are counted towards the cost of the episode.

A payment construct built on such a system leverages the trigger criteria and builds a time window around it. This makes the services included during the episode time window a measurable unit of accounting and useful for accountability. Such a system tracks services and costs related to that condition, and uses information about the presence of the condition to set cost expectations related to that condition, as well as likely other conditions that may be caused or exacerbated by the underlying condition.

In terms of episode definitions, condition-specific EPMs along with event-based EPMs for procedural and medical conditions should be broadly aligned with the EGM, and to the extent they are not, our experience building a comprehensive episode-of-care payment system suggests that a moderate number of modifications should make EGM able to implement these types of EPMs. The EGM organizes Medicare beneficiary total costs around two constructs: episodes of specific conditions and episodes for specific treatments.

Condition-specific episodes represent disease states and permit comparisons of resource use that vary depending on (a) physicians' actions or inactions, and (b) decisions whether to treat and how to treat the condition, and resulting complications (important for payment redesign). Treatment episodes permit comparisons of resource use by specialists, performing the procedure, or providing the specified treatment for a predefined period of time. Treatment episodes are contingent on providing that treatment, which can vary depending on factors such as treatment intensity, setting, and complications.

Thus, condition and treatment episodes can be viewed as continuous sequelae for every Medicare beneficiary, and the costs of treatment episodes can be packaged into the costs of managing underlying condition episodes. Stated in payment terms and incentives, outpatient cardiologists managing CAD can be rewarded for managing beneficiaries such that revascularization procedures are performed according to appropriate-use criteria for coronary revascularization and/or the appropriateness guidelines for bypass surgery developed by the Society of Thoracic Surgeons (STS). Treatment episodes can also be bundled apart from condition bundles to provide incentives to surgeons and interventional cardiologists for better surgical management when the invasive procedures are clinically indicated. In either instance, complications such as AMIs could count against the total expected cost of the event- or condition-based episode payments, creating a significant incentive for the physicians to reduce the incidence of such complications.

3. Beginning and ending episodes.
While determining if an episode is triggered, the triggering criteria also include a specification for the start date of the episode. The start date can be different from the trigger date in order to capture the tests and other services that led to the confirmation of the episode. Hence, the period between the start date and the trigger date is a "look-back" and helps to better define the condition. Episode triggers are accompanied by time criteria with each episode having its own expected course of time.

Condition-specific episodes continue through the life of the beneficiary (in most cases) and treatment episodes have defined start and end dates. For operational payment purposes we recommend patients with chronic conditions be flagged as "provisional" in the benefit year

of diagnosis to then be included in the "management" episode at the beginning of the next benefit year for payment. This simplifies the operation of the episode with regard to quality measurement data and reconciliation of payments. Thereafter, chronic-condition patient cohorts are automatically rolled over as management episodes for each subsequent benefit year, keeping patient populations aligned with long-term care management goals.

4. Pricing episodes, including risk-adjustment;
5. Sharing of responsibility for quality and spending between primary care providers, specialty physicians, and other health care professionals; and,
6. Incentivizing the engagement of physicians and other providers and suppliers in the episode care.

The EGM examines utilization patterns and cost, performs comparative analyses for similar conditions, and identifies care-improvement opportunities. This construct could be leveraged to calculate unique severity-adjusted budgets for each triggered episode for each patient (multiple concurrent episodes for complex patients). This means that in addition to reporting, it could also be redesigned to function as an Advanced APM.

We assert this with some authority because this is how the HCI^3 analytics and payment software is designed to work; namely, in addition to being a risk-adjusted episode-of-care contracting model, PROMETHEUS Analytics performs double duty as a highly refined reporting package. Since HCI^3 worked with Brandeis early on in the design of EGM, we believe EGM could be trained to these purposes as well.

We propose some simple but flexible techniques to leverage the EGM tool developed by CMS, and use it to develop specialty payment models. Returning to CAD, we propose two approaches. The first, and more simple, is a treatment episode for specialty interventionists. Although it could be implemented in large, sophisticated systems, it is also geared towards subsets of specialists who are not interested in joining large systems and would want to maintain their independent practices. The second, intended for more sophisticated delivery systems, is a condition-specific episode with a treatment episode bundled as a downstream nested event.

- PCI Procedural Episode Payment

Inasmuch as PCIs are increasingly replacing the more resource-intensive CABG procedures, it's a good candidate for episode construction and to illustrate an EPM model (although the description below would work as well for CABG procedures). Additionally, since PCIs can be done both in an inpatient as well as outpatient setting, it illustrates an EPM that could be site-agnostic, and that would create an incentive to use the place of service that is best suited for the patient, given their age and comorbid conditions. In laying out these scenarios, the cost figures we'll use below are rough estimates based on our own work using claims from private payers, and should be considered as such.

In this scenario, a Medicare participating cardiologist (Specialist A) has determined that Medicare beneficiary B (Patient B) has significant narrowing of the coronary arteries (Ischemia), caused by a buildup of plaque (fatty material) within the walls of the arteries. Specialist A determines that PCI is indicated for Patient B and arranges a date for performing the outpatient procedure at Hospital C. On that date, Specialist A has a number of clinical choices to assist the PCI.

As the catheter is inserted into the artery, to better "see" the extent and sites of arterial blockage, Specialist A may resort to one of two techniques:

- Angiography, a special type of X-ray, similar to an X-ray "movie" that assists Specialist A in the location of blockages in the coronary arteries as the contrast dye moves through the arteries, or
- Intravascular ultrasound (IVUS), a technique that uses a computer and a transducer that sends out sound waves to create images of the blood vessels. IVUS provides direct visualization and measurement of the inside of the blood vessels.

Angiography or IVUS can assist the Specialist A in selecting the appropriate size of balloons and/or stents, to ensure that a stent, if used, is properly opened, or to evaluate the use of other angioplasty instruments. Moreover, fractional flow reserve (FFR) assessment is often used during a catheterization to assist in determining the significance of a moderate coronary narrowing. The technique involves placing a pressure-transducing wire across the narrowing, and after a brief infusion of medication, measuring the pressure change in the coronary artery. This may assist the doctor in deciding whether PCI or stenting is appropriate.

Furthermore, as Patient B lies on the table, Specialist A may determine that atherectomy (removal of plaque) at the site of the narrowing of the artery is necessary. In atherectomy, tiny blades on a balloon or a rotating tip at the end of the catheter break up plaque at the narrowing of the artery. Additionally the specialist may decide if the patient needs a stent to be placed in the coronary artery that is being dilated. If a stent has been placed, tissue will begin to form over it within a few days after the procedure. The stent will be completely covered by tissue within a month or so. Therefore, as follow-up care, Specialist A may prescribe aspirin, clopidogrel (Plavix), prasugrel (Effient), or ticagrelor (Brilinta), which decrease the "stickiness" of platelets in order to prevent blood clots from forming inside the stent. Or he may place a drug-eluting stent to prevent scar tissue build up. If scar tissue does form inside the stent, a repeat procedure may be performed, either with balloon angioplasty or with a second stent, or occasionally with local radiation therapy (called brachytherapy).

After Patient B is released from Hospital C the same day as the intervention, a 30-day “look-forward” period is included as part of the episode definition, for follow-up work, to assess the functioning of the heart. These assessments may include resting or exercise electrocardiogram (ECG or EKG), chest X-ray and echocardiogram of the heart. In addition, the physician may decide to do one or more of the following procedures based on patient’s signs and symptoms, his suspicion of complications, or as part of a more detailed post-procedural evaluation. These services may include but are not limited to cardiac catheterization, computed tomography (CT scan) of the chest, magnetic resonance imaging (MRI) of the heart, myocardial perfusion scans, radionuclide angiography, or a cardiac CT scan. Additional procedures such as Holter monitor, signal-averaged ECG, electrophysiological studies may be performed if the patient has palpitations or significant arrhythmias after PCI. Patient B’s compliance with prescribed medications is also monitored.
We point out these procedural and pharmacological choices because each of these represents cost variation under Specialist A’s control and can be bundled into the episode of care payment (i.e., IVUS is more expensive than Angiography, stenting more expensive than balloon angioplasty). It also shows why seemingly “simple” procedural episodes are not so simple, and why any grouping methodology must reflect these clinical realities and factor them into the budgeting process.

Having discussed the clinical parameters of PCI, we can now think about dollars and payment. Looking into the results of some of our own analyses, we know that, on an

average, PCI costs about $44,000 per patient with the median cost being about $43,000, and a standard deviation of about $30,000. That means that PCI costs for any CAD population are fairly tight (few large outliers). We also know that cost of complications fall into the range of 8 to 9 percent of total costs of PCI. If Specialist A performs 30 PCIs per year (the minimum threshold) for a given CAD population, we know he represents a historical baseline cost of $1,320,000. If Specialist A preforms as an average specialist, we would expect a complication rate of 9 percent, or $118,800 towards costs of complications. The expected cost of complications ($118,800) would be the incentive target. If he lowers the complication rate to 6 percent ($79,200), CMS could share the savings of the difference off the baseline ($39,600). If savings were shared equally with Specialist A, then Specialist A would receive a supplemental payment of $19,800.

- CAD Condition Specific Episode Payment (with or without PCI or CABG) in a coordinated care setting

Under this scenario, we reconsider Patient B with the same chronic condition in an outpatient setting. Specialist A is managing her, except now, he practices in a large group setting of 100 or more physicians. Medicare already knows the size of the practice because it queried its Provider Enrollment, Chain and Ownership System (PECOS) and performed confirming claims analysis. Since we know fewer than 50 percent of stable CAD patients receive Optimal Medical Therapy (OMT), one purpose for changing specialty payment would be to bring the percentages of CAD populations up to OMT guidelines. That alone would lower costs. Moreover, the benefits of performing PCI without trying OMT in patients have been called into question. Recent research indicates that there is no benefit of PCI in preventing myocardial infarction or death in patients with CAD.

As CMS contemplates episode payment reform, staff may be comforted by the fact that American College of Cardiology Foundation (ACCF), the American Heart Association (AHA), and the Physician Consortium for Performance Improvement (PCPI) Work Group have recognized the significant gaps that exist in the care of these patients in the outpatient settings. Working in concert, they defined quality measures aimed at improving outcomes for these patients and recently updated the Chronic Stable Coronary Artery Disease Performance Measurement Set, which provides benchmarks for improving the care of patients in the outpatient setting. These should be factored into the reformed payment structure, especially in reducing the frequency of non-beneficial PCIs. According to ACC guidelines, only about 10 percent of PCIs in any given CAD population are considered clinically indicated and part of quality care (3 vessels with 90 percent blockage).
In the procedural example, we did not consider comorbid conditions. But chronically ill Medicare beneficiaries are predominately complex patients. EGM takes comorbid conditions into account and calculates a risk-adjusted budget for each Condition Specific patient. We highlight this because building a condition-based payment model that only considers a simple, isolated CAD episode is not realistic. Most of the beneficiaries would fall out of the payment model, thwarting the goals of the program.

So, in addition to a primary diagnosis of CAD, Patient B has a history of type two diabetes, hyperlipidemia, and hypertension. Pulling the diagnosis codes from submitted claims, EGM calculates the expected costs for CAD adjusted for all her relevant conditions that impact CAD. We know from our own analyses that average outpatient cost for CAD patients is approximately $6,000 per year, with median costs being $2,200 and a standard deviation of over $15,000. As opposed to PCI, where cost variation is tight around the mean (as it is for most procedural episodes), there is wide variation in costs for chronic heart disease

patients. The percentage of total costs represented by avoidable complications is 36 percent for this population -- four times the rate for PCI.

Continuing with Patient B, EGM triggers a CAD condition episode with a risk-adjusted budget of $8,700 (factoring in type two diabetes, hyperlipidemia and hypertension) for one year's worth of care. Her fellow beneficiaries triggering condition CAD episodes also have risk-adjusted budgets, and going with the population average of $6,000, and a total group practice panel of 500 CAD patients (Specialist A with designated care team), we arrive at an aggregated population budget of $3,000,000 and an aggregated complication costs of $1,080,000. As we did with PCI in isolation, a reduction of, say, 6 percent complication rates is targeted. EGM calculates the reduction savings as $64,800. With a 50 percent gain-share arrangement, the practice would receive a supplemental payment of $32,400, over and above normal FFS billings, contingent on meeting quality measures.

Another reason for combining the condition CAD episode with PCI is that it addresses the conflict between a cardiologist acting as primary care specialist and interventionist. Bundling PCI alone provides an incentive to optimize the mix of services within the time frame of the episode, but it does not resolve the issue of reducing the incentive to order the procedure as a self-referral. Packaging the two episodes into a predicted population budget does.

Therefore, the policy advantages of operationalizing EGM for condition-specific EPMs would be:

- Ease with which assigning responsibility for episode management;
- Resolve the incentives for non-indicated PCI or CABG self-referrals, including unnecessary acute procedures;
- Bring greater numbers of CAD Medicare populations and their physicians into standard society designed guidelines;
- Reduce baseline frequencies of avoidable complications;
- Enhance physician engagement and encourage physician practice re-engineering to make them active recipients of cost-sharing arrangements

At the very least, these policies will reverse the downward percentage of physician compensation as a function of total episode reimbursement, and make it profitable to re-engineer care.

7. Designating the accountable entity for the quality and cost of the episode, including the role of physician-led opportunities; and,
8. Interfacing with other CMS models and programs responsible for population health and costs, such as ACOs and Primary Care Medical Homes (PCMHs)
We believe that CMS should be expansive in its view of organized provider models qualifying for condition-specific EPMs. Willing organizations dedicated to integrating and coordinating the work of practicing physicians and health care providers across the care continuum should be deemed appropriate for assuming risk and managing a bundled payment program so that innovation and market-based arrangements dedicated to EPM are encourage to come forth. CMS should promote flexible collaboration so that care teams for each chronic condition, whether hospital-based or not, may share the risks and rewards associated with creating seamless, efficient, patient-centered care processes. These would include ACO, PCMH, IPA, PHO and other models, some perhaps yet to be conceived, so long as these organizations are totally committed to coordinated care planning, shared

decision-making, comparative quality information, chronic disease management processes, transparency of payment information, and care transition coaching and support.

Creating such an atmosphere for change may allow new models to emerge where post-acute care providers, physician group practices and even non-physician care coordination coaches may assume financial responsibility for costs of the episode care and use hospitals and physician as consultants for clinical outreach, as is happening in the Minnesota Birthing Centers for maternity care.

9. Measuring quality and including quality performance and improvement in the payment methodology

In addition to the quality performance and measurement instruments we mentioned in previous sections, there are additional considerations CMS may explore. These might potentially include:

- ACCF/AHA/AMA-recommended measures for CAD and hypertension;
- The Seattle Angina Questionnaire for patient-reported outcomes;
- Quality / outcome measures as validated by the National Quality Forum.

Through its management of Bridges to Excellence and PROMETHEUS Payment programs, HCI^3 has consistently maintained that quality improvement programs should focus less on process of care measures and more on episode of care outcomes, particularly on lowering rates of potentially avoidable complications such as avoidable readmissions, emergency room visits, and specific adverse events highlighting overuse, misuse and underuse of services. We believe CMS should adopt a similar position as it considers condition-specific EPMs and event-based procedural models.

10. Other considerations specific to identifying future models as Advanced APMs; and any other issues of importance for the design of such an EPM

Current claims adjudication systems are structured to accept and process fee-for-service claims but cannot create budgets or process payments for an advanced EPM. An updated claims adjudication system is the urgent need of the hour to move towards true value-based arrangements. Further, contracting tools that would help divide up payments amongst downstream providers would encourage participation and assumption of financial responsibility. Participating providers including those in post-acute care settings would be encouraged to improve their care pathways to create winning arrangements and would steer towards wider adoption of EMRs and care-coordination tools. Providers holding joint responsibility for the patient's clinical and financial outcomes would create seamless data channels to integrate care across the entire care continuum. As we speak, there are a handful of companies pushing in this direction. An RFI from CMS/CMMI would spur innovation and be electric, and would pump considerable energy into what is now only a nascent entrepreneurial movement.

ACS-Brandeis Condition and Procedure Episodes

Key blue = episode for profiling; green = procedure episode

Clinical Chapter	EGM Condition Name		
BEHAV HTH	Adjustment Ds	Mental Retardation	
	Affective Ds Other (Acute)	Obsessive Compulsive Hyperactive Ds	
	Affective Ds Other (Chronic)	Personality Ds	
	Anxiety Ds (Acute)	Phobias	
	Anxiety Ds (Chronic)	Psychotic Ds Other (Acute)	
	Bipolar Ds Acute - Single Manic Episode	Psychotic Ds Other (Chronic)	
	Bipolar Ds Chronic	Psychotic Ds Schizophrenia Acute	
	Bipolar Ds Chronic (Acute)	Psychotic Ds Schizophrenia Chronic (Acute)	
	Conduct Ds (Acute)	Psychotic Ds Schizophrenia Chronic (Chronic)	
	Conduct Ds (Chronic)	Stress Ds	
	Major Depression Acute - Single Episode	Substance Abuse Alcohol	
	Major Depression Chronic	Substance Abuse Other	
	Major Depression Chronic (Acute)	Tobacco Use	
Chest	Abscess of Lung	Chronic Pulmonary Embolism	Pneumonia Aspiration
	Acute URI Complicated	Chronic Resp Failure	Primary Pulmonary HTN
	Acute URI Simple	Diaphragm Injury	Pulmonary Eosinophilia
	Airway Burn	Empyema	Radiation Pneumonitis
	Airway Injury/Foreign Body	Extrinsis Allergic Alveolitis	Resp Cmplctns Acute
	Airway Lung Neoplasm - Benign	Hydro- and/or Pneumo-Thorax	Resp Distress Syndrome
	Airway Lung Neoplasm - in Situ/Uncertn Behvr	Idiopathic Pulmonary Fibrosis	Resp Failure
	Airway Lung Neoplasm - Malignant	Lung Contusion-Laceration-Other	Septic Pulmonary Embolism
	Alveolar/Interstitial Chronic Ds	Malignant Neoplsm Chest Wall	Subcut Emphysema
	Asthma/COPD Acute	Malignant Neoplsm Thymus	Thorax (Not Lung/Pleura) Neoplasm
	Asthma/COPD Chronic	Meconium Aspiration	Thorax Pulmonary Injury
	Benign Neoplsm Chest Wall	Mediastinitis/Mediastinal Abscess	Thymus Ds (Not Neoplasm)
	Benign Neoplsm Mediastinum	Mesothelioma and Related	Tietze's Disease
	Benign Neoplsm Thymus	Metastatic Neoplasm Chest	Ventilator Associated Pneumonia
	Bronchiectasis	Obesity Hypoventilation Syndrome	Lung resection
	Bronchitis, Bronchiolitis nos	Pleural Ds Effusion	
	Bronchopulm Dysplasis Related	Pleural Neoplasm - Benign	
	Chest Wall Injury Complicated Severe	Pneumoconiosis and Related	
	Chest Wall Injury Simple Mild-Mod	Pneumonia	

Clinical Chapter	Condition Name		
CVAS	Abdomen/Pelvis Vessel Injury	Hypertension Essential (Chronic)	Valve Ds Aortic & Mitral (Acute)
	Abdominal Aortic Aneurysm	Heart Failure (Acute)	Valve Ds Aortic & Mitral (Chronic)
	Abdominal Ruptured Aortic Aneurysm	Heart Failure (Chronic)	Post-Op Hemorrhage/Hematoma
	ACS Other Than AMI	Heart Injury Include Hemopericardium	Postoperative Shock
	Acute DVT Extremity/nOS	Heart Neopalsm	Prinzmetal Angina
	Acute Myocardial Infarction	Heart Transplant CAD	Pulmonary Valve Atresia/Stenosis - Congenital
	Acute Pulmonary Embolism	Heart Transplant Cmplctns Acute	Raynaud's Syndrome
	Aortic Dissection Thoracic/Abdominal	Hereditary Hemorrhagic Telangiectasia	Renal Artery Ds
	Aortic Valve Insufficiency - Congenital	Hypersensitivity Angiitis	Sick Sinus Syndrome
	Arrhythmias Other/Unspecified (Acute)	Hypertension Secondary (Acute)	Stricture of Artery
	Arrhythmias Other/Unspecified (Chronic)	Hypertension Secondary (Chronic)	Valve Ds Aortic (Acute)
	Arrhythmias Sudden Death	Iliac Artery Aneurysm/Dissection	Valve Ds Aortic (Chronic)
	Arterial Thromboembolism	Ischemic Heart Disease	Valve Ds Mitral (Acute)
	Arteritis	Lower Extremity Aneurysm	Valve Ds Mitral (Chronic)
	Atherosclerosis Aorta	Lower Extremity Vessel Injury	Valve Ds Right (Acute)
	Atrial Fibrillation/Flutter (Acute)	Lower Limb Vessel Anomaly	Valve Ds Right (Chronic)
	Atrial Fibrillation/Flutter (Chronic)	Lymphangioma nos	Valve Replacement Comp/Malfnctn
	Atrial Premature Beats (Acute)	Lymphedema	Varices nos
	Atrial Premature Beats (Chronic)	Myocarditis	Vasc Device or Graft Comp/Malfnctn
	Card Device or Graft Comp/Malfnctn	Neck Artery Dissection/Aneurysm	Vascular Cmplctns Acute
	Cardiac Aneurysm	Non-Operative Shock	Vein Disease Thoracic and Abdominal
	Cardiac Tamponade	Pacer/AICD Comp/Malfnctn	Venous Insufficiency Varicosities
	Cardiomyopathy	Paroxysmal Supraventricular Tachycardia (Acute)	Ventricular Premature Beats (Acute)
	Carotid/Aortic Body Neoplasm	Paroxysmal Supraventricular Tachycardia (Chronic)	Ventricular Premature Beats (Chronic)
	Chordae/Papllary Rupure and Related	Pericarditis, Inflammatory	Ventricular Tachycardia
	Chronic Embolism/Thrombosis	Pericarditis, Other	Vf/Cardiac Arrest Vfib/Vflutr
	Cor Pulmonale (Acute)	Peripheral ASVD	Cardiac catheterization
	Cor Pulmonale (Chronic)	Phlebitis/Thrombophlebitis	CABG
	Coronary Bypass Graft Mlfnctn	Polyarteritis	Percutaneous cardiac intervention
	Endocarditis	Post MI Syndrome and Related	Insertion of permanent pacemaker/AICD
	Fluid Ds Hypo/Hyper-Volemia	Thoracic Aortic Aneurysm	Open heart valve surgery
	Gangrene	Thoracic Ruptured Aortic Aneurysm	Aortic repair
	Heart Block	Thorax Vessel Injury	Leg vein ablation
	Hypertension Complic, Malig (Acute)	Thrombotic Microangiopthy	Leg revascularization
	Hypertension Complic, Malig (Chronic)	Upper Extremity Aneurysm	Leg vein angioplasty
	Hypertension Essential (Acute)	Upper Extremity Vessel Injury	

Clinical Chapter	Condition Name		
Dermatology	1st/2nd Degree Burn, Extremity	Dermatophytosis Foot, Nail	Poly/Dermatmyositis
	1st/2nd Degree Burn, Head And Neck	Dermatophytosis Other	Psoriasis
	1st/2nd Degree Burn, Trunk	Epidermal Necrolysis	Pyoderma Gangrenosum
	1st/2nd Degree Burn, Whole Body	Erythema Multiforme	Rosacea
	3rd Degree Burn, Extremity	Extremity Contusion/Abrasion/FB	Scabies
	3rd Degree Burn, Head And Neck	Extremity Open Wound	Sebaceous Cyst
	3rd Degree Burn, Trunk	Extrinsic/Contact Dermatitis (also Sun/Radiation)	Seborrhea
	3rd Degree Burn, Whole Body	Head Face Neck Contusion/Abrasion/FB	Shingles
	Allergic Dermatitis Urticaria	Head Face Neck Unspecified Burn	Skin Graft Complctn
	Cellulitis Face & Neck	Herpes Simplex	Skin Neoplasm - Benign
	Cellulitis, Trunk and Extremities	Kaposi's Sarcoma Soft Tissue nos	Skin Neoplasm - in Situ/Uncrtn
	Chronic Cutaneous Ulcer	Keratosis Actinic/Seborrheic	Skin Neoplasm - Malignant (Not Melanoma)
	Decubitus Ulcer	Late Effects of Burn	Skin Neoplasm - Melanoma
	Deep 3rd Degree Burn, Extremity	Metastatic Neoplasm Skin/Subq	Trunk Open Wound
	Deep 3rd Degree Burn, Trunk	Molluscum Contagiosum	Viral Warts
	Deep 3rd Degree Burn, Whole Body Nos	Pediculosis	
ENDO/MET	Acid-Base Ds	Diabetes Type II (Acute)	Malignant Neoplsm Endo nos
	Adrenal Insufficiency	Diabetes Type II (Chronic)	Malignant Neoplsm Parathyroid
	Benign Neoplsm Adrenal	Diabetic Ketoacidosis DKA	Malnutrition
	Benign Neoplsm Endo Nos	Disaccharidase Deficiency	Neoplsm Uncertn Behvr Adrenal
	Benign Neoplsm Parathyroid	Electrolyte Ds	Neoplsm Uncertn Behvr Endo Other
	Benign Neoplsm Thyroid	Goiter +/- Thyrotoxicosis	Obesity
	Calcium Ds nec/nos	Gout	Parathyroid Ds
	Carcinoid Syndrome	Hemochromatosis	Pituitary Ds
	Cushings Syndrome	Hyperaldosteronism	Polyglandular Dysfnctn
	Diabetes Hyperosm/Coma	Hypercalcemia	Thyroid Neoplasm Malignant
	Diabetes I/II Complicated (Acute)	Hypocalcemia	Thyroiditis
	Diabetes I/II Complicated (Chronic)	Hypoglycemia	Thyrotoxicosis w/o Goiter
	Diabetes Secondary (Acute)	Hypothyroidism	Vitamin A/Thiamin Deficiency
	Diabetes Secondary (Chronic)	Insulin Pump Care/Complication	Vitamin B Deficiency
	Diabetes Type I (Acute)	Lipid Ds	Vitamin D Deficiency
	Diabetes Type I (Chronic)	Malignant Neoplsm Adrenal	Parathyroidectomy

Clinical Chapter	Condition Name		
ENTD	Acute Tonsilitis Peritonsillar Abscess	Larynx Cellulitis	Oral Thrush
	Barotrauma Ear/Sinus	Larynx Neoplasm - Benign	Oral/Pharynx Neoplasm - Malignant
	Benign Neoplsm Cranium/Facial Bones	Larynx Neoplasm - Malignant	Oropharynx Cellulitis/Abscess
	Benign Neoplsm Head/Neck	Larynx/Trachea Open Wound	Otitis Externa
	Benign Neoplsm Jaw	Larynx/Trachea Other Injury	Otitis Media Acute
	Cleft Lip w/ or w/o Cleft Palate	Lip Neoplasm - Malignant	Otitis Media Chronic
	Cranium/Facial Bones Neoplasm - Malignant	Lip/Oral/Pharynx Neoplasm - Benign	Palate/Uvula Neoplasm - Malignant
	Deviated Nasal Septum	Malignant Neoplasm Jaw	Perforated Eardrum
	Ear Ds Other, Foreign Body	Mandible Fx	Salivary Gland Ds
	Ear Neoplasm - Malignant	Mastoiditis Acute/Chronic	Salivary Gland Neoplasm - Benign
	Ear/Auditory Structures Open Wound	Mouth/Palate Open Wound	Salivary Gland Neoplasm - Malignant
	Epiglottitis/Supraglottitis	Mouth/Pharynx Foreign Body	Sinus Open Wound
	Face Fx Maxilla/Zygoma	Mouth/Pharynx Open Wound	Sinusitis Acute
	Face Open Wound	Mouth/Pharynx/Salivary Neoplasm - Uncertn Behvr	Sinusitis Chronic
	Face Orbital Floor Fx	Nasal Bone Fx	Stomatitis/Mucositis
	Face/Neck/Scalp Crushing Injury	Nasal Ds Other	Strep Throat
	Face/Neck/Scalp Other Injury	Nasal Ds Polyps	Thyroid Gland Open Wound
	Facial Bones Fx Other	Nasal Injury Other	Tonsil Neoplasm - Benign
	Head/Neck Infection	Nasal/Sinus Neoplasm - Malignant	Tonsil Neoplasm - Malignant
	Head/Neck Nos Neoplasm - Malilgnant	Nasopharyngitis Allergic/Chronic	Tonsils/Adenoids Chronic Ds
	Herpangina	Neck Open Wound	Endoscopic sinus surgery
	Jaw Sprain	Nose/Sinus Neoplasm - Benign	Thyroidectomy
	Laryngitis Chronic	Oral Soft Tissues Ds	
EYE	Cataract	Inflammation Eyelid	Retinal Ds Vascular Occlusion
	Conjuctival Hemorrhage	Lens Ds Other	Visual Impairment/Blind
	Conjunctivitis	Macular Degeneration	Vitreous Opacities/Degeneration
	Corneal Ulcer	Macular Ds Other	Vitrious Hemorrhage
	Diabetic Retinopathy	Optic Atrophy	Cataract surgery IOL
	Eye Neoplasm - Benign	Optic Nerve/Pathways Injury	Cataract surgery sec mem
	Eye Neoplasm - Malignant	Other Keratitis	Glaucoma surgery
	Eyelid Neoplasm - Malignant (Not Melanoma)	Post-Cataract Ds	Retina and vitreous procedures
	Glaucoma	Pterygium	Retina/choroid destructive therapy
	Hypertensive Retinopathy	Retinal Detachment	

Clinical Chapter	Condition Name		
F-GEN	Bartholin's Cyst/Abscess		
	Benign Fibrocystic/Dysplastic Breast Dis		
	Breast Implant Complctn	Gyn nos Neoplasm - Malignant	Uterus Neoplasm - Malignant
	Breast Neoplasm - Malignant	Leiomyoma Uterus	Vagina/Vulva Neoplasm - Benign
	Breast Neoplasm - Uncertn Behav	Menopausal Sx	Vagina/Vulva Neoplasm - in-Situ
	Cervical Dysplasia	Ovarian Cyst	Vagina/Vulva Neoplasm - Malignant
	Cervix Neoplasm - Benign	Ovarian Failure	Vulvovaginitis
	Cervix Neoplasm - Malignant	Ovary/Adnex Neoplasm - Benign	Mammaplasty
	Complications Gyn Surgery	Ovary/Adnex Neoplasm - Malignant	Mastectomy
	Endometrial Hyperplasia/Polyp	Pelvic Floor Relaxation/Prolapse	Breast reconstruction
	Endometriosis	PID & Related	Colpopexy
	Female Genital Tract Fistula	Polycystic Ovaries and Other Ds	Colporrhaphy
	Gyn Neoplasm - Benign	Uterine Neoplasm - in Situ/Uncrtn	Hysterectomy
	Gyn Nos Neoplasm - in Situ/Uncrtn	Uterine Neoplasm - Malignant	
GEN/UNSP	Amyloidosis	Lupus (SLE)	Reattached Body Part Complctn
	Back Crushing Injury	Lyme Ds	Retroperitoneum Injury
	Behcet's Syndrome	Malignant Neoplsm nos	Rheumatoid Arthritis
	Benign Neoplsm nos	Maltreatment, Abuse, Neglect	RSV Infection nos
	Candida Infection nos	Measles Infection nos	Rubella Infection nos
	Carcinoid Tumor (not GI)	Medication Adverse Effect - Therapeutic Use	Scleroderma
	Chronic Pain Cancer	Merkel Cell Carcinoma nos	Sepsis, SIRS
	Cystic Fibrosis	Metastatic Neoplasm Kidney	Sicca Syndrome
	Cytomegalovirus Infection nos	Metastatic Neoplasm non-Nodal	Staph Infection nos
	Device/Graft nos Complctn	Neoplasm Uncertn Behvr nos	Strep Infection nos
	Down's Syndrome	Non-Healing Surgical Wound	Surgical Complctn nos
	Erythema Infectiosum	Other Mycoses Infection nos	Syphilis General
	FB From Procedure	Other Viral nec/nos	Transplant nos Complctn
	Herpes Simplex Infection nos	Other/nos - Juvenile Idiopathic Arthritis	Tuberculosis General
	HIV Infection	Other/nos - Sepsis, SIRS Other	Unspecified Arthropathies
	Human Papilloma Virus	Pelvic Organ Injury	Varicella Infection nos
	Immune Ds Anaphylaxis	Peritoneum Injury	Wegener's Granulomatosis
	Infectious Mononucleosis	Polio Infection nos	
	Kaposi's Sarcoma nos	Post-Op Wound Disrupt	

Clinical Chapter	Condition Name		
GI	Anal Fistula	Esophagitis (Chronic)	Liver Transplant Complications
	Anal/Rectal Abscess	Esophagus Foreign Body	Malignant Neoplsm Spleen
	Anal/Rectal Polyp	Esophagus Neoplasm - in-Situ	Meckel's Diverticulum
	Anal/Rectal Ulcer Fistula	Esophagus Neoplasm - Malignant	Metastatic Neoplasm to GI Organs
	Angiodysplasia - Vascular Lesions of Intestine(Acute)	Femoral Hernia	Mucositis
	Angiodysplasia - Vascular Lesions Of Intestine(Chronic)	Gallbladder Ds, Other	Other GI Neopasm - Malignant
	Appendicitis	Gallbladder Stones	Other GI Neopasm - Uncertn Behav
	Atrophic Gastritis Achlorhydria Related	Gastroduodenitis(Acute)	Other GI Neoplasm - Benign
	Bariatric Surgery Complications	Gastroduodenitis(Chronic)	Pancreas Transplant Complications
	Biliary Stones +/- Obstruction (Acute)	Gastroenteritis	Pancreatic Ds- nec/nos
	Biliary Stones +/- Obstruction (Chronic)	Gastroparesis Dilation of Stomach	Pancreatic Neoplasm - Benign
	Biliary Tract Disease nos	Gastrostomy Complications	Pancreatic Neoplasm - Malignant
	Biliary Tract Obstruction not Stones	GI Hemorrhage	Pancreatitis Acute
	Carcinoid Tumor GI Tract	GI Solid Organ Injury	Pancreatitis Chronic
	Carcinoma in Situ GI nos	GI Tract Foreign Body	Peptic Ulcer(Acute)
	Carcinoma in Situ Lower GI nos	Hemorrhoids(Acute)	Peptic Ulcer(Chronic)
	C-Difficile Colitis	Hemorrhoids(Chronic)	Perinatal Jaundice
	Cholecystitis (Acute)	Hepatic Encephalopathy	Peritoneal Dialysis Cath Complctn
	Cholecystitis (Chronic)	Hepatitis A, Acute	Peritonitis
	Cirrhosis	Hepatitis B (Acute)	Pyloric Stenosis
	Cirrhosis Billiary	Hepatitis B (Chronic)	Small Bowel Neoplasm - Benign
	Cirrhosis EtOH	Hepatitis C (Acute)	Small Bowel Neoplasm - Malignant
	Cirrhosis Other	Hepatitis C (Chronic)	Stomach Neoplasm - Benign
	Colorectal Neoplasm - Benign	Hepatitis EtOH	Stomach Neoplasm - in Situ
	Colorectal Neoplasm - in-Situ/Uncertn	Hepatitis Other	Stomach Neoplasm - Malignant
	Colorectal Neoplasm - Malignant	Hepatobiliary Neoplasm - Benign	Upper GI Bleeding - Other(Acute)
	Colostomy/Enterostomy Complication	Hepatobiliary Neoplasm - in-Situ/Uncertn	Upper GI Bleeding - Other(Chronic)
	Complications Esophagostomy	Hepatobiliary Neoplasm - Malignant	Vascular Insuff Intestines Acute
	Complications GI Other	Hernia Diaphragmatic	Vascular Insuff Intestines Chronic
	Complications Other GI Surgery	Hernia Other nec/nos	Appendectomy
	Diverticular Ds Diverticulitis, Small Bowel	Hernia Other Umbilical Ventral	Cholecystectomy
	Diverticulitis of Colon	Inflamm Bowel Ds Ulcerative Colitis	Colonoscopy
	Diverticulosis of Intestine(Acute)	Inguinal Hernia	Colectomy
	Diverticulosis of Intestine(Chronic)	Intestinal Abscess	EGD endoscopy
	Ds of the Spleen, Neoplasm	Intestinal Obstruction	ERCP
	Enteritis	Intestinal Obstruction, Congenital	Esophagectomy
	Esophageal Atresia/Tracheoesoph fistula	Intestinal Transplant Complications	Bariatric surgery
	Esophageal Dyskinesia	Intestine Fistula	Foregut Procedures
	Esophageal Perf, Fistula, Stricture	Intestine Perforation	Repair inguinal hernia
	Esophageal Varices(Acute)	Irritable Bowel and Related	Repair ventral hernia

	Esophageal Varices(Chronic)	Liver Abscess	Pancreatectomy
	Esophagitis (Acute)	Liver Disease Chronic Other	Liver transplant

Clinical Chapter	Condition Name		
HEM/LYMPH	Anemia Acute	Hypercoagulable State	Myelodysplasia
	Anemia Chronic	Immune Deficiency Disease	Neutropenia
	Aplastic Anemia	Kaposi's Sarcoma Lymph Nodes	Other Blood and Lymphatic Ds
	Blood Tranfsn Reaction	Leukemia Acute	Plasma Protein Ds Alpha-1 Antitrypsin Deficiency
	Bone Marrow Trnsplt Complctn	Leukemia Chronic	Plasma Protein Ds Macroglobulinemia
	Coagulopathy Acquired	Lymphadenitis	Plasma Protein Ds Other
	Coagulopathy Hemophilia/Related	Lymphoma Hodgkin	Polycythemia
	Complication - Blood Transfsn Rxn Incompatibility Acute	Lymphoma Mycosis Fungoides	Purpura and Thrombocytopenia
	Erythremia	Lymphoma Other non-Hodgkin	Sarcoidosis
	Essential Thrombocythemia	Mast Cell Tumor	Serum Reactions
	Graft vs. Host Dis	Metastatic Neoplasm to Lymph Nodes	Sickle Cell Disease
	Heparin-Induced Thrombocytopenia	Mucocut Lymph Node Syndrome	Thalassemias and Other Hemoglobinopathies
	Histiocytosis	Multiple Myeloma	
M-GEN	Benign Prostatic Hypertrophy	Penis Neoplasm - in Situ/Uncrtn	Scrotum/Contents Neoplasm - Benign
	Hydrocele	Penis Neoplasm - Malignant	Scrotum/Contents Neoplasm - in Situ/Uncrtn
	Hypospadias/Epispadias	Peyronie's Disease	Scrotum/Contents Neoplasm - Malignant
	Lipoma Spermatic Cord	Prostate Abscess	Testicular Dysfunction
	Male Breast Neoplasm - Malignant	Prostate Neoplasm - Benign	Testicular Torsion
	Male Repro Neoplasm nos - Uncrtn Behavior	Prostate Neoplasm - in Situ/Uncrtn	Undescended Testicle
	Orchitis/Epididymitis	Prostate Neoplasm - Malignant	Prostatectomy
	Penis Neoplasm - Benign	Prostatitis Acute	TURP
		Prostatitis Chronic Other	

Clinical Chapter	Condition Name		
MSK	Achilles Bursitis or Tendinitis	Hip Fracture	Spine Cervical Fx/Dislocation
	Amputation	Hip Other Arthropathy	Spine Deformity
	Ankl/Foot Contusion/Laceration	Hip Sprain/Strain Other	Spine Lower Fx/Dislocation
	Ankle/Foot Arthropathy nos	Infectious Tenosynovitis	Spine Lower Sprn/Strn
	Ankle/Foot Fx/Dislocation	Joint nos Ganglion/Cyst	Spine Post-Laminectomy Syndrome
	Ankle/Foot Sprain/Strain	Joint Replace Complcn	Spine Stenosis/Spondylosis Cervical
	Aseptic Necrosis	Knee Bursitis Various	Spine Stenosis/Spondylosis Lumbar
	Bone nos Aseptic Necrosis	Knee Fx/Disloc	Spine Stenosis/Spondylosis Thoracic
	Bone nos Fx Malunion/Nonunion	Low Back Pain	Spine Stenosis/Spondylosis/Spondylolisthesis nos
	Bone nos Fx Stress	Lower Extremity Compartment Syndrome	Spondylolysthesis
	Bone/Cartilage Ds Other	Lower Extremity Dislocation Other	Synovitis/Tenosynovitis Location nos
	Carpal Tunnel & Related Syndromes	Lower Extremity Infectious Arthritis	Tenosynovitis Ankle/Foot
	Clavicle Fracture	Lower Extremity nos Injury nos	Tibia/Fibula Fx
	Elbow Dislocation	Lower Extremity Osteomyelitis	Upper Arm Fx Humerus
	Elbow Joint Derangmnt	Lower Extremity Tendon Rupture	Upper Extremity Enthesopathy
	Elbow Lateral Epicondylitis	Lower Extremity/nos Fx	Upper Extremity Fx nos
	Elbow Medial Epicondylitis	Metastatic Neoplasm Bone	Upper Extremity Infectious Arthritis
	Elbow Olecranon Bursitis	MSK nos Neoplasm - Malignant	Upper Extremity Joint Derangmnt Other
	Elbow Sprain/Strain	MSK nos Neoplasm - Uncertn Behav	Upper Extremity nos Other Inj
	Extremity Arthropathy Arm/Elbow	Myositis	Upper Extremity Osteomyelitis
	Extremity Arthropathy Forearm/Wrist	Orthopedic Dvc/Grft Complcn/Malfnctn	Wrist Fracture/Dislocation
	Extremity nos Infectious Arthritis	Osteoarthritis	Wrist Sprain/Strain
	Extremity nos Neoplasm	Osteomyelitis nos	leg amputation
	Femur Fx	Osteoporosis	Knee arthroscopy
	Finger/Wrist/Hand Synvtis/Tensyn	Pelvic Fracture	Hip replacement
	Foot Juvenile Osteochondrosis	Periostitis nos	Knee replacement
	Foot Plantar Fascitis	Psoas Abscess	Shoulder arthroscopy / rotator cuff repair
	Forearm Fx	Renal Osteodystrophy	Shoulder total arthroplasty
	Hand Fracture/Dislocation	Rhabdomyolysis	Lumbar and sacral spine surgery
	Hand Sprain/Strain	Shoulder Dislocation	Fracture/dislocation treatment arm/wrist/hand
	Hand/Wrist/Forearm Contracture	Shoulder Fx Prox Humerus	Fracture/dislocation treatment knee
	Hip Aseptic Necrosis	Shoulder Fx Scapula	Fracture/dislocation treatment lower leg/ankle/foot
	Hip Dislocation	Shoulder Tendon Ds Rotator Cuff & Soft Tissue	Fracture/dislocation treatment pelvis/hip/femur

Clinical Chapter	Condition Name		
NEURO	Acute Ischemic Stroke	Head Trauma Closed Intracranial Hemorrhg	Neuro Device/Graft Complctn
	ALS/Related	Head Trauma Closed Subdural Hematoma	Neurofibromatosis
	Anoxic Brain Injury	Head Trauma nos w Intracranial Inj	Other Dystonia
	Bell's Palsy	Head Trauma nos w/Hemorrhg w/o Intracranial Inj	Paraplegia
	Cauda Equina Syndrome	Head/Neck Blood Vessels Inj	Parkinsons Ds
	Cerebral Aneurysm, Nonruptured	Head/Neck Peripheral Nerve Inj	Peripheral Nerve Inj
	Cerebral Degeneration	Head/Neck Vessel Inj Late Effects	Polyneuropathy EtOH/Cancer/Other
	Cerebral Degeneration - nos Pediatric	Headache Migraine	Polyneuropathy Heriditary
	Cerebral Edema/Compression	Headache Tension	Post-Op Stroke
	Cerebral Palsy/Related	Hemangioma Brain/Meninges	Prion/Slow Virus Infection
	Cerebrovascular Disease, Occlusive/nos	Hydrocephalus Acquired	Pseudobulbar Palsy and Related
	Chronic Progressive Dystonia	Hydrocephalus Congenital	Pseudotumor Cerebri
	CNS Hemorrhg	Ill-Defined Cerebrovascular Ds - Acute	Quadriplegia
	CNS Lymphoma	Ill-Defined Cerebrovascular Ds - Chronic	Reflex Sympathetic Dystrophy
	CNS Neoplasm	Insomnia	Seizures Convulsions Epilipsy (Acute)
	CNS nos Neoplasm - Malignant	Intracranial and/or Intraspinal Abscess	Seizures Convulsions Epilipsy (Chronic)
	Coma	Lumbar Punct Reactn	Sleep Apnea
	Cranial Nerve Inj	Meningial Neoplasm - Malignant	Spina Bifida
	Crervical Post Laminectomy Syndrome	Meningioma and Related	Spinal-Muscular Atrophy
	Dementia	Meningitis	Spinocerebellar Ds
	Diabetic Polyneuropathy	Microcephalus	Surgical - CNS Complctn
	Drug-Induced Dystonia	Mononeuritis Multiplex and Related	Thoracic Postlaminectomy Syndrome
	Early Onset Dystonia	Multiple Sclerosis	Transient Ischemic Attack
	Encephalitis	Myasthenia Gravis/Related	Transient Organic Psychosis/Delirium
	Encephalopathy	Myelitis	Trigeminal Neuralgia/Related
	Head Injury	Myopathy	Carotid Revascularization
URO/GEN	Acute Kidney Failure	Cystostomy Complications	Renal Vascular Ds
	Anomaly of Bladder and Urethra	Gu Device/Catheter Complication	Renovascular Injury
	Bladder Ds nec/nos	Hemorrhage Into Bladder Wall	Small Kidney(s)
	Bladder Dysfunction nos	Kidney Anomaly	Trichimonas
	Bladder Fistula	Kidney Neoplasm - Benign	Urethral Stricture/Other Ds
	Bladder Neoplasm - Benign	Kidney Neoplasm - Malignant	Urinary Obstruction
	Bladder Neoplasm - in Situ/Uncrtn Beh	Kidney Transplant Complication	Urinary Stone Disease
	Bladder Neoplasm - Malignant	Nephritis and Nephropathy	Urinary Tract nos Neoplasm - Benign
	Bladder/Urethra Foreign Body	Polycystic Kidney Ds	Urinary Tract nos Neoplasm - Malignant
	Chronic Kidney Disease	Pyeloureteritis Cystica	Urinary Tract nos Neoplasm - Uncrtn Beh
	Cystic Kidney nos	Renal Cyst	UTI
	Cystitis	Renal Dial Graft Complication	Kidney transplant
	Cystitis Irradiation	Renal Failure Effects Nephrogenic DI	Urinary endoscopy
			Nephrectomy

Responses to PTAC PRT Questions Batch 2

Questions about Payment Approach:

1. There are no changes proposed in the current payment system for any providers -- physicians, hospitals, or post-acute care providers. Does that mean you believe they will all continue to deliver essentially the same services as they do today and that the current payment rates for those services are adequate?

Implementing the ACS-Brandeis model would not require CMS to modify its prevailing payment systems or authorize payment for newly covered services. We acknowledge there are other forums for addressing coverage rules and payment rates (e.g., the RVS Update Committee). Implementation of this model does not preclude expanding the menu of covered services or modifying payment rates where appropriate, but the model is not dependent on such changes.

However, the ACS-Brandeis model does propose changes affecting payment to advanced APM entities that are beyond the FFS transactions occurring with professionals, suppliers, and facilities. In this model, the current payments such as FFS continue but occur within risk environments. Those entities delivering excessive services would be at risk of a penalty.

The model is not strictly limited to original Medicare FFS and could be retro-fitted into an ACO-like model. Currently, our efforts with large ACOs include targeted research focusing on the Clinical Affinity Group (CAG) activity inside the ACO. Lacking the structure and tools like those provided within our proposal, it can be difficult for ACOs to define and to specify meaningful benchmarks for episodes or bundles of care. The methods integral to the ACS-Brandeis model would offer that ability to population-based, risk environments such as ACOs, medical homes, and even Medicare Advantage plans.[1]

2. Are there any services you expect will be delivered that are not currently paid for? How will those providers be compensated?

The ACS-Brandeis model does not include requests for new covered services. We understand that CMS has in the past, and may again, test hypotheses regarding the cost-effectiveness of new covered services such as for care coordination. To the extent those tests are confirmatory, and new covered services become available, they could help to facilitate new utilization patterns in our proposed model as well. We also understand the implicit advantages of prospective payments (e.g., capitation) that can permit plans to cover services that are not reimbursed under Medicare's prevailing coverage rules. Later, we discuss how CMS may use the ACS-Brandeis model as a bridge to prospective payment, but we are not proposing that for the first stages of implementation.

We expect the CAGs and APM entities to identify potential investments in care redesign, guidelines and protocols, and supporting structures. And, we do anticipate new services and care pathways in the ACS-Brandeis APM, including the investment in new technology, such as telemedicine or cross-setting EHRs. For the most part, we expect the APM to reward new

[1] CMS requires MA plans to submit "encounter data," which have record formats similar to original Medicare.

technology that improves efficiency and to discourage investment in technology that provides insufficient improvements in cost or quality. For this to happen, APM entities need confidence in the model's stability so they can get a return on their investment, and working capital to finance novel structures and pathways.

To date, most CMS demonstration participants have made relatively low-risk investments, such as re-deploying staff. Longer term investments, such as an EHR or quality monitoring systems, may be in the works, but can take years to pay off. With a small portion of business in the APM (e.g., a handful of bundles in BPCI), it can be hard to justify larger, systemic investments. As providers shift larger portions of their business into the ACS-Brandeis APM, the opportunities for larger investments with positive returns also should increase.

All new business models, especially those based on value, require some retooling, new workflows and new resources. In a value-based arrangement within a payer risk environment, there are many factors to consider. First, the fiscal risks are all interrelated. Do the providers understand the actuarial risks associated with the clinical affinity groups and episodes in their population? Is this a well-controlled diabetic population with a history of controlled HbA 1Cs, or is this a poorly controlled population? It will be important for QP to have feedback for the conditions and episodes under consideration for risk based payments. Second, does the care delivery team have the operational infrastructure to take risk? Is the culture ready for a risk arrangement and a competitive market? The QPs need to understand their position in the market in order to stimulate the clinical transformations essential to performing against benchmark. Third, do the providers have a fiscal ability to cover any losses so that the practice remains, corrects, and recovers? The operational risks require clinical alignment, care delivery, information technology, data management and analytics, contract planning and management.

In order for any team to assume risks, the QPs must work with the payers to understand their current status relative to benchmarks. Small and rural communities may need support services to build the teams, create the operational framework and provide the data essential to population management for a given condition or episode of care. These small and rural communities may benefit from a capital partner and an operational consultant to bring together the essential elements of care within a CAG. Is this front-loaded by the payer? Is it a joint partnership with the payer? Do large delivery systems extend services to these communities for tertiary referrals? Does the payer use market levers to force movement based on incentives/disincentives?

For smaller entities, capitalization could remain an issue. It is not clear if the private market will solve this problem, such as regional collaboratives designed for joint purchasing of technology. If there is a market failure, as may be the case with rural or critical access facilities, CMS will need to decide if and how to finance care redesign. The ACO Investment Model (AIM) is one example of CMS experimenting with financing care redesign. The relatively low uptake beyond a few large convener groups suggests the terms of the financing may need further work.

3. What will happen as the expected costs of episodes decrease over time? Won't savings bonuses decrease and won't physicians have higher risks of experiencing costs higher than budgets? How will new/different services be paid for if there are no longer large shared savings payments?

The essence of the ACS-Brandeis model is to respect the body of work performed by each clinician, and to articulate fiscal attribution and the value proposition within a consistent and comprehensive episode framework. The premise of the question is actually the goal to which we aspire, namely that excellent care is provided routinely and reimbursed adequately. Given that the production function for healthcare is so complex and largely not understood, we do not attempt to specify the inputs to production and their budget requirements.

In our proposal to PTAC, we discussed how CMS and other payers may consider one or more payment approaches, which we believe could be compatible with the ACS-Brandeis model while representing different perspectives on care management and determination of savings to Medicare. To the extent that savings are defined in terms of a provider's performance compared to the average, then general convergence toward the average will reduce and possibly eliminate those savings. And to the extent that such convergence answers the question about resources required for excellent care, then it can serve as input into prospective payments – i.e., budgets.

The staged implementation we proposed for the ACS-Brandeis model reflects a starting point and then expansion into larger frontiers for improvement. Initial focus on procedures can help CAGs and delivery systems to implement uniformly excellent care with respect to all phases of surgical care. Expanding to condition episodes can engage other CAG members and help to tip delivery systems toward higher value. Expanding to chronic conditions also helps to intervene earlier with beneficiaries with prevention and slowing of disease progression. All stages of implementation maintain the focus on team-based, patient-centered care.

The problem of unsustainable growth in health care costs is not limited to, or even primarily a function of cross-sectional variation in utilization patterns. In other words, even compressing production processes and costs into a narrow band reflecting optimal utilization patterns will not necessarily or by itself slow the long-term growth in healthcare costs. That will require "bending" the long-run demand curve for healthcare (e.g., prevention and better "cures") and/or the long-run supply curve. Over the long-term, we understand that all inputs into healthcare production are "variable," including the mix of healthcare professionals, the types of technologies (chemical, electronic, devices, information), and physical capacity by type of setting.

For the time-being, i.e., over the short- and medium-term, much of healthcare inputs are fixed to one degree or another. That includes the number and mix of healthcare professionals, available technologies, the physical capacity (e.g., number of inpatient beds, and outpatient alternatives), as well as the prevailing "culture" of how to provide healthcare.

Using the terminology of the ACS-Brandeis model, we propose that the locus of decision-making should include the respective CAGs who have the knowledge and hands-on opportunity to envision and then implement transformations to healthcare production. In the short-term, we intend to empower CAGs as a cognitive catalyst for change, and their member-clinicians participating in patient care for each type and family of episodes, to begin modifying utilization patterns by redirecting patients toward efficient substitutions of inputs to production, and pressing toward improvement in quality outcomes via shared accountability in team-based care.

Supporting the premise of the question, that should compress variation toward production of excellent care. Hopefully, it will commoditize tomorrow what is exceptional care today. And

continuing to agree with the question, removing inefficiencies in normative care will lower the expected cost of production, and the savings defined by relative efficiency.

After several years of success, some considerations include:

- As the practices that have honed and demonstrated the success and high value in Medicare, they can seek competitive rewards from other payers, which generally are much abler than Medicare to shift patient volume toward efficient providers. This could involve attention to patient experience ("customer service") and price.
- The CAGs can continue to guide transformation. For example, diligent attention to high value can inform the adoption, diffusion, and utilization of new technologies. With interest in the natural history of various conditions, increasing attention can be given to prevention and early interventions that could slow the progression of illness, avoid costly and damaging acute exacerbations and sequelae.

Anticipating these dynamics, we have proposed compatible "payment models" for the ACS-Brandeis model that can be implemented flexibly in order to communicate needed incentives and to permit workable budgets, beginning in 2018 and continuing over the long-run. How long those payment models remain viable would depend on the rate at which entities could continue to generate new savings over time by emulating current best performers, and eventually surpassing them by redefining the efficiency frontier. Also important would be how frequently or completely CMS would "rebase" the targets through updated data versus trending forward historical target amounts.

4. Will the episode "budget" be the same as the current expected average spending level, or will there be a "discount" in setting the target, and how big will that discount be?

In the ACS-Brandeis model, the expected cost per episode is derived from EGM using representative claims data to produce normative (average) cost, and adjusted according to appropriate risk factors. CMS can request applications for entities to enter risk arrangements in which the true expected cost is "discounted" as a means of ensuring savings to Medicare, whether or not the entity truly generated savings, with the percentages conditional on the quality performance of the entity. Alternatively, CMS could seek participation from entities willing to operate under risk arrangements that specify budgets equal to the undiscounted expected cost, and call for some allocation or split of actual (positive or negative) savings between Medicare and the entity based on quality performance.

The difference between the approaches would depend on the amount of savings that an entity would perceive as achievable, and the amount of risk-taking the entity would consider in pursuit of those savings. For example, CMS has proposed discounts of around one percent or perhaps three percent of the expected average spending level, depending on quality performance. If savings are potentially a much larger proportion of the expected cost, then a two percent discount could be a "small price to pay" for the opportunity to keep and invest much more than that in return. However, since entities also would face equivalent risk for losses under the discount

model, the entity would need to have confidence and comparatively more financial backing to enter such contracts.

Alternatively, under scenarios in which anticipated savings are more modest, and hence closer to three percent of the expected cost, then a discount of up to three percent could wipe out expectations for shared savings. This problem can be worse as the model is scaled to include many services and costs that may not be targeted at a given time. For example, an entity that is managing cost for a population will have targets of opportunity, but expected savings from those may be a fairly small percentage of the entire population budget. This has been a problem in the ACO world in which two-percent savings per year (from bending the cost curve) are considered within the margin of error.

5. How will the hospital and post-acute care providers be paid? Will savings only be shared with physicians, not hospitals or post-acute care providers?

The ACS-Brandeis model consists of several layers affecting compensation. The first layer consists of the prevailing payment systems used by Medicare for professionals, suppliers, and facilities; the model does not disturb or modify those systems.

The second layer consists of the fiscal attribution logic, which is guided by clinicians' episode clusters and corresponding shares of the positive or negative savings. In the proposal model, there are no shares attributed to facilities or suppliers. However, the fiscal attribution culminates in budgets and financial determinations occurring for the advanced APM entity operating under the terms of its contract. This second layer applies to CMS and the entity as a whole, and not the constituent elements of the delivery system or affiliated components of the entity.

The relationship between the APM entity and the components of the delivery system are matters for its internal governance and network contracting. These include teaming arrangements and compensation systems comprising the third payment layer, which could include arrangements with hospitals and post-acute facilities.

6. How would monetary rewards and penalties be calculated and allocated among clinical participants?

CMS will specify how MIPS-eligible clinicians are deemed to be qualified participants in an advanced APM entity, which determines their reporting requirements and eligibility for the 5% bonus in professional fees. The APM entity accepts the risks for all its affiliated clinicians who participate within the designated episodes, which are used to calculate the rewards and penalties according to the entity's contract with the payer. The intrinsic logic of the model stops there.

Separately, the APM entity also can specify its own risk relationships with professionals, suppliers, and facilities. It is possible that the APM entity will impose a minimum risk on the individual clinician, which translates into an asymmetric risk between the APM entity and the clinician. If a health system or convener organization were to serve as an APM entity, it could assume more of the downside risk and share the upside risk with the clinicians. The APM entity could also provide the risk-based capital and the operational elements needed to create the

alignment around a CAG. We imagine advanced delivery systems, insurance companies or other third-party conveners working with community physicians to build APM entities, analogous to Independent Practice Associations, to provide a CAG with operational management, actuarial analysis, data management, risk-based capital, and so forth.

7. Expected savings:

a. How much savings do you expect to achieve?

Savings that are achievable from the model are a function of several factors. The ACS-Brandeis model is based on the CMS EGM, which supports potentially several hundred types of episodes accounting for approximately three-fourths of Medicare Part A and Part B spending. The amount of savings achievable depends first on the opportunities made available to APM entities in the form of supported episodes. On implementation, a second factor is the number of entities and the number and mix of episodes that are included in their risk-based contacts.

A third factor is the ability of entities to identify opportunities for cost savings. EGM is able to track every dollar spent on the supported episodes, provide standardized comparisons of actual to expected costs, and with the attribution logic proposed in the model, identify all clinicians participating in the care. Information shared with CAGs and providers involved in team-based care can include the cost implications of different treatment pathways, including the choice of surgical approach and setting of care. Hence, a related fourth factor is the clinical strategies adopted by entities individually. The savings here will depend on the extent there is "room for improvement" with respect to the entities' historical performance relative to benchmarks, and the extent to which entities are able to achieve improvement in those areas.

Finally, there are two additional factors that are as "cultural" as they are technical. More specifically, a fifth factor is the extent to which the APM entity is able to garner a critical mass among its QPs toward a general mindset of cost-consciousness, allowing for more sweeping changes in the delivery system. The ACS-Brandeis model is not intended to isolate a small fraction of a clinician's work for clinical redesign, meaning exclusive focus on a small number of episodes and corresponding indifference to other episodes. By analogy, Medicare did not implement DRGs one at a time, but rather swept in a new incentive structure and mindset that was largely inclusive of all lines of service. The ACS-Brandeis model aspires to move quickly beyond the tipping point for QPs and their locations of service, replacing the FFS "RVU productivity" mindset with a transformative value proposition.

A sixth factor is the extent to which clinical strategies emerge from the collective work across entities and are able to transform the community standards of care. This is the much sought after "bending the cost curve" that could result from adoption of new community standards, including regional or national adoption of cost-saving technologies, and similarly, cessation of the technological "arms race" involving widespread and often profligate adoption of expensive and duplicative technologies within markets, which can hinder or lower, rather than raise, net value in the population.

In a test sample of approximately 5 million Medicare beneficiaries there were 21 million EGM chronic condition episodes totaling $18 billion in Part A and B expenditures. One substantial opportunity for cost saving would be reducing inpatient hospital admissions for acute

exacerbations. Another opportunity for entities at risk for the cost of managing conditions would be to lower the incidence of procedural episodes. In the test sample, there were approximately $2.6 billion in hospital admissions for acute exacerbations and other sequelae, and another $3.7 billion for procedural episodes. Not all of these events can be prevented, but these estimates begin to point toward the tremendous opportunity for cost savings.

There are also saving opportunities within the remaining $11 billion of spending for these episodes, including changes in the setting and intensity of care. Each type of episode has its own opportunities to improve efficiency. Rather than attempting a full simulation and accounting of all the factors listed above, we merely illustrate the nature and potential magnitude of some of the savings in section c below.

b. How would you expect the model to achieve savings / What changes in care delivery will produce those savings?

To address this question, initially we will use two points of reference, which are two types of models already implemented by CMS, namely, hospital-based payment bundles, and population-based ACOs or medical homes. Some of the episodes supported by EGM can capture many of the same hospital admissions that are included in the roster of MS-DRGs that define models such as BPCI and CJR. As such, the ACS-Brandeis model could support or induce similar savings that are anticipated for those models, such as redirection of beneficiaries after discharge toward less expensive post-acute service patterns.

Models based on MS-DRGs could be viewed as constrained subsets of the savings opportunities available through the ACS-Brandeis model, which for example, could unleash savings from avoidance of the inpatient admission and MS-DRG payment. In addition, the proposed model can be more inclusive with respect to the inpatient admissions that do occur, allowing high-performing sites to exhibit savings by avoiding adverse consequences associated with ICU admissions and a range of possible MS-DRGs representing untoward events and worse outcomes.

Moving beyond BPCI, CJR and other CMS bundle models, the underlying clinical logic of EGM can trigger procedural episodes that are site-agnostic. Thus, entities can perform against cost benchmarks that represent an historical mix of settings, and can generate savings by shifting volume away from more expensive settings and toward clinically-appropriate but less expensive settings. This means, for example, shifting surgeries from the inpatient to the outpatient setting. A similar and sometimes related consideration is the historical tendency to use particular surgical or treatment approaches, which can drive cost outcomes and often determine the setting of care. This could include laparoscopic versus open surgery, single versus multiple surgeries for bilateral treatment, or the use of lower cost technology, such as high-cost versus low-cost clotting factors in emergency medicine.

More expansive implementation of the ACS-Brandeis model could provide savings opportunities that are otherwise associated with population-based approaches. By using a wide array of episodes that cut across clinical domains, the model is able to track actual versus expected costs by condition, and convey opportunities and incentives involving broad lines of service and ultimately the care of the whole patient. Unlike the ACO and medical home models, the ACS-

Brandeis model is able to retain a sharp focus on the particular episodes and clinicians' roles within the larger picture of the patient population and delivery system. Figuratively, the flood lamp that is cast upon the patient and provider populations is enhanced by spotlights aimed at the team-based care for each episode and for each patient, and further, a laser beam focused on each clinician according to his or her respective role in the patient-centered outcomes.

Similarly, condition episodes represent opportunities to avoid expensive settings of care. Proactive medical management can help to delay, avoid, or lessen the severity of acute illnesses and acute exacerbation of chronic illnesses. It is widely recognized that chronic conditions contribute substantially to total Medicare expenditures, and it is often the case that a significant portion of those expenditures are for the treatment of acute exacerbations. This is shown in the table below for six chronic condition episodes where we see acute exacerbations accounting for 30 to 60 percent of the total expenditures within the episodes in a single year. Thus, an entity working under risk arrangements to manage patient cohorts with various combinations of chronic illnesses may generate considerable savings by avoiding such acute exacerbations, or secondarily, reducing their severity and investing in capacity to handle acute events outside of the hospital inpatient setting.

Condition episode	Total episodes	Actual costs (Winsorized)	Epi with sequelae	Total costs sequelae	Percent episodes with sequelae	Percent dollars spent on sequelae
Asthma/COPD	63,236	67,959,444	4,224	40,665,922	7%	60%
Heart failure	39,407	81,498,043	6,924	50,892,397	18%	62%
IHD	74,537	113,783,003	7,084	49,629,020	10%	44%
Aortic valve disease	16,842	14,885,576	467	9,018,654	3%	61%
Cholecystitis	987	12,398,743	474	3,776,339	48%	30%
Esophagitis	45,797	10,430,674	2,617	3,761,721	6%	36%

c. Would any specific areas of utilization be reduced, and if so, what are they?

The ACS-Brandeis APM is designed to induce systemic change across a number of different episodes making it difficult to point to specific utilization that would be reduced. However, we can give some examples of how cost savings and service reductions may play out for specific conditions.

Savings can be achieved in an existing care pathway, without significant care redesign, through several mechanisms. For APMs narrowly construed as applying to a single procedure or a single provider organization, similar to the existing BPCI bundles, savings can be expected through eliminating unnecessary care and through improved care coordination and communication through the existing care pathway. For example, in an ACS/Brandeis APM focused on colectomy, the EGM captures all relevant services before the surgical procedure in the "look-back" period, and both services and outcomes after the procedure. The financial incentives inherent in our APM would encourage providers to manage and eliminate unnecessary services

performed throughout the care period. Improved communication and care coordination between the providers participating in the APM will result in better preoperative preparation and improved operative and perioperative care for the patient, improved outcomes after the procedure, and thus lower ICU and hospital lengths of stay, decreased rates of readmission and increased rates of discharge to home compared to other less favorable destinations. Finally, all other considerations being equal, and unlike in the BPCI program, the incentives in the ACS-Brandeis APM would encourage surgeons to move care from the inpatient to the outpatient setting. In our Medicare data set, the risk-adjusted costs for inpatient and outpatient cholecystectomy were $ 12,971 and $ 6,575, respectively.

The potential for savings increases for APM entities organized to manage the continuum of care for a patient population, and taking fiscal responsibility for acute and chronic condition episodes. The mechanisms outlined above will still apply. However, in these more comprehensive APM entities, the possibility exists for both improved care and additional savings through care redesign. For example, in an APM focused on gastrointestinal disease, the potential exists for care redesign resulting in both significant upstream and downstream savings through improved care. Appropriate aggressive screening for colon cancer, using colonoscopy or various visualization techniques, can result in earlier and more effective identification and treatment of polyps before they become cancerous, and thus lead to lower rates of colectomy for cancer, improved care with fewer complications for those patients proceeding to colectomy, lower rates of colon cancer overall, and multiple downstream savings opportunities. In our Medicare data set the risk-adjusted cost of a colectomy episode is dramatically affected by the presence or absence of significant postoperative sequelae. Patients with low actual-to-expected cost ratios had 1/3 the number of sequela compared to patients with high actual-to-expected cost ratios. Those patients who never need a colectomy avoid all of the surgical complications.

This approach could also work for chronic medical conditions. For example, an APM entity might be organized to provide enhanced care for patients with chronic medical conditions such as chronic obstructive pulmonary disease (COPD), diabetes, hypertension and congestive heart failure. Improved medical care for the patient with COPD might include innovative care coordination between patient and providers using mobile and internet technology developed or purchased by the APM entity. Improved care coordination for these patients would result in improved early care for the patient suffering an acute COPD exacerbation, including care acceleration while the patient is still at home, leading to fewer emergency room visits, fewer hospital admissions, and shorter lengths of stay and improved outcomes for those patients who do end up being admitted. For APMs that develop innovative care pathways, using innovative means of care coordination and focused on underlying chronic condition episodes as well as any acute condition and procedure episodes that the patient may experience, the savings will come through reductions in unnecessary services, through fewer inpatient admissions and ultimately through improved patient outcomes.

d. What data do you have showing the potential for savings for the episodes you are proposing to use?

Thus far there have been no real world tests of the ACS-Brandeis APM so we do not have evaluation data to help assess the potential behavioral response to the model. We are starting to conduct empirical simulations to get a better understanding of the upper and lower bounds of

savings and losses at the entity and market level.

8. Are there any data available that would indicate, either directly or indirectly, how the model would be expected to perform?

The ACS-Brandeis team has been using a developmental data set of 4.8 million Medicare beneficiaries that was purchased with private funding to refine clinical specifications, and develop other aspects of the proposed model including the fiscal attribution algorithms. The data include all Part A and B claims from 2012-2014 for beneficiaries residing in any of 18 market areas sampled from across the country.

The database is sufficiently large and diverse to specify risk-adjustment models for all supported episodes. Also, the large database can be used to illustrate instances of episodes that are stratified by selected attributes. EGM is able to configure episodes that are limited to certain attributes, such as a particular type of surgical technique, or surgeries for one type of indication (e.g., cancer) separated from other indications. These attributes are also stored as potential risk factors to adjust expected costs during implementation of the model. Thus, the enhanced capabilities of the EGM to configure episodes according to the needs of a particular use case also provide capabilities that readily format results in order to monitor performance or pose "what if?" questions.

The ACS-Brandeis model has not been implemented as a payment model; hence, we do not have experimental data showing results from this model post-implementation. However, the model is able to construct incentives systems that can emulate most models that have been implemented, ranging from defined segments of care (e.g., acute or post-acute bundles), or comprehensive, population-based models for all covered services. Our answers to question 7 above illustrate how Medicare spending can be framed as attributable and potentially avoidable.

Responses to PRT questions from review of American College of Surgeons' responses to questions on:

ACS-Brandeis Advanced Alternative Payment Model

Overarching Comment: The PTAC Preliminary Review Team notes that in many instances, the proposal appears to leave many implementation decisions to CMS. Wherever possible, the PTAC would like to know how you believe the various aspects of the models should be implemented by CMS. This will enable PTAC to more fully understand how the model would likely work so it can be evaluated against the Secretary's regulatory criteria under MACRA.

Questions:

1. The name of the proposal is the ACS-Brandeis proposal, but the proposal includes no letter or statement from Brandeis. Please provide a letter from Brandeis clarifying its level of support for and anticipated involvement in the proposed model, if implemented.

Please see the attached letter of support.

2. We understand that you view the ACS-Brandeis model as applicable to a broad range of conditions and procedures, that care changes and potential savings will differ for every condition and procedure, and that different approaches may be used in different organizations and communities. While it has been helpful to understand the breadth and flexibility you have designed in the model, we are having difficulty understanding exactly how you envision the model would work in any individual case. We believe that the most effective way to address this would be for you to provide two detailed examples of how all aspects of the model might be implemented for one procedure (e.g., colectomy) and for one condition (e.g., stable ischemic heart disease). We understand that various aspects of the example you give would reflect only one of several possible ways that physicians could implement care or distribute funds under the payment model, but we want to see at least one complete example of how you believe the model would be likely to be implemented for a procedure and a condition by the physicians who have expressed interest to you in implementing the model. Include in each of your illustrative examples the following:

Redesigning care

a) How the alternative payment entity would be structured, including the nature of the financial participation and decision-making involvement of physicians (you are welcome to provide several alternative options if you wish, but please make sure that there is at least one example with adequate detail);

First, it may help to consider how CMS may qualify APM entities, recognizing that many aspects are required by MACRA or stipulated in regulations. These entities must enter risk-based contracting arrangements with the payer (in this case, Medicare). The risk-based (APM) contracting involves risks for the episodes selected by the APM entity, which we refer to as the entity's episode library. The library would include episodes associated with the eligible clinician (EC) who would consider a risk relationship with the APM entity. Generally, across most or all of the options:

- The performance period will be the calendar year (12 months), although an entity could enter the program midway through the first calendar year of performance, such as July 1
- An entity must be registered prior to the start of its performance period
- Each EC must enter a business associate agreement with the entity. The ECs may act independently or based on a group decision (i.e., a common TIN, or a group practice). These ECs become the QPs (or partial QPs) affiliated with the entity.
- An entity will select which types of episodes, such as colectomy or IHD, are in its episode library, i.e., covered in the risk-based contract. The instances of those episodes (i.e., the patients) that are included in the risk-based contract are those in which one or more affiliated QPs participate.
- Performance expectations for the entity are specified according to each of the episode types covered in its APM contract. These include risk-adjusted target expenditures for each type of episode, as well as relevant quality measures.
- Each entity will need formal agreement regarding shared governance, such as for adding or removing affiliated QPs, and a legal structure to disperse payments to QPs or other components of the delivery system (e.g., facilities) based on its share of savings. Similarly, the entity will need a legal structure to make payments owed to the payer (CMS).
- The BAA for each QP must stipulate the applicable risk/reward parameters, i.e., the circumstances and extent to which a QP is compensated or at risk for the financial results pertaining to episodes in which he or she participated (or not), and their respective clinical roles in those episodes (e.g., episodic or supporting provider). The parameters can refer to absolute dollar amounts (e.g., caps on amounts owed) or percentages (e.g., 10 percent of positive savings or 5 percent of losses).
- The entity and QPs also must agree to support the mission to improve value, such as an agreement to share data appropriately, agreements to use technology as required for an advanced APM, and agreement on working toward common clinical outcomes and cost results.

The APM entity could be a surgical or medical practice, a delivery system consisting of clinicians and one or more facilities, or several groups who assemble to manage a specified episode library. Any of these APM entities may elect to bring local hospitals into their APM partnership. CMS is undoubtedly determining general principles and specific requirements for Advanced APMs generally and in relation to different types of models; e.g., population-based or bundled segments of care. The ACS-Brandeis model might fit well onto an emerging chassis such as the Next Generation ACO with regard to ownership, capital requirements, and the intersection with state insurance laws. However, especially in the early years, APM participants are likely to have scope of responsibility that is much less than an entire beneficiary population, perhaps allowing for requirements that are more streamlined.

As an example, colectomy could be one of the episodes included in the APM entity's episode library and included in the episode clusters for QPs who participate in the care for patients undergoing colectomy. As another example, a primary care group may wish to employ IHD and the top 10 chronic condition episodes in their APM entity. The EGM logic assigns services to all episodes based on their direct clinical relevance, and distinguishes (excludes) all other services, some of which may be assigned to nested or different concurrent episodes. More details about service assignment are provided in our answer to 2.b.

At the conclusion of the year, a retrospective analysis would evaluate the services provided to the patient who had the episode of interest and establish a patient-specific, risk-adjusted target by comparing this patient to similar patients. If a patient undergoing colectomy had a cost profile that saved $1000, the quality of care would then affect how much of the savings would be shared with the team. Excellent care receives the full shared-savings opportunity. The affiliated QPs' shares would extend to the APM entity from CMS. The APM entity would reconcile all the other episodes in each provider's cluster of episodes. The individual surgeon may have several more colectomy episodes that also would be reconciled. The surgeon also may have 25-50% of his or her clinical practice in other episodes. If the surgeon is due a reward in shared savings for this colectomy, the funds are added to the surgeon's overall pool of dollars for all the episodes. The net of all losses or gains will establish the level of reward or penalty the surgeon will have. The sum would be held at the APM for final reconciliation.

b) What services would be included in the episode, and what, if any, services (that might be considered to be related to the procedure or condition) would be excluded (you can provide the detailed methodology and codes from the grouper if you wish).

Generally, procedure episodes such as colectomy are defined by trigger codes (i.e., CPT procedure codes) that represent the definitive surgery or other treatment of interest, such as the following:

- removal of colon, ileostomy
- partial colectomy with anastomosis
- laparoscopic left hemicolectomy
- Open and other multiple segmental resection of large intestine.

Once criteria are met to trigger an episode for a patient, EGM creates an "episode shell" for that type of episode with start and end dates. Services billed during the episode time window are eligible for assignment to the episode according to their clinical relevance. Services that include trigger codes for an episode, such as any of the various specific diagnosis codes for IHD, are generally assigned to that episode. This is one of the most common ways a service is assigned to an episode.

Clinical specifications for episodes in EGM also contain relevant services, which are procedure codes deemed to have plausible clinical purpose related to that episode. These are assigned to the episode based on a combination of the procedure and diagnosis code. For colectomy, these include:

- Anesthesia for anorectal procedure

- Intubation, endotracheal, emergency procedure
- Suture of small intestine (enterorrhaphy) for perforated ulcer, diverticulum, wound, injury or rupture
- Closure of enterostomy, large or small intestine
- Magnetic resonance (e.g., proton) imaging, abdomen
- Ostomy skin barrier, with flange (solid, flexible, or accordion)

Clinical specifications for episodes in EGM also contain codes for relevant diagnoses that are considered plausible findings, symptoms, or various presentations that often occur in relation to a given episode. Examples for colectomy include:

- abdominal pain, right lower quadrant
- abdominal or pelvic swelling, mass, or lump, epigastric
- personal history of malignant neoplasm of large intestine
- aftercare following surgery for neoplasm.

Including relevant diagnoses for each episode helps to capture the range of services and costs that are related to an episode even when diagnoses that are more specific are not included on the claim. This has the additional advantage of comparing the efficiency of providers more fairly by including services and costs that reflect non-specific diagnoses, which may partly be a reflection of variation in coding practices.

Clinical specifications for episodes in EGM also contain assertions about the relationships among a patient's episodes. One such relationship is that of sequelae, which are aftereffects or secondary results that can occur from a parent or causal episode. With colectomy, for example, potential sequelae include cellulitis, pneumonia, and electrolyte disorders.

Another relationship among episodes recognized by EGM is the indication, or in other words, the condition being treated by the surgery. Examples for colectomy include intestinal blockage or neoplasm. Identifying the indication allows the procedural episode to be nested within the appropriate condition episode, creating a fuller picture of the cost of treating the cancer or intestinal blockage. In turn, for the procedural episode, its indication can be used to stratify episodes (e.g., restrict comparisons only to colectomies done to treat benign colorectal neoplasm), or to risk-adjust cost models according to specific characteristics of each patient.

For condition episodes, the episode construction process is similar. Both ischemic heart disease (IHD) and acute myocardial infarction (AMI) are triggered by specific diagnosis codes on an inpatient (in the case of AMI or IHD) or outpatient (in the case of IHD) claims. Examples of diagnostic trigger codes for IHD include:

- chronic ischemic heart disease, unspecified
- coronary atherosclerosis due to calcified coronary lesion
- coronary atherosclerosis of artery bypass graft
- coronary atherosclerosis of native coronary artery.

For AMI, trigger codes include:

- acute myocardial infarction of other lateral wall,
- acute myocardial infarction of anterolateral wall
- acute myocardial infarction of inferoposterior wall.

Procedural episodes and acute condition episode include sub-categories that can be used to stratify or select episodes that are more narrowly defined, or for risk-adjusting costs. Sub-categories for AMI include: STEMI, NSTEMI and acute coronary syndrome (unstable angina w/o AMI).

As with procedural episodes, condition episodes also have relevant services and diagnoses that are used to assign claims to a specific episode. For IHD, these include:

- Myocardial imaging
- Lipid panel
- Electrocardiogram
- Computed tomography, heart.

For AMI, relevant services include many of the same imaging and blood tests as IHD. Additional relevant services include:

- Creatine kinase
- Troponin, quantitative,
- Injection, eptifibatide, 5 mg.

Relevant diagnoses are symptoms and other clinical indicators that can be assigned to episodes. For IHD examples include:

- abnormal cardiovascular function study
- chest pain, unspecified
- long-term (current) use of antiplatelet/antithrombotic.

Relevant diagnoses for AMI include:

- hypotension
- shortness of breath
- tachypnea.

Finally, condition episodes also have sequelae. AMI, in fact, is a sequela of IHD. Other sequelae for IHD include acute ischemic stroke and acute heart failure. In terms of AMI, potential sequelae include acute pulmonary embolism, non-operative shock, and respiratory failure.

c) How the target price for the episode would be established, when and how the determination would be made as to whether actual episode spending was above or below the target price, and

in what circumstances would a patient case with spending above or below the target price be excluded from the calculations;

In our response here, and generally for the APM, all instances of colectomy episodes would be included in the calculations except for one type of situation involving assignment of the inpatient hospital claim to some other episode. In EGM, procedure episodes that are triggered during an inpatient hospitalization that is assigned to a different episode are excluded from cost comparisons involving other instances of that type of episode. That is because the DRG payment lumps together all of the facility-based services, including parallel or incidental procedures, and distorts or obscures their distinctive cost for a patient. Thus, cases with facility payments assigned to the episode of interest are not comparable to cases with facility payments that are assigned to some other episode.

Calculating the expected value or the target price for colectomy episodes for an APM Entity will involve two components:

- Determine parameters for the payment model using data for all colectomy episodes nationwide during a base period, except those excluded from the APM model as discussed above.
- Apply those parameters to compute the target price for each colectomy episode attributed to a particular APM Entity.

Payment model parameters

Payment model parameters will be determined using data for episodes starting during the one-year base period prior to the performance period for which a price is to be set. After processing with the EGM software, claims data will include both the actual allowed amounts for each service assigned to each episode and a price-standardized amount that removes pass-through amounts (e.g., IME) and geographic variations in price (e.g., wage adjustments). These amounts will be summed to give both actual and price-standardized costs separately for each episode.

The parameters to be computed for colectomy (and each other type of episode) are:

- Winsorization threshold (i.e., the dollar amount at which each case is capped)
- Average Winsorized price-standardized cost[1]
- Patient risk factors
- Entity adjustment factors
- Entity price indices[2]

Patient risk factors and the entity adjustment factors will be estimated from a hierarchical linear model with instances of the colectomy episode as the unit of observation. The dependent variable will be the

[1] The Winsorized price-standardized cost for each episode is the lower of (a) the total price-standardized cost for the episode, or (b) the Winsorization threshold, which is the average price-standardized cost over all episodes plus twice the standard deviation of the price-standardized episode costs.

[2] The entity price index is the ratio of its average actual cost per episode to its average price standardized cost per episode.

Winsorized price-standardized cost. The fixed factors will be patient and episode attributes, which are discussed further below. The second-level random intercepts will be the TIN of the episodic provider, or a contracted APM entity other than a TIN if applicable.

Computing target prices

The base rate for each colectomy episode with an episodic provider who participates in a particular Entity[3] will be (a) the sum of the average Winsorized price-standardized cost for the base period plus the that Entity's adjustment factor, times (b) 1 + the average national price change between the base period and the reconciliation period to which the target price will apply, times (c) 1 + the Entity's price index)

The target price for each colectomy episode will be the product of (a) this base rate, times (b) the episode's risk index. The risk index of an episode will be (a) the expected cost of an episode with the subject episode's risk factors with an episodic provider in an 'average' entity (i.e., an entity with an adjustment factor of zero), divided by (b) the average of such expected cost amounts over all included colectomy episodes.

Reconciliation

Reconciliation is the process of comparing expected costs (target prices) with Winsorized actual episode costs to determine what if any payments are due from the Entity to CMS, or vice versa. This will likely occur quarterly, 3 months after the end of each quarter, although annual reconciliation is also a possibility. While this example uses colectomy, all episodes in the Entity's library will be reconciled together.

The Winsorized actual cost will be the lower of (a) the allowed amount of all services assigned to the episode, or (b) the Winsorization threshold for colectomy, times the entity price index for the TIN or entity of the episodic provider.

The Entity's attributed savings (over/under target price) for each colectomy episode will be (a) the Winsorized actual cost minus the target price, times (b) the Entity's attributed share of the colectomy episode. The sum of this amount over all episodes included in the Entity's library (not only colectomy) will be the total over/under amount. If this number is positive, then the Entity will pay a specified amount to CMS; if it is negative, then CMS will pay a specified amount to the Entity.

d) What factors would be used to risk adjust actual spending. Please provide a few patient examples and show how much the adjustment would be for each.

[3] Note that some of the colectomy episodes attributed to a particular Entity may have an episodic provider who is not an affiliated QP in that Entity. In such a case, the target price will be computed using the base rate for the TIN or applicable APM entity of the episodic provider.

The risk factors used to compute the risk index described above are:

- Patient demographics: These are age, gender and Medicare eligibility status.
- Attributes of the episode: These are specific to the episode. Examples are laterality, sub-category (e.g., STEMI or non-STEMI AMI), and indication.
- Patient clinical history as described by other EGM episodes, either already open at the time the subject episode is triggered, or that occurred in the (relatively) recent past. The episodes used are specific to the subject episode.

Table W shows the risk factors applicable to four illustrative colectomy patients, with the resulting risk index for each patient. Each row is a risk factor applicable to one or more of the four patients. These are identified by the first two columns. The last four columns show the parameters applicable to the four patients, respectively. An empty cell means the factor value is not applicable to that patient. The first three rows show the resulting expected cost (excluding the entity adjustment factor) and risk index. The four patients range in their risk index from 0.4 for Patient A to 2.3 for Patient D based on differences in demographics, reason for Medicare eligibility, indication for the surgery, aspects of anatomy or surgical approach, concurrent comorbidities, or interactions with other contemporaneous procedures.

Tables X, Y, and Z show similar results for the condition episode IHD, and two of its nested procedural episodes, PCI and CABG, respectively.

Table _W: Illustrative Risk-Adjusted Expected Costs for Four Patients (Colectomy)

		Applicable parameters for illustrative patients			
Risk factor	**Factor category**	**Patient A**	**Patient B**	**Patient C**	**Patient D**
risk_index		0.4	0.91	1.1	2.3
pred_fixed_only		$ 9,910	$ 22,263	$ 26,949	$ 56,185
avg_pred_fixed_only		$ 24,337	$ 24,337	$ 24,337	$ 24,337
Intercept		$ 43,347	$ 43,347	$ 43,347	$ 43,347
bene_gender_age	F55-59			$ 1,481	
bene_gender_age	F80-84	$ 2,354	$ 2,354		
bene_gender_age	M70-74				$ 1,467
bene_mdcr_status	Aged without ESRD	$ (17,241)	$ (17,241)		$ (17,241)
bene_mdcr_status	Disabled with ESRD			$ (14,748)	
primary_indication	diverticulitis of colon				$ (4,470)
primary_indication	colorectal neoplasm malignant		$ (4,539)		
primary_indication	GI hemorrhage	$ (5,461)			
primary_indication	diverticulosis of intestine(chronic)			$ (3,476)	
sub_cat	Anastomosis			$ (3,892)	$ (3,892)
sub_cat	unspecified	$ -	$ -		
combined_tx	none	$ (2,644)			$ (2,644)
combined_tx	colonoscopy			$ 328	
combined_tx	cystoscopy		$ -		
Trig cd approach: Laparoscopic				$ (4,768)	
Trig cd detail: Anastomosis				$ 5,427	$ 5,427
Trig cd anatomy: Partial colon				$ 1,250	$ 1,250
Trig cd approach: Open		$ (1,420)			$ (1,420)
Trig cd detail: Ostomy					$ 11,389
Trig cd anatomy: Rectum		$ (5,604)			
Open sepsis, SIRS					$ 5,423
Open resp failure					$ 7,163
Open peritonitis					$ 4,190
Open colorectal neoplasm malignant			$ 1,762		$ 1,762
Open intestinal obstruction					$ 234
Open intestine perforation					$ 4,201
Open anemia chronic				$ 2,000	
Open Colonoscopy		$ (3,421)	$ (3,421)		

Table _X: Illustrative Risk-Adjusted Expected Costs for Four Patients (IHD)

		Applicable parameters for illustrative patients			
Risk factor	**Factor category**	**Patient A**	**Patient B**	**Patient C**	**Patient D**
risk_index		0.4	0.9	1.1	2.1
pred_fixed_only		$ 298	$ 671	$ 820	$ 1,566
avg_pred_fixed_only		$ 746	$ 746	$ 746	$ 746
Intercept		$ 1,142	$ 1,142	$ 1,142	$ 1,142
bene_gender_age	F75-79		$ (166)		
bene_gender_age	F95-GT			$ (105)	
bene_gender_age	M75-79	$ (150)			
bene_gender_age	M90-94				$ (107)
bene_mdcr_status	Aged without ESRD	$ (603)	$ (603)	$ (603)	$ (603)
period_category					$ (503)
Open benign prostatic hypertrophy		$ (15)			
Open cerebrovascular disease, occlusive/nos		$ 68		$ 68	
Open acute myocardial infarction					$ 1,389
Open heart failure (chronic)					$ 338
Open atrial fibrillation/flutter (chronic)					$ (27)
Open hypertension essential (chronic)		$ 56	$ 56	$ 56	$ 56
Open Diabetes Type II (chronic)		$ 90			$ 90
Open lipid ds		$ (62)	$ (62)	$ (62)	$ (62)
Open esophagitis (chronic)					$ 39
Recent acute myocardial infarction			$ 164		
Trig cd:old myocardial infarction		$ 26	$ 26		$ 26
Trig cd:coronary atherosclerosis of unspecified type of vessel, native or graft		$ (189)		$ (189)	$ (189)
Trig cd:coronary atherosclerosis of native coronary artery		$ 49	$ 49		$ 49
Old Percutaneous cardiac intervention			$ 148		

Table _Y: Illustrative Risk-Adjusted Expected Costs for Four Patients (PCI)

		Applicable parameters for illustrative patients			
Risk factor	**Factor category**	**Patient A**	**Patient B**	**Patient C**	**Patient D**
risk_index		0.41	0.9	1.1	2.1
pred_fixed_only		$ 7,367.00	$ 15,975.00	$ 19,490.00	$37,312.00
avg_pred_fixed_only		$ 17,716.00	$ 17,716.00	$ 17,716.00	$17,716.00
Intercept		$ 28,403.00	$ 28,403.00	$ 28,403.00	$28,403.00
bene_gender_age	F75-79				$ (2,982.00)
bene_gender_age	M55-59			$ (3,841.00)	
bene_gender_age	M60-64		$ (3,298.00)		
bene_gender_age	M70-74	$ (4,293.00)			
bene_mdcr_status	Aged without ESRD	$ (3,360.00)			$ (3,360.00)
bene_mdcr_status	Disabled without ESRD		$ (4,992.00)	$ (4,992.00)	
primary_indication	acute myocardial infarction		$ (643.00)		
primary_indication	ischemic heart disease	$ (880.00)		$ (880.00)	$ (880.00)
sub_cat	Angioplasty	$ (1,298.00)			
sub_cat	Revascularization		$ (1,926.00)	$ (1,926.00)	
sub_cat	Stent				$ (898.00)
combined_tx	none	$(13,113.00)			
combined_tx	cardiac cath		$(11,120.00)	$(11,120.00)	
combined_tx	insert perm pacemaker/AICD and cath				$ -
Trig cd approach: Angioplasty		$ 3,275.00			
Trig cd anatomy: Single vessel		$ (164.00)	$ (164.00)	$ (164.00)	$ (164.00)
Trig cd approach: Revascularization			$ 5,734.00	$ 5,734.00	
Trig cd approach: Stent					$ 5,206.00
Open acute kidney failure					$ 2,715.00
Open acs subsequent/other				$ 819.00	
Open acute myocardial infarction			$ 3,981.00		
Open card device or graft comp/malfnctn				$ 3,042.00	
Open cardiomyopathy				$ 515.00	
Open heart failure (chronic)				$ 3,025.00	$ 3,025.00
Open ischemic heart disease		$ 876.00		$ 876.00	$ 876.00
Open valve ds aortic (chronic)					$ 352.00
Open resp failure					$ 5,021.00
Open Cardiac catheterization		$ (1,237.00)			
Open CABG		$ (841.00)			

Table _Z: Illustrative Risk-Adjusted Expected Costs for Four Patients (CABG)

		Applicable parameters for illustrative patients			
Risk factor	**Factor category**	**Patient A**	**Patient B**	**Patient C**	**Patient D**
risk_index		0.4	0.9	1.09	2.1
pred_fixed_only		$ 17,529.00	$ 38,498.00	$ 47,002.00	$ 89,893.00
avg_pred_fixed_only		$ 42,771.00	$ 42,771.00	$ 42,771.00	$ 42,771.00
Intercept		$ 54,084.00	$ 54,084.00	$ 54,084.00	$ 54,084.00
bene_gender_age	F70-74			$ 10,030.00	$ 10,030.00
bene_gender_age	F75-79		$ 11,642.00		
bene_gender_age	M65-69	$ 7,486.00			
bene_mdcr_status	Aged without ESRD	$ (6,793.00)	$ (6,793.00)	$ (6,793.00)	$ (6,793.00)
primary_indication	acs other than ami	$ (7,743.00)			
primary_indication	ischemic heart disease		$ (4,425.00)	$ (4,425.00)	$ (4,425.00)
sub_cat	1 vessel	$ 2,369.00	$ 2,369.00	$ 2,369.00	$ 2,369.00
combined_tx	none	$ (25,951.00)	$ (25,951.00)		
combined_tx	cardiac cath				$ (14,043.00)
combined_tx	open heart valve surg			$ (14,673.00)	
Trig cd anatomy: 1 vessel		$ (6,563.00)	$ (6,563.00)	$ (6,563.00)	$ (6,563.00)
Trig cd detail: Arterial graft		$ 4,566.00	$ 4,566.00	$ 4,566.00	$ 4,566.00
Open acute ischemic stroke					$ 8,997.00
Open acute kidney failure					$ 6,384.00
Open acute myocardial infarction					$ 2,106.00
Open heart failure (chronic)			$ 6,269.00	$ 6,269.00	$ 6,269.00
Open atrial fibrillation/flutter (chronic)			$ 3,485.00		
Open malnutrition					$ 19,354.00
Open resp failure				$ 6,136.00	$ 6,136.00
Open Cardiac catheterization			$ (185.00)	$ (185.00)	
Open Percutaneous cardiac intervention		$ (3,925.00)			
Open EGD endoscopy					$ 1,423.00
Open Leg revascularization				$ (3,812.00)	

e) How the roles for various clinicians in care related to the procedure or condition would be determined and assigned;

Sorting out (or assigning) clinical roles in relation to patient care is a complicated undertaking that involves a number of principles and steps. Our answer here is a summary of those principles and steps; Appendix X discusses the specific steps in more detail.

Algorithms are applied to the data in order to infer from service patterns the logical role each clinician has with respect to the patient and episode. The algorithms attribute each episode for a patient to a set of providers according to patient relationship categories (PRCs) inspired by MACRA, as shown in our proposal to PTAC, and again in Appendix X. The names we have given to the clinical roles are Principal, Primary, Supporting, Ancillary, and Episodic.

Many Medicare beneficiaries have one or more chronic conditions. EGM episodes for chronic conditions can remain open indefinitely, spanning many months or years. EGM refreshes calculations for each chronic condition episode every 90 days, including factors used for risk adjustment, and estimates of future costs (i.e., the next 90 days). The ACS-Brandeis model's fiscal attribution logic piggybacks on that structure by inferring clinical roles for providers from the pattern of services observed over 90-day periods.

The ACS-Brandeis model is intended to focus accountability on events and consequences that have not yet occurred, such as potential future acute exacerbations, or discretionary or avoidable services, and sequelae (including complications). Thus, participation in the care for a patient during one time-period activates accountability and incentives that anticipate future costs. Lowering actual cost below the estimated expected cost generates savings, which translate into incentive payments that acknowledge and reward the relative efficiency. Hence, the structure of accountability observes service patterns in one or more quarters, and continues accountability into the next quarter. Even if a provider does not provide a service in the subsequent quarter, the accountability continues for that long, which we call a "warranty" period to reflect the responsibility for consequences that would take time to manifest.

In each successive quarter, a clinician's services for that chronic condition episode (e.g., IHD) are categorized into ancillary, E&M, or non-E&M. Ancillary services are limited to a defined set such as reading test results, which would be expected by specialties like general radiology or pathology.

- Any clinician who provides only ancillary services will be assigned the role of Ancillary provider in the current and subsequent (warranty) quarter.
- Any clinician who provides only non-E&M (beyond any ancillary) services will be assigned the role of Supporting provider in the current and subsequent (warranty) quarter.
- Any clinician who provides any E&M (beyond any other) services for two consecutive quarters will be assigned the role of Principal provider starting in the second such quarter, and will continue as Principal provider in the subsequent (warranty) quarter.

- Any clinician who qualifies for the role of Principal provider for two or more chronic condition episodes that reflect different clinical domains (e.g., cardiovascular and muscular-skeletal), and whose specialty is general (e.g., internist) will be assigned the role of Primary provider for the patient instead of Principal provider for that condition episode.

Episodes that are for acute conditions or defined procedures can occur at any time, and begin and end within 90 days. In contrast to chronic condition episodes, for acute conditions and procedural episodes there is an Episodic provider in addition to clinicians with other roles.

- For procedural episodes, the Episodic provider is the surgeon who conducts (bills for) the definitive procedure for that episode.
- For acute condition episodes, the Episodic provider is determined based on claims patterns related to diagnosis codes and timing. Specifically, for an acute condition, the Episodic provider is the clinician with the most E&M services on the date on which the episode is triggered.

In addition to the Episodic provider, fiscal attribution for acute conditions and procedural episodes includes other clinical roles. Ancillary and Supporting providers are defined with algorithms similar to chronic condition episodes: Ancillary providers bill only for ancillary services. Supporting providers bill for services beyond ancillary.

The clinical roles of Principal provider and Primary provider for acute episodes borrow from the established roles that are determined over time from chronic condition episodes. If the patient has a Primary provider during the quarter in which the acute episode begins, that provider is assigned the Primary provider role for the acute condition or procedural episode of interest. For acute condition episodes, there is a Principal provider if the acute condition is an exacerbation or other sequela of a chronic condition episode for which there is a Principal provider. Similarly for procedural episodes, there is a Principal provider if the condition episode for which the procedure is indicated is a chronic condition or an acute condition that is an exacerbation or other sequela of a chronic condition episode for which there is a Principal provider.

The EGM attribution logic uses the services provided and timing of care to determine each provider's role in the case. The table below shows all of the providers associated with a single colectomy and the services provided. As shown in the table, the primary provider has a relationship with the patient over time, managing a number of different conditions. In this particular case, the primary provider is involved in chronic conditions like COPD, affective disorder and hypertension, along with having a role in an endoscopy and the colectomy.

The principal provider is a medical specialist focused on gastroenterology related issues. This provider primarily bills for evaluation and management care, including services related to the colectomy episode. The Episodic provider is a general surgeon who does the definitive treatment (pxdef) which, in this case, is a colectomy.

The supporting providers include a nurse anesthetist and physician anesthesiologist, a physician assistant, a nurse practitioner and medical generalists. Each of those providers either billed for supporting services related to the surgery or evaluation and management care, most likely after the surgery. Finally, there are a small number of Ancillary providers including a radiologist and pathologist.

	Start of services	End of Services	Payments	Service type	Service count	Episode
Primary						
PROV 1: Physician/Internal Medicine	4/26/2012	7/31/2013	775.23	em	2	affective ds other (chronic)
				em	6	asthma/copd chronic
				em, tst/lab	17	atrial fibrillation/flutter (chronic)
				em	2	bone/cartlg ds ne
				tst/lab	1	EGD endoscopy
				text/lab	9	Colectomy
				em, test/img	20	hypertension essential (chronic)
				em	13	lipid ds
				em, tst/lab	9	low back pain
				em, therapy	4	other
Principal						
PROV 2: Physician/Gastroenterology	4/25/2012	5/1/2013	664.88			
				pxdef	7	Colonoscopy
				em	5	colorectal neoplasm benign
				em	3	EGD endoscopy
				em	1	Colectomy
				em	2	other
Episodic						
PROV 3: Physician/General Surgery	4/22/2013	5/9/2013	108.38	em, pxdef	3	Colectomy
Supporting						
PROV 4: Physician/Gastroenterology	5/1/2013	5/1/2013	75.06	em	1	Colectomy
PROV 5: Certified Registered Nurse Anesthetist (CRNA)	5/9/2013	5/9/2013	163.68	pxsup	1	Colectomy
Prov 6: Physician/Anesthesiology	5/9/2013	5/9/2013	163.68	pxsup	1	Colectomy
PROV 7: Physician assistant	5/17/2013	5/17/2013	115.04	em	1	Colectomy
PROV 8: Physician/Family Practice	5/16/2013	5/16/2013	164.78	em	1	Colectomy
PROV 9: Nurse Practitioner	5/16/2013	5/16/2013	142.20	em	1	Colectomy
Ancilary						
PROV 10: Physician/Diagnostic Radiology	7/11/2013	7/11/2013	9.00	img	1	Colectomy
PROV 11: Pathology	5/9/2013	5/9/2013	84.06	tst/lab	1	Colectomy
PROV 12: Physician/Internal Medicine	4/26/2013	7/11/2013	10.69	tst/lab,testing/img	10	Colectomy

f) The percentage of financial responsibility that would be assigned to each physician/provider type and whether it was dictated by the model or whether it was chosen by the participating physicians;

This is where the ACS-Brandeis model has a major pivot point. On the one hand, CMS and other payers will need to determine standard rules by which the financial outcomes are attributed to clinicians

participating in patient care. On the other hand, the participating entities will need to establish ground rules and specific business relationships with clinicians who are affiliated QPs. We interpret this question (2.f) as pertaining mainly to the relationship between the payer and providers/entities; and later questions (2.g. and 2.h below) as pertaining mainly to the relationships occurring within entities and among providers.

An important intrinsic ability of the ACS-Brandeis model is to serve simultaneously as a budget tool and incentive system. Many APMs are developed to change incentives, and many attempt to quantify "budgets" for providers and health systems, often defined as target prices. Additionally, a major concern for the payer is keeping track of its own budget, across payment systems including APMs, and the source of savings attributable to any of those APMs. Hence, it could be problematic to include the same dollars in more than one of the attributed "budgets" and savings estimates. For each dollar that is truly saved, the payer would not want to count it twice, but would want to attribute the savings to the provider or entity that was induced by the APM (or MIPS) to generate the savings.

This problem could manifest in situations where the respective budgets pertaining to the same patient(s) are nested, such as a procedure within a condition, or an acute condition within a chronic condition, or other overlapping procedures and conditions. Within the ACS-Brandeis model, EGM can handle these situations by apportioning dollars for the same services across episodes without double-counting dollars, and by "rolling up" budgets within budgets without double-counting savings.

Layered onto EGM in the ACS-Brandeis model is the fiscal attribution logic. The problem of double-counting dollars or savings could occur if not for the logical structure that includes fixed percentages of fiscal responsibility across the clinical roles. Consider what could happen if the percentages were free to vary by episode or entity. For example, suppose in a procedural episode the surgeon (episodic provider) "negotiates" an allocation of 60%, and at the same time, the anesthesiologist also negotiates an allocation of 60%. If an episode within that context had $1,000 in savings, obviously CMS would not provide incentive payments for the individual efforts by double-counting the savings and paying an entity on the basis of more than 100% of the $1000: 60% plus 60% plus X% of for other clinicians.

A similar problem could occur across APM entities. Suppose the surgeon and the anesthesiologist in the example were affiliated with different entities. Entity 1 might "claim" more than 60% of the $1,000 because the surgeon and other QPs participated in the care; while Entity 2 might also claim more than 60% of the $1,000 because the anesthesiologist and other QPs participated in the care. Would CMS maintain budget integrity by making incentive payments that exceeded 120% of the actual savings? No, CMS would want the sum of the percentages for each episode to equal 100. That is the purpose and benefit of having fixed percentages for each type of episode. *

A different issue entirely is how the fixed percentages are determined. Nothing intrinsic to the ACS-Brandeis model dictates that 40% is the perfect or only possible allocation for the Episodic provider. Our proposal suggests that 40% might be acceptable. All of our webinars and project materials throughout the process have used 40% as a working example without serious disagreement. Various participants have asked where the number came from, or whether any of the percentages could be changed, should

there be a potential reason to do so. We believe that any serious alternatives should be considered, and determined by consensus or by policy leadership as necessary. The model starts with the premise that the whole team, and every member of the team, makes incremental contributions to the overall results. The percentages are intended to respect the likely degree to which participants in care might tend to affect the overall performance of team-based care considering all instances of an episode.

g) How individual physicians would be paid for their services, including those who are part of the Clinical Affinity Group and those who are not, and also how hospitals, skilled nursing facilities, laboratories, etc. would be paid;

Medicare would pay all providers and facilities in the first instance according to the applicable payment system. Within the APM entity, there would be rules for gainsharing among team members, or to contribute to entity costs of business such as capital investments or reserves.

h) How monetary rewards and penalties would be calculated and allocated among clinical participants;

Once CMS and the APM entity have settled all the episodes for all the clinicians, the APM entity must reconcile the risks with the clinicians and other elements of the delivery system. The APM entity may elect several ways to reconcile or distribute its risk as earnings or penalties. The APM entity could consider the same data and logic used by CMS for the team-based fiscal attribution as input for criteria to determine how it invests or distributes internally its end-of-year balance from the payments made by CMS to the APM entity. APM entities might choose to distribute risk asymmetrically to its clinical members. For example, the hospitals could take more downside risk than the clinicians, or vice versa. These are local market forces that the ACS-Brandeis proposal has established as flexibility within the model.

Some of the logic that entities could consider include categories of savings attributed to certain components of the delivery system or scenarios. For example, facilities may be recognized for increasing urgent care or observation stays and thereby reducing index admissions or rapid readmissions. Extended office hours may account for reduced urgent or emergent care services. Radiology appropriateness criteria and decision-support could lead to fewer or less intensive imaging studies. In general, internal protocols and assessments could steer rewards to attributable clinicians, facilities, and QI programs.

i) The sources of funds that would be used to repay Medicare if total spending on the episodes exceeded the target spending amount, including the amounts that would come from the participating physicians, either directly or indirectly, and how those amounts would be determined.

What happens when the APM entity has a loss due to CMS based on the patients and the teams in all the episodes deployed from its episode library? CMS could implement payback mechanisms such as reduced payment amounts for services to the entity and QPs in the following year. CMS also or

alternatively could qualify APM entities with risk-based capital requirements. Such requirements would involve reinsurance and capital reserves. Industry standards consistent with other programs in CMS would establish the criteria CMS uses to qualify the fiscal readiness of the APM entity. In the event of a fiscal loss with accounts payable due to CMS, the APM entity can agree to reduced fees and/or use its reserves in risk-based capital or assess its members to cover the losses. It is possible that CMS could also move the accounts payable forward into the following year. An appeal process typically involves risk-based payments to assure audit-based payments are valid.

j) How the care delivered for the procedure or condition would differ from the care that is routinely delivered today, how the payment model would make that change in care more feasible for the physicians to implement than the current payment system, what benefits the change in care would produce for the patient, and what savings the care change would create for Medicare. (We understand that the care changes, benefits, and savings would likely vary from provider site to provider site, but we would like to see a description of a specific example of how care delivery might be changed and what implications that would have under the payment model.)

One objective of the ACS-Brandeis APM is to align the incentives of medical specialists with the goals of increased efficiency and higher quality care. The existing fee-for-service infrastructure rewards volume of care provided and encourages providers to consider only their own part of the care continuum. By adjusting the provider incentives, the APM encourages providers to consider the entire episode of care and thus every patient's long-term goals for health and function. Stated differently, an objective is to encourage providers to redesign care for optimal quality and efficiency.

In traditional fee-for-service healthcare, the analytic space is the professional service provided by the caregiver, care design is centered around that service, and the metrics evaluating the provider are also centered at that service. At the other end of the spectrum is traditional managed care, in which the analytic space is the overall care provided to a defined population, care design is center around population health, and the metrics evaluating providers are also centered around this global service to the population. Incentives in fee-for-service care encourage unnecessarily high volumes of care, while incentives in fully- or partially-capitated managed care encourage potentially inappropriate restrictions on the provision of care. One of the unique advantages of the ACS-Brandeis APM is the analytic capability of the Brandeis grouper, combined with the clinical logic encoded into the grouper databases, that allows accurate accounting of both the quality and costs associated with an episode of care. This engine allows the ACS-Brandeis APM to function reliably and with high validity in the episode analytic space, and will encourage APM entity organizations to innovate in care design within the episode space. With evaluation metrics concentrated on the episode of care, our APM will encourage providers and delivery systems to design care pathways, care coordination, care transitions, and communication between providers in ways not seen before.

For surgical episodes, the initial opportunities for care redesign extend from the pre-op period (usually 30 days before surgery) through 90 days after the procedure. The narrow emphasis here is on getting the patient through the surgical procedure efficiently and with good outcomes. When condition episodes are implemented, the performance metrics will reflect broader efficiencies including possibly lower rates of procedures, different procedures to attain the same outcomes, and novel care pathways to treat the condition. The ACS-Brandeis model envisions the clinical affinity groups working together to optimize patient health across the spectrum of medical, surgical, and allied health services.

Some of the episodes available in the ACS-Brandeis APM can resemble the existing CMS bundles, and have most of the cost savings potential hypothesized for BPCI, CJR, AMI, or similar bundled payment APMs. Participants in the BPCI demonstration focused primarily on the low-hanging fruit of reducing readmissions and the use of skilled nursing facilities in the post-discharge period. The evaluation for Year 2 of BPCI showed that, for several types of bundles, outcomes included decreased lengths of stay and less use of skilled nursing facilities (SNF) by participating providers as compared to non-participants, although this did not always result in cost savings. The most significant finding across all sites and all 48 bundles was that a reduction in SNF services provided drove the reductions in mean episode costs for major joint replacement of the lower extremity.

The ACS-Brandeis model can engage and activate entire clinical departments and diverse specialties toward care improvement for entire clinical domains: not just hips, but most musculoskeletal conditions; not just AMI, but most cardiovascular conditions, not just acute diabetic ketoacidosis but chronic care of the diabetic patient etc. For procedural episodes there are often varying levels of care redesign that an APM Entity or CAG could directly affect. These could include the development of risk criteria for the appropriate selection of patients for surgery and decisions about the particular procedure appropriate for the patient, choice of setting for care (e.g., inpatient versus ambulatory surgery center), innovative protocols for perioperative care to minimize complications, and new options for post-acute and aftercare. Team-based clinicians also can influence the use of unnecessary services such as excess or repeat imaging, the size and composition of the clinical team including innovative roles for existing members and entirely new members, and the coordination of post-discharge care. There are a number of patient considerations that can affect a patient's trajectory during an episode of care, such as nutrition and substance abuse and mobility/frailty. Typically, these are evaluated and treated, if at all, by separate departments of a facility. Under the ACS-Brandeis model, CAGs can work across departments to implement more optimal approaches to care, starting at the pre-op phase with home visits or pre-operative nutrition and physical therapy, all the way through post-discharge planning and maintenance care. This approach can apply to surgical episodes, acute medical condition episodes and the management of chronic condition episodes.

The possibilities of care redesign in an episode environment can be demonstrated in a commonly performed surgical procedure. In colorectal surgery, the stapled gastrointestinal anastomosis has become the dominant technique over hand sewing, growing from 46 to 80 percent between 2004 and

2011 (Amri et al, 2014).[4] Laparoscopic colectomy using this technique is rapidly supplanting traditional open colectomy, and is associated with less pain, more rapid recovery, lower complication rates, shorter lengths of stay and quicker return to work. This care redesign has occurred within the traditional fee-for-service environment. However, if the entire episode of colon cancer is considered, there may be many other ways to improve efficiency and quality beyond those associated with the procedure itself. Given that surgical outcomes often depend upon the condition of the patient when he or she presents for the procedure, more aggressive assessment and preoperative optimization for select populations of patients, by medicine members of the gastrointestinal cancer team guided by advanced clinical support and communications technology, could lead to better outcomes through less complications. Real time perioperative risk stratification (as is being developed to recognize and prevent complications such as acute kidney injury, and that requires close coordination between the surgeon, the anesthesiologist, and the hospital information technology and data processing experts as well as significant investment in resources,) is an example of a technology that will provide a return on investment for the team caring for the entire episode of care. Process redesign, as surgeons have begun to develop in 'fast track pathways' and "Enhanced Recovery After Surgery" protocols, will be enhanced as a well-coordinated team, responsible for the patient throughout the entire episode, works to find optimal pathways and technologies. Aggressive preoperative preparation, close coordination between anesthesia and surgery and critical care in the perioperative period, multi-modal pain management coordinated with early feeding and early ambulation in the postoperative period, and close coordination and communication after the patient is discharged from the hospital are examples of an optimized episode of surgical care. In our own data analysis of risk-adjusted cost of colectomy episodes, we see large differences in episode cost depending upon the presence or absence of significant postoperative sequelae. Patients with low actual-to-expected cost ratios had 1/3 the number of sequelae compared to patients with high actual-to-expected cost ratios, suggesting that efforts to reduce sequelae could lead to significant cost savings. Over time, the ACS-Brandeis APM should instill a generalized mindset of cost-consciousness alongside clinical excellence, leading to optimal approaches and technologies emerging and diffusing.

The possibilities for care redesign associated with condition episodes have both similarities and differences compared to procedure episodes. Congestive heart failure (CHF), a common sequela of poorly treated or untreated ischemic heart disease (IHD), affects 5.7 million people in the U.S with approximately 670,000 new cases annually[5]. Care redesign in the managed care environment has focused mainly upon preventing one of the biggest drivers of cost in these patients: the frequent and/or preventable hospital admission for an acute exacerbation. Care coordination, telemonitoring, and ambulatory care managers have been used to lower hospital readmission rates with varying, but overall minimal, success. In an environment where quality of care and outcomes for the episode are being

[4] Amri R, Bordeianou LG, Sylla P, Berger DL (2014). Renewed assessment of the stapled anastomosis with the increasing role of laparoscopic colectomy for colon cancer. Surg Endosc. 29 (9): 2675-2082.

[5] Ambrosy, A. P., Fonarow, G., Butler, J., Chioncel, O., Greene, S., Vaduganathan, M., . . . Gheorghiade, M. (2014). The global health and economic burden of hospitalizations for heart failure. Journal of the American College of Cardiology, 63(12), 1123–1133. doi:10.1016/j.jacc.2013.11.053

evaluated and which then determine reimbursement, investment in techniques to change the trajectory of the condition, rather than just optimally deal with the condition when it happens, will become common.

The development of personalized medicine, including the ability to predict disease before it happens and then act to prevent and mitigate it, is in its infancy. In episodic care using a personalized medicine approach for IHD and CHF including genomics and deep learning approaches to the assessment of the social determinants of health for a patient, primary care providers will be able to identify the risks of developing IHD, healthful behaviors will be promoted, and disease will be either prevented or treated early and aggressively. For the patient who develops IHD, a team-based approach will emphasize placing each patient within the optimal pathway towards best outcomes so that, for example, the patient with single vessel coronary artery disease will always be treated by the interventional cardiologist rather than the cardiac surgeon, while the surgeon only operates on the patients with multi-vessel disease. For the patient who develops CHF, ambulatory care will be optimized by care coordination and communication technologies, perhaps using smart phones and remote monitoring, that are not utilized in a reimbursement environment where unbillable services are an investment that pays no dividend. If the patient is admitted to the hospital, and the hospital is a partner in the APM entity focused on the care of patients with IHD and CHF, the hospital can be expected to invest in resources to achieve economies of scale, smart scheduling algorithms, and robust modeling for predicting resource and performance requirements for these patients. Hospitals will combine clinical insights from practitioners with operations research and analytics expertise from within the institution to optimize care for these complicated and costly patients.

The ACS-Brandeis APM provides incentives to encourage providers to consider the entire episode of care and thus every patient's long-term goals for health and function. These incentives will encourage APM entities to invest in care redesign that will move the healthcare system towards optimal quality and efficiency.

k) How patients would be informed about the care the Clinical Affinity Group plans to deliver and what choices of providers would be available to the patients. In particular, please describe how the following practice from page 12 would be implemented: "In situations where beneficiaries **choose clinicians** [all, some or just one?] who are participating in the APM entity, we do not expect that those patients will be able to opt out of the team based protocols intended to improve value . . . In other words, if the **patient's providers** [again: all, some or just one?] have opted for the APM, then the patient's experience will reflect **life in the APM**, and not MIPS." [Emphasis added]

It is generally the case that demonstration sites inform beneficiaries about the nature and purpose of the demonstration. This information may or may not affect beneficiaries' choices with regard to providers or treatment options. This is similar to the Belmont principle of "respect" for individuals and

disclosure of information that might affect key decisions.[6] At the same time, it is important to structure and monitor the APM to ensure beneficence,[7] i.e., net improvement for beneficiaries who participate.

Whether an Advanced APM is pilot-tested or implemented straightaway, it departs from original Medicare as commonly understood by beneficiaries. Thus, CMS may wish to educate beneficiaries about the nature and purpose of an APM. In demonstration contexts, some provider organizations have attempted to go beyond simple notification in order to engage beneficiaries in the improvement process. For example, in the early phases of BPCI, participating providers needed to make a concerted effort to let beneficiaries know they were receiving care under a demonstration. This posed some challenges because the DRG that defines a bundle is not determined until after the inpatient stay. However, there are organizations that took this as an opportunity to engage people in their own care, creating a patient compact that included action items such as "call the practice before you call an ambulance."

We are not proposing a patient compact be a formal component in the model, but we do suggest that patient notification can be a form of engagement. This could start, for example, with the surgeon and patient planning surgery. The ACS-Brandeis model emphasizes team-based care and shared accountability. The surgeon will want to identify the other clinicians on the team, including for example, the patient's PCP and regular medical specialist (the Primary and Principal Providers, respectively). All clinicians who are already functioning within the APM will be accumulating their respective shares in the quality and cost outcomes, and implicitly will want any other clinicians participating in the patient's care also to strive for excellent outcomes.

The point here is to guide improvement and not to ensure the status quo. In some cases, the "teams" are too large and include redundant or unnecessary consultations and tests. In other cases, the setting of care is suboptimal because it is more expensive than necessary or has lower quality than available alternatives. Planning by providers and patients could include such topics as which setting is most appropriate for the given surgery options, or what additional medical specialists, if any, to engage in the patient's care. Disclosing the options and rationale is a potential tool for building trust and managing patient expectations.

There might be providers who participate in the care but are not in the APM. The model allows non-participating providers to continue to be paid on a traditional fee-for-service basis without the obligations or consequences that are special to the APM. Patients are not "locked into" specific providers or locations of care.

A related consideration, however, is the length of time for which the Entity maintains fiscal responsibility even after a beneficiary has switched to providers outside of the Entity. For example, a patient with IHD may be seen by Primary and Principal providers within an Entity during the first two

[6] https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/#xrespect
[7] https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/#xbenefit

quarters of a calendar year, but then switch to clinicians who are not affiliated with the entity or possibly the APM at all. Our proposal suggests a policy parameter that would continue fiscal attribution to those QPs and the Entity during the third quarter as well, which we call a warranty period. Is one quarter long enough? Should it be two quarters, or "the remainder of the year?" In any case, the ACS-Brandeis model does not prevent beneficiaries from seeking care from any given provider.

l) The process and outcome measures that would be used and any other mechanisms that would be used to ensure quality of care, appropriateness of care, etc.;

The APM entity would work with all the shared accountable providers to agree upon the episode-specific measures from the measure sets. In the instance of colectomy, the surgical phases of care measures contain high-value process measures, outcomes, care coordination, and patient-reported outcomes (in development). The APM entity or the clinicians themselves would select measures to fulfill the requirements related to the four tiers of quality (Excellent, Good, Acceptable, and Unacceptable). We believe these measures will mature, and the requirements to achieve higher rankings will progress from levels of participation to levels to performance.

To illustrate the colectomy episode, the care team would select from the pre-operative phase to include 1. Surgical plans and goals of care (appropriateness); 2. Tobacco screening and cessation (preventive); 3. Surgical Risk Calculator and communicate risk (Appropriateness and Informed Consent/Shared Decision Making).

Other measures would come from other phases of care such as 4. Postop plan and communicate (Shared decision-making); 5. Surgical CAHPS assessment (Patient Experience of Care); and finally from the post-discharge phase of care, the measure under consideration might be 6. Unplanned readmission within 30 days (Outcomes).

m) If you can provide any estimated cost savings for either or both of the examples, please provide this data and the estimation methodology.

There are many different ways to estimate a behavioral response and potential cost savings in the ACS-Brandeis APM. We have written previously to PTAC that savings can be achieved in the short-term by reducing unnecessary utilization, or by shifting services to less intensive settings or approaches. Also, savings over the long-term relate to lowering the long-run demand and/or supply curves, for example, through prevention, medical management, and adoption of cost-lowering technologies. It would be a considerable undertaking to articulate a detailed inventory of how clinicians, delivery systems, and researchers could plan or implement the nearly countless options. From a common short-term "bundle" mindset, the ACS-Brandeis model can induce and quantify many types of savings often mentioned in relation to those models, such as reducing SNF or hospital admission following discharge for an acute event. Similarly, for savings commonly sought in a medical home or ACO, the ACS-Brandeis model operating with condition episodes in the library encourages savings related to care setting and avoiding acute events.

In our last round of responses to PTAC we quantified some sequelae expenses, suggesting these are indicative of unnecessary or potentially avoidable costs. For this round of questions, we are focusing on provider level variation within a single, mid-sized market with approximately half a million Medicare beneficiaries and a few hundred TINs (our proxy for provider group/organization). As shown below, the number of episodes varies by type with approximately 1,500 CABG procedure episodes and 4,000 PCIs in a year. For the chronic condition of IHD we see many more episodes, in part because these episodes remain open as long as the beneficiary continues receiving care for the condition. In our example market, this results in approximately 127,000 IHD episodes in 2013.

For the cost savings estimate, we start with the observed and expected episode expenditure for each case within a given TIN. As shown in the table below, there is wide variation in expenditures by episode. Focusing specifically on procedures, we see almost a $25,000 difference between the 75th and 25th percentile for CABG, a relatively high-cost procedure. PCI is less costly on average, but still has a $20,000 difference between the values at the 25th and 75th percentiles.

Procedure	25% Percentile	50% Percentile (Median)	75% Percentile
CABG	$ 35,435	$ 45,333	$ 60,698
Colectomy	$ 16,113	$ 22,893	$ 36,666
PCI	$ 13,633	$ 17,072	$ 23,956

In the table below, we show the average observed and expected costs for the whole market. The final column in the table shows the expected cost. This is calculated for each case and represents the target price for that particular episode, given the patient's demographic and risk profile. When the difference between the expected and observed expenditure is negative this represents an opportunity for improved efficiency. In other words, the observed costs for a given provider are higher than the risk adjusted target prices, suggesting there are ways the TIN could lower costs.

Episode Name	Episode length	Average Observed	Average Expected
CABG	90 days	$ 48,182	$ 48,166
PCI	90 days	$ 19,467	$ 19,173

Colectomy	90 days	$ 27,252	$ 27,630
AMI	90 days	$ 10,354	$ 10,354
IHD	on-going	$ 1,750	$ 1,836

Drawing on this logic, the table below aggregates the observed and expected costs for all TINs in the market. Looking at PCI, for example, the total observed costs in the market were $79.2 million dollars and the total expected costs were $78 million. Across individual TINs in the market there is a wide range of negative and positive deviations from the targets. Aggregating the amounts where the observed cost is higher than the expected cost results in $3 million of potential savings for PCI episodes in a single market. This approach is extended in the table to show potential savings for CABG, colectomy, AMI and IHD.

Episode Name	Episode Count	Sum TIN Observed	Sum TIN Expected	Estimated Savings
CABG	1,548	$ 74,621,631	$ 74,595,842	$ 2,857,076
PCI	4,069	$ 79,213,869	$ 78,019,484	$ 3,045,381
Colectomy	2,169	$ 59,117,270	$ 59,937,864	$ 2,049,881
AMI *	1,401	$ 14,508,186	$ 14,508,277	$ 1,065,940
IHD	127,099	$ 187,575,621	$ 196,803,303	$ 12,043,308

* AMI episodes are undercounted in this illustration.

3. We could not understand from your previous answers whether there would be any minimum number or types of physicians that would be required to participate in the APM. Please provide a one-sentence statement as to what would be required and what would not be required.

In order for a clinical affinity group to form, typically a minimum of two groups of physicians would be involved in an episode but more are preferred. In a surgical case, a surgeon and anesthesia team or a surgeon and a post-acute care team would represent two minimum groups.

4. Please identify the individual types of physicians, specialty societies, or provider groups that have provided input into your proposed payment model as opposed to providing input only into the definitions of episodes in the EGM episode grouper.

Except in the EGM design report (Appendix C in the proposal to PTAC), which acknowledges contributions from many clinical experts into EGM itself, our references to input and support for the ACS-Brandeis model refer to subsequent and additional contributions.

While the ACS-Brandeis Advanced APM was initiated by ACS, the product as submitted is built on the input of the larger physician community. In addition to the direct input from specialty societies in the form of clinical data review in the episode definitions, over the last year we have held a robust series of online and in-person meetings. These meetings, totaling more than 10 hours, were all interactive and provided opportunities for questions and feedback from any interested in participation. These sessions were critical in shaping the proposal and covered a wide range of topics including, attribution, quality measurement, payment systems, risk, and episode formation among others. Representatives from the following societies and organizations participated in one or more of these sessions: AAFPRS, AAMC, AANS, AAO, AAOHNS, AAOS, ACOG, ACOS, ACP, AMA, AGA, APSA, APTA, ASA, ASBS, ASCRS, ASPS, ASTS, AUA, ASMBS, FAH, LUGPA, NASS, Premier, SAGES, SGO, SHM, STS, SVS. It is our understanding that several of the aforementioned organizations provided positive comment letters to the PTAC during the public comment period. In addition to these sessions, ACS has presented on our proposal at meetings of several other groups, including the AMA's APM Workgroup, which is typically attended by representatives of a wide variety of physician specialties.

5. Would there be any provisions in the model to avoid adversely affecting hospitals?

There are no provisions specifically aimed at hospitals in the proposal, and it is not our intention to affect them or other health facilities adversely. We recognize that certain metrics for success in the model such as reduced readmissions or complications could reduce hospital revenues, albeit because of providing higher quality care to the patient. Similar dynamics could occur for clinical professionals or other inputs to care, with potentially fewer consults, tests, or medical supplies.

We welcome hospitals to participate in, or to form and own APM entities under the model. Unlike other bundled payment proposals, we do not *require* hospital participation. Hospital participation could have benefits such as sharing ownership of risk, optimizing care pathways, team-building efforts across departments, facilitating care coordination during patient transfers, and so forth. Hospitals are more likely to have the financial resources necessary to meet financial risk requirements conditional on the methods CMS might adopt to collect on losses. Entities that formally include hospitals (or other facilities) would need to negotiate the facilities' shares in the risks and rewards of the model, along with the affiliated QPs. The proposal developers have already received interest from hospital organizations for this type of engagement.

The inclusion of hospitals in the APM entity is also a good example of the distinction between our proposed framework for fiscal attribution by the payer based on clinical role, and the assignment of financial risk and reward by the entity under the model. Our Physician-Focused Payment Model is premised on the concept that physicians manage the patients, conditions, and procedures; and their decisions influence the utilization of most types of services.

Under MACRA law and regulations, the APM entity itself must take on greater than nominal fiscal risk. An APM entity that includes a hospital would go at risk for the amount required by CMS, but would have the ability to share any repayments or shared savings with the affiliated participants under the entity. The entity is not required to share that upside/downside risk among participants in percentages equal to the fiscal attribution framework. The hospital could retain a portion of shared savings (e.g., 15 percent) to offset changes in practice patterns that result in reduced revenues, or to build up reserves to offset future risks, while passing through the rest to the APM participants based on any agreement they have made with the entity.

Some physicians, particularly those in ancillary roles, may wish to participate in the Advanced APM in the early years mostly for the initial 5 percent incentive, the higher updates after 2026, or to be free from MIPS reporting requirements. Some could contribute to team-base care and yet continue to receive Medicare reimbursements or operate under terms similar to a traditional employment contract without taking on the additional risk of the APM, or sharing in any rewards.

6. The response to question 5 states:

   "One theme in our proposed APM is that CMS ensure a widespread but consistent diffusion of the underlying technologies, including the EGM software itself, as well as the clinical metadata used to specify episodes. We call this the "single-grouper" solution, and it is intended to create a consistent national standard for defining clinical concepts and episodes, determining how to assign services and cost to those episodes, and communicating important clinical associations such as indications for procedures and related sequelae . . . .

   CMS owns the software . . . We wish for a situation in which the software and metadata are licensed or at least copyright protected.

   The current model is built as a business construct using the EGM developed for CMS by Brandeis. The ACS-Brandeis construct of a business model is built on **this work product** which represents Clinical Affinity Groups that participate in episodes, and built into clusters of episodes for contracts to a third party such as through an APM entity or payer. All copies of the clinical metadata and measurement algorithms for this APM currently reside at Brandeis. Further, ACS has created a phases-of-care quality overlay with dyads of measures that are patient-centric, CAG-centric measures with shared accountability. The IP aspect of these elements of the proposal are currently under internal review with regard to their proprietary nature. Our intent is for this model to be freely licensed as an APM for all payers and is not subject to change without review and approval by the ACS. . . However, development costs and maintenance cost for performance measurement require resources. To the extent that payers

do not support these development and maintenance expenses, we would expect licensing agreements that support a going concern in these programs."

We have several questions about this portion of the proposal:

a) We are aware that in 2012, CMS awarded a contract to Brandeis to develop a public domain episode grouper for Medicare (National Quality Forum, Evaluating Episode Groupers, 2014). Are you proposing that the new EGM software should no longer be in the public domain, but instead be licensed?

Our understanding is that CMS has considered putting EGM into the public domain, and possibly under the auspices of a licensing arrangement between CMS and the user. We are not proposing that CMS refrain from making EGM software available. We defer completely to CMS regarding any licensing arrangements that CMS may choose to have with users.

b) With respect to, "CMS owns the software . . . We wish for a situation in which the software and metadata are licensed or at least copyright protected," who are you proposing should hold the license for the software? CMS, ACS, Brandeis, some other party?

Please consider our language as meant to be practical considerations and not legal opinions. See our answer to the prior question (6.a) regarding the software and any licensing arrangements. The software and the metadata must work together properly, and any changes to either will affect results. Part of our intention in the proposal is that the clinical specifications and episode construction logic in EGM can become reference standards for our model; additionally, CMS, other payers, and providers could use the same reference standards for other APMs, and MIPS or similar VBPs. We call this the single-grouper solution, and is intended to preclude the alternative, in which all results are qualified and distinguished according to their idiosyncratic logic, specifications, or other parameters. To the extent that APMs, payers, and providers can embrace the single grouper as they enter risk arrangements, and evaluate and compare their results, then everyone can proceed with the real work of improving care. A practical benefit here is to pool the cognitive and administrative resources required to maintain the system over time. With so many benefits accruing to payers and providers, such investments would seem to be more than worthwhile.

The references to copyrighted materials were to emphasize the need for discipline with respect to maintaining identical copies of the software and metadata when making comparison or inferences across providers, regions, payers, episodes, etc. An example to make the point could be assertions about sequelae for a given type of episode. If somebody deleted some assertions in the metadata, such as heart failure can result from AMI, then the total costs calculated for AMI episodes would appear lower because they would omit spending for heart failure following AMI. It isn't our intention to forbid changes to metadata that are available in the public domain, but to make sure that all stakeholders could be sure that results were based on an identical and specified version of EGM/metadata.

Neither Brandeis nor ACS is seeking (or refusing necessarily) to hold copyrights on materials related to the grouper, but would again defer to CMS for implementing and maintaining standard versions.

c) With respect to, "The IP aspect of **these elements** of the proposal are currently under internal review with regard to their propriety nature," please clarify:
    a. To what does "these elements" refer?

The proposal's elements developed or adapted by ACS-Brandeis include: the APM entity; configurations and specifications for EGM; episode clusters for individual physicians (including no dollars accounted more than once); the clinical/fiscal attribution model; the episode-based tiered quality model; the episode-based measure framework with shared accountability; the phases-of-care measure framework; and the high-value process measure in a dyad with linked PROs.

The ACS-Brandeis proposal carries the ACS and Brandeis brands. Since this is a risk model tied to payment, ACS & Brandeis wish to be prudent about the impact of branding a model used in the public domain. As a CMS proposal, we have intended this model to be freely available to CMS for use in the A-APM and MIPS-APM program. We also realize the model may be modified by CMS prior to its implementation. ACS and Brandeis may accept those modifications as improvements to the model. If ACS or Brandeis does not accept the improvements, we expect CMS may elect to implement the model with their own modifications. However, in the instance where ACS or Brandeis do not agree with the modified model, we would seek to identify the CMS model separately from ACS or Brandeis.

We also seek to implement the model with private health insurers in their payment models. Again, these entities may wish to modify the ACS-Brandeis model. We accept these modifications in the spirit of alternative payment innovation. However, given the risk-based nature, we are interested in how modifications may be branded. Controlling the IP may be the most rational method for doing so.

    b. Who is conducting the internal review, what is the scope and question(s) being addressed by the internal review, and when will the results of the internal review be available to the PTAC?

ACS legal review is underway. The ACS executive director and the executive officers have provided ACS legal counsel with the entire submission. The A-APM project team provided the legal counsel with the elements noted above in 6(c)a. The ACS leadership provided guidance to the legal counsel review team to protect the proposal from plagiarism and to identify the extent to which the ACS & Brandeis brand for the original proposal would be protected if modifications are applied to the model. The guidance to the legal review included that we expect CMS to consider modifications and improvements. We also wish to protect against private payer modifications without oversight by ACS and Brandeis. ACS has also sought guidance from legal counsel about the mix of elements, some of which were developed prior to and outside of this proposal before being incorporated. Other elements were developed within the scope of

innovation for this proposal (fiscal attribution models, tiered quality models, episode-based measure framework, phases of care measure sets, and process-PRO dyads).

d) With respect to, "To the extent that payers do not support these development and maintenance expenses, we would expect licensing agreements that support a going concern in these programs," do you mean that unless multiple payers financially pay for the cost of measure development that the party holding the license will only provide a license for a fee? ACS

The proposal contemplates several specific focus areas that will require governance and management over time. As a payment model, these are typically operational expenses of an insurer within one of their payment programs. Some of the examples of ongoing maintenance and operational refinements include updates to the metadata files used in the EGM logic, clinical fiscal attribution rules, and refinements to the quality tiers and the episode based measure framework. Typically, insurers would contract with advisory panels and experts to support their administrative efforts.

Additional advances in risk adjustment have been proposed by specialties with clinical registries. Ongoing work in the next phase of this model would seek to compare the current risk adjustment model for target pricing to adjustments that would come from clinical registry-based risk-adjustment. One specialty that supports the model has already stepped forward to begin this next phase of work.

In all these instances, the operational, maintenance and further developmental costs require a business model for the payer to consider. We have considered many mechanisms for parsing the work and gaining the fiscal support to accomplish the task. Government contracts with entities such as the HCP-LAN could be a resource to greatly aid in a multi-stakeholder set of inputs over some of the aspects of the model, such as metadata file updates, risk adjustment models, and clinical fiscal risk attribution. The National Quality Forum and the Measures Application Partnership would be an excellent resource for the episode-based measure framework, the phases-of-care measurement, and the HVPM/PRO dyads.

Separately from each payer modifying the model, the entire program could be moved into a non-profit collaborative with control over licensure of the elements of the program. A licensing fee to all users would support the infrastructure needed to maintain the overall program. ACS-Brandeis has limited development of sustaining business models until further understanding of the value of the model to CMS. By no means do we propose a single solution. Our intent is rather simple, that these are critical maintenance functions that have fiscal impacts in supporting the program and require a business model that will assure the integrity of the program.

e) With respect to, "ACS has created a phases-of-care quality overlay with **dyads of measures** that are patient-centric, CAG-centric measures with shared accountability," measure dyads were not discussed in the initial proposal submission. Please explain and provide some examples of the "dyads of measures." ACS

The ACS has many dimensions to its efforts to support the programs in MACRA. These efforts, just to name a few, include our efforts to improve quality measurement with the phases-of-care model, the creation of high-value process measures, our work in developing PROs, the creation of HVP/PRO dyads, our national clinical registries, ACS support of interoperability, our work on the national cancer database and the Vice President's Cancer Moonshot, and our efforts with DOD and VA for enhancing overall battlefield and post-battlefield medicine.

Part of our overall strategy in MACRA creates a transition from MIPS to APMs. We believe this includes quality measurement as well as risk-based payment models. To achieve a smooth transition, we have tried to foster a consistent measurement model that is meaningful to surgeons and patients and would work in both the MIPS environment and transitions well to APMs.

Creating measures that are more meaningful to patients and surgeons is less about a CMS payment program and more about overall outcome and improvement. We have introduced the phases-of-care and HVPM/PRO dyad concept to CMS and a multi-stakeholder group for review. CMS sought them for inclusion in the MIPS MUC list, which CMS shares with the NQF's MAP for comment. We continue to work with CMS by adding these to the A-APM in the episode-based quality framework. Given CMS' interest in outcome measures and in PROs in our conversations, we have added the dyad of high-value process measures (HVPM) combined with a focused, narrow PRO. CMS asked ACS to add these to the MUC list, prior to ACS full development and testing, representing support for the concept and a desire to receive review and feedback from the MAP. ACS sought to remove these from the MUC list until initial testing in a QCDR had occurred but ACS supported presentation to the MAP. We presented to the MAP and received overwhelming support for further development and advancing of the episode-based quality measure framework and the dyads.

The dyad development has begun with our development team headed by Dr. Andrea Pusic, MD and Larissa Temple, MD. Both are recognized international experts in PROs. The initial scope of PRO work for 2017 focuses on identifying the general surgical episodes and their high value process measures. The HVPM + PROs as a dyad may be cross-cutting, and work for many surgical and non-surgical disciplines.

It is premature to provide PTAC with explicit measures while these measures are in their developmental phase. Perhaps a measure concept would help to illustrate the dyad. One concept would be a HVPM for the goal of surgical care and include confirmation that the patient/family, surgeon(s), anesthesia, and PCP have reviewed and concur with the treatment plan. The elements of the treatment plan must address specific goals such as relief from a condition, establish a diagnosis, and improve QOL. The team members may asynchronously agree to the plan using shared HIT resources. The dyad is completed when the patient submits a PRO for surgical goals at 30 days or beyond in their post procedural care. The PRO would focus on how well the patient was informed and the level of goal attainment, and would assess the satisfaction with their overall care.

f) Does the phrase “this work product” refer to the EGM developed for CMS by Brandeis?

This work product refers to the proposal submitted to PTAC.

7. Pages 10-11 and Exhibit 5 in the initial submission state, “Each clinical role is allocated a fixed proportion of the savings amount (Exhibit 5):

Exhibit 5: Percentage Shares for Fiscal Attribution by Clinical Role

Class of Episode	Clinical Role				
	Primary	Principal	Episodic	Supporting	Ancillary
Procedural	10%	15%	40%	30%	5%
Acute Condition	10%	15%	40%	30%	5%
Chronic Condition	40%	35%	N/A	20%	5%

We could not understand from your previous answers whether the percentage allocations among physicians that you described would be required by the payer or whether they would be under the control of the physicians. Please provide a one-sentence statement as to whether the allocations are required or not. Then please explain how you would envision the percent allocations being determined. Are the categories labeled “primary, principal, episodic, supporting or ancillary” formal and required elements of the model, or are they merely illustrative of how physicians might choose to make allocations? [PRC] If they are formal/required elements, how are physicians assigned to these categories? Are the assignments based on their CMS specialty designations? Can a physician’s designation change depending on the actual care they deliver? How often and when can the designations change?

The percentage allocations must be the same across APM entities for purposes of allocating provider responsibility but are not necessarily equivalent to the share of potential savings or repayments required to the physician. Please see the responses to questions 2.e and 5 above, as well as the Appendix for more on this.

In August, we held a webinar where we discussed this issue and took questions from participants but did not hear significant push back on the proposed percentages. Obviously, not all physician specialties were included in this discussion, and we would be open to additional clarifications or adjustments to the percentages, provided the percentages remain the same across entities and payers.

8. If the model does not require all physicians to share in the risk, have surgeons indicated to you that they will participate in this model for surgical episodes if they are the only ones accepting the financial risk, and if not, what other physicians would need to participate?

MACRA seemingly intends that the Medicare program as a whole instill cost- and quality-consciousness generally for all providers, whether their work is done under MIPS, an APM, or some combination. A truly coherent solution for Medicare would be to measure cost and quality similarly across that spectrum of participation, so that staying in MIPS or moving partially or completely to the APM does not mean changing the definition of value. Thus, whether a particular provider was practicing at nominal risk or more than nominal risk, he or she would realize shared accountability and understand that true success depends on team-based care, regardless.

The question here is accentuated to the extent that avoidance of the ACS-Brandeis model signals to providers and avoidance of accountability, such as through lack of structure to evaluate performance precisely in a general medical home or ACO, or for lack of meaningful measures in MIPS.

The ACS-Brandeis model is intended to appeal to the professional interest in excellent care. The team-based accountability coincides with the team-based care. Each specialty, and ultimately each potential participant needs to see the value proposition, and the vision for a win-win. That should follow from further details about how their engagement can manifest.

We have not formalized market research to test surgeon or physician level of interest. Rather, we have relied on specialty society level of engagement in the overall project. Almost all surgical disciplines have been involved and remain very engaged in building out the elements of the overall episodes. Specifically, they have participated in the metadata assessments for plausible inclusions and exclusions. They have shown keen interest in risk adjustment comparatives with their clinical registries. They have requested to develop new episodes to add to the mix. And, they are engaging in the episode based measure framework. In addition, medical specialties and other societies are seeking to engage.

Achieving adoption at the surgeon level will include an education program befitting this A-APM. Also, physicians and surgeons are no different than most people; they are risk averse. Building a risk model may require adjustments to gain initial uptake. Subsequently, the risk models and levels or depth of asymmetry of risk may be modified.

9. Do you anticipate that the model will have any implications for the application of "safe harbor'' regulations or need for waivers of the Physician Self-Referral law or the Federal Anti-Kickback statute?

We do not believe that elements of our submission raise Physician-Self Referral (Stark) and Anti-Kickback Statute (AKS) concerns beyond those that already exist for other programs that CMS has implemented that include a gainsharing component. We believe all APM entities that engage in risk-sharing arrangements with physicians and other providers would be expected to comply with all fraud and abuse prevention laws and regulations (including Stark and AKS). As HHS and CMS indicated in its *Report to Congress: Fraud and Abuse Laws Regarding Gainsharing or Similar Arrangements between Physicians and Hospitals As Required by Section 512(b) of the Medicare Access and CHIP Reauthorization Act of 2015*,[8] the Secretary retains the authority to waive certain fraud and abuse laws in testing models under the authority of CMMI, and as such the Secretary and the OIG have issued waivers for several programs. We believe that the previously issued waivers will serve as a resource for future waivers necessary to provide the APM entities participating under the model included in this submission with the flexibility needed to improve care delivery and reduce resource utilization without risk to patients or risk of program abuse.

[8] https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/Report-to-Congress-2015.pdf

10. Please clarify what is in the table you submitted titled, *ACS- Brandeis Condition and Procedure Episodes*. The key to this table states, "Key blue = episode for profiling; green = procedure episode."

    a) If green items are procedures, what are "episodes for profiling?" Are they condition episodes? If so, why is "TURP" blue?

Episodes for profiling are fully developed with trigger codes, trigger rules, relevant services and diagnoses, sequelae and, for procedures, indications. Each of these episodes also has a customized risk adjustment model that includes co-morbidities and severity markers. These are the episodes that have undergone expert review and are most appropriate for use in the alternative payment model.

The remaining episodes play a support role, absorbing services based on trigger codes only. Over time, many of these can and should be developed into fuller episodes.

TURP should be green since this is a procedure episode. This was an error.

    b) Are these the procedure episodes the model proposes for initial implementation? If not, what are they? If so, why were these procedures chosen?

The 54 procedure episodes shown in green in the appendix are all fully developed and ready for additional clinical review and use in the APM.

    c) Which of these episodes will be fully ready for implementation by January 2018?

All episodes shown in green are ready for implementation in 2018, and the condition episodes listed in blue could be made ready.

Brandeis University

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February 3, 2017

Physician-Focused Payment Model Technical Advisory Committee
c/o U.S. DHHS Asst. Sec. of Planning and Evaluation Office of Health Policy 200 Independence Avenue S.W. Washington, D.C. 20201

Letter of Support – Brandeis University, ACS-Brandeis Advanced Alternative Payment Model

We can imagine many scenarios in which various reforms under MACRA sputter, stall, or splinter, and ultimately disappoint. The "whole" may be less than the sum of the parts under scenarios of duplicative and misaligned efforts, with many working at cross-purposes. In contrast, we believe that the ACS-Brandeis model could help to establish and leverage an information and incentive platform that not only succeeds for its "part," but also helps to shape and guide others' efforts ultimately toward greater success.

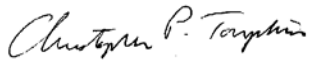
Many small groups or even large companies have endeavored to create their own episode groupers, each representing one of a potentially infinite number of very different or slightly different ways to make inferences from claims data. That scenario can take us to the Tower of Babel, where multiple languages divide payers and providers into so many idiosyncratic conversations about how to measure cost and performance, but which fail to make reasonable, apples-to-apples comparisons and judgments.

A key aspect of the envisioned ACS-Brandeis platform is embodied in EGM, which is integral to our proposed strategy that calls upon CMS to lead national reforms via a "single-grouper solution." EGM is a robust tool that recognizes every diagnosis and procedure code in relation to meaningful clinical concepts that can inform cost drivers and fiscal incentives. CMS can support EGM as a national resource that invites and rewards review and input from all medical and surgical specialties. Everybody benefits from others' contributions within and across all clinical domains, so the benefits from all contributions are multiplied, rather than divided.

Historically, attempts at reform have tried carrots and sticks but few have succeeded in engaging the professionals with respect to their specific clinical work and the need for collaboration toward more excellent patient care. We believe that the ACS-Brandeis model will provide the missing hook, or impetus to engage, because it establishes a comprehensive yet clinically precise episode framework that is amenable to the merging of cost and clinical data, and to the most serious analysis in support of team-based care and shared accountability.

Brandeis University was the first-ever, and remains the most enduring external research and development partner for CMS. Our novel contributions to the field include diagnosis-based risk-adjustment for cost, the shared-savings payment model, hospital value-based purchasing, and the Episode Grouper for Medicare. We welcome opportunities to continue supporting CMS and the ACS-Brandeis model. At this point, we are uniquely qualified to configure, modify, and optimize the logic and specifications comprising the model, and to help educate others who can support and benefit from the model.

Sincerely,



Christopher P. Tompkins, PhD
Associate Professor
Director, Institute on Healthcare Systems

Appendix X

Clinicians and Roles: Patient Relationship Categories

The specific services assigned directly to each episode can identify each clinician participating in a specific patient's episode of care. Each clinician who bills Part B for a clinically relevant service for that patient and for that episode, i.e., a service that is assigned directly to the episode,[9] is a member of the "team," i.e., the set of caregivers for that episode. Each clinician participating in the patient's caregiver "team" for that episode will have a proportion of the overall accountability for that episode, defined and gauged according to his or her relationship to the patient and the episode.

Algorithms are applied to the data in order to infer from service patterns the logical role each clinician has with respect to the patient and episode.[10] The algorithms attribute each episode for a patient to a set of providers according to patient relationship categories (PRCs) inspired by MACRA, as shown in Exhibit A-1.

For each type of episode that begins and ends within 90 days (i.e., an acute condition or procedure), there is a single Episodic provider. For procedural episodes, the Episodic provider is the surgeon who conducts (bills for) the definitive procedure for that episode. For acute condition episodes, the Episodic provider is determined based on billing patterns related to diagnosis codes and timing. Specifically, for an acute condition treated in a hospital inpatient setting, the Episodic provider is the clinician with the most E&M services on the date on which the episode is triggered. For example, if a patient enters the hospital for a pneumonia episode, the Episodic provider is determined based on billing for pneumonia on the first day of admission. This approach emphasizes timing over volume criteria such as the most E&M visits or most dollars over the course of the inpatient stay or the whole episode. The purpose for that is to avoid defining responsibility after the patient's trajectory has ensued. For example, using service volume alone, the designation of Episodic provider might often fall upon clinicians who entered the case only after untoward events such as complications or deterioration. Instead, the locus of responsibility should be upstream for events and consequences yet to come, acknowledging that in some cases those events are potentially avoidable, and framing accountability and incentives to avoid them whenever possible.

[9] Assigned "directly" means the service is clinically relevant to that episode versus all open episodes for that patient. Direct assignment is distinguished from indirect assignment, where the latter refers to services included in the episode through an associated sequela. For example, the services assigned directly to a surgical infection episode are assigned indirectly to the causal procedural episode by way of a sequela relationship.

[10] The point here is not that all of the clinicians function as though they were part of a coordinated team, or even that they all know or are aware of each other. Furthermore, it need not be the case that all caregivers are affiliated with the same, or any Medicare APM. The narrower point here is that each clinician is contributing to the care, and to the cost and other outcomes of the episode.

Exhibit A-1: Patient Relationship Categories (Patterned after MACRA)

Relationship to Patient/Episode	Description	Examples
Primary Provider	Primary care role Manages patient over time	• Internist • Pediatrician • Family practitioner
Principal Provider	Manages specific condition(s) over time; specialist	• Psychiatrist • Nephrologist • Cardiologist
Episodic Provider	Manages an acute condition episode Manages a procedural episode	• Surgeon • Hospital medicine • Specialist
Supporting Provider	Supporting role during an episode	• Anesthesiologist • Radiation oncologist • Consulting specialist
Ancillary Provider	Focused role during a single service	• Diagnostic radiologist • Pathologist • Cardiologist (reading ECG)

Also part of the team-based approach to accountability are the Primary and Principal providers. Identifying clinicians in these roles continues the logic of identifying providers who are involved early or already in a patient's episode(s) of care, in advance of potential downstream events and outcomes. Hence, the approach is to identify providers who are involved with a patient and episode before the performance period of interest; i.e., from which there will be estimates of savings. This means identifying a patient's caregivers in order to reward effective patient management, and before the onset of a procedural episode, or an acute exacerbation or other sequela to a pre-existing condition.

Clinicians who are seeing and treating a patient in one time-period are seen as having opportunity and responsibility regarding ensuing events and trajectories, as opposed to a provider who becomes involved only after important decisions and events have occurred that shaped the trajectories. As such, acute events comprise part of the responsibility and accountability attributed to primary and relevant principal providers.

For many patients there will be one or more providers who serves in a primary role. This is a provider managing the patient over time, or, in the context of episodes of care, someone who is participating in episodes that could be dissimilar with respect to clinical topics (e.g., cardiovascular, orthopedic, neurological, psychiatric, and so on). In many cases, there will also be one or more principal providers who help manage a patient's condition(s) within their respective specialty areas. The logic for the two categorical roles is similar, but identification of Principal providers is restricted to clinicians billing clinically relevant services to one or more conditions within a clinical chapter or condition family over time. For example, Internists, Cardiologists, or other clinicians could provide E&M services for the conditions such as IHD, hypertension, and cardiac arrhythmia. The attribution logic looks at patterns of care, as well as physician specialty, to determine who qualifies as principal and who qualifies as primary.

More details about these definitions are as follows:

- Identification of episodic, supporting, and ancillary providers for a procedural or acute condition episode is limited to service patterns within the time window of that particular episode (90 days).
- In contrast, identification of principal and primary providers is based on service patterns observed for chronic conditions over time. Principal providers participate in care for one or more conditions over time (i.e., specialty care); and primary providers participate in care for a patient over time, including a diversity of clinical conditions (i.e., general care).
- Hence, those categories are identified based on historical patterns and applied as of the beginning of the episode or performance period of interest.[11] EGM processes and updates attributes of chronic condition episodes every 90 days. For example, risk factors are updated in order to predict expected cost for that patient in the upcoming 90 days. For each patient, service patterns are examined each quarter to determine the clinicians who are providing services for each open chronic condition episode. Thus, for each 90-day period there is a list of zero, one, or more clinicians who have billed services for that patient's open episode(s).[12] This results in the roster of clinicians participating in care for that patient and the episode of interest.

[1111] For the APM entity, the period of performance will likely be a calendar year. Meanwhile, episodes are constructed for a patient based on service dates. EGM can translate episode results into calendar dates conforming to formal periods of performance.

[12] It is fairly common for beneficiaries with open chronic condition episodes to have no relevant services during a given 90-day period.

- Each clinician participating in care for that 90-day period is assigned to one of the four patient-relationship categories applicable to chronic conditions (episodic provider is N/A for chronic conditions).
    - A clinician who provides only ancillary services in one period, or multiple periods, will be an ancillary provider during each such period.
    - All providers who provide E&M or any other services beyond or in addition to any ancillary services will be assigned to one of the three remaining categories (principal, primary, or supporting).
    - The assignment of a provider to one category versus the others is determined by a combination of billing patterns during the current period of interest, and the billing patterns and category assignments in recent periods.
    - Again, some information is accumulated over time and used to assign clinicians into roles going forward. This reflects the accountability for downstream consequences and to promote continuity of interest over time.
- The first quarter in which a physician bills a relevant service for that episode, he or she is either an Ancillary Provider (if all bills are for ancillary services) or a Supporting Provider with respect to that episode. This is intended to reflect limited responsibility and accountability corresponding to the first instance (period) that a clinician becomes involve with the patient's care. The logic does not make clinicians who are new to the case accountable for consequences that are rooted in the past.
- The attribution logic distinguishes between E&M services (patient encounters involving evaluation and management) and all other (non-E&M) professional services billed under Part B. Specifically, billing for E&M services can qualify a clinician to be a principal or primary provider, whereas other Part B services cannot. Consequently, a clinician who bills only for non-E&M services will not qualify to be the principal or primary provider for that patient or episode.
- A clinician who is a supporting provider in one quarter and who bills again as a supporting provider in the subsequent quarter (non-E&M services) will again be a supporting (or ancillary) provider in that second quarter. This reflects the continuing status as supporting provider. During that second quarter, that clinician is held accountable with respect to cost for that episode.
- A clinician who is a supporting provider in one quarter, and whose services in the subsequent quarter would not qualify the clinician as supporting provider, nevertheless will automatically be assigned supporting status in the subsequent quarter. This reflects conveyance of responsibility and accountability for consequences partially rooted in the past. During that second quarter, that clinician is held accountable with respect to cost for that episode.

- We refer to this feature as a "warranty" because participants in team-based patient care continue to bear some responsibility for outcomes even for a period after their last observed service for that patient.
- A clinician who is a supporting provider in one quarter and whose claims included E&M services for that episode may qualify to become a principal or primary provider for that episode and patient. Again, this determination is made partially with respect to continuity of care for the patient, and partially with the type of services provided by that clinician. Specifically, a clinician bills for E&M services with respect to the same chronic condition episode in two successive quarters will be assigned the role of principal provider for that episode as of the beginning of the latter quarter. During that second quarter, that clinician is held accountable as a primary provider with respect to cost for that episode.
- A clinician who is a principal provider in one quarter and who bills for any E&M services for that episode in the subsequent quarter will again be a principal provider for that episode. This reflects the continuing status as principal provider.
- A clinician who is a principal provider in one quarter, and whose services in the subsequent quarter would not qualify the clinician as principal provider (no E&M services), nevertheless will automatically be assigned principal status in the subsequent quarter. This reflects conveyance of responsibility and accountability for consequences rooted in the past (i.e., the warranty). During that second quarter, that clinician is held accountable with respect to cost for that episode.
- The logic for assigning roles distinguishes between a principal provider and a primary provider in the following way.
    - The role of principal provider is determined within each chronic condition episode. The principal provider is one who manages that condition over time, and often will be a medical or surgical specialist.
    - A primary provider, in contrast to a principal provider, is said to manage the patient over time. In other words, the management is not in reference to a single chronic condition episode, but instead to any number of chronic conditions that may be present for the patient. Thus, the attribution logic observes whether a clinician is eligible to be a principal provider with respect to each open chronic condition episode, and then looks across all such episodes and qualifying status as principal provider, in order to determine whether to reassign that clinician to primary provider with respect to the whole patient.
    - In the situation where a clinician qualifies to be a principal provider in more than one chronic condition for a patient, the attribution logic applies to additional tests to determine whether that clinician instead should be designated a primary provider.

        - The first of these tests compares the chronic conditions themselves. If all chronic conditions for which a clinician qualifies to be principal provider fall into the same clinical domain (clinical chapter in EGM), then the clinician remains principal provider for each of those episodes. If any of those episodes fall into different clinical domains (chapters), then the clinician is assigned status as primary provider for that patient, and is not assigned status as principal provider for any of those chronic conditions.
        - The second test refers to the specialty of the clinician. There is a designated list of clinical specialties that alone can qualify a principal provider to be reassigned as primary provider. These are general medical specialties including internal medicine, family medicine, geriatrics, general medicine, and ob-gyn. Only clinicians with one of those designated specialties are considered to become primary providers; clinicians of any other specialty are excluded as primary providers, and would remain principal providers for the respective episodes.
        - It may be that some other specialists (not on the short list of specialties) truly manage some patients over time. However, it is common for many professional claims to include a wide range of diagnosis codes because they are accurate for the patient, even though the particular specialist is not managing those conditions. For example, a claim from an orthopedist for the management of knee arthritis may include a reference to glaucoma, this should not lead to an inference that the orthopedist is managing the glaucoma, or by extension, the whole patient. In contrast, a PCP may monitor glaucoma as an aspect of total patient management.
    - The pattern of assignment continues over successive quarters: each quarter with a qualifying service renews the status of that clinician in that role, and any quarter that lacks such qualifying services nevertheless will continue the role assignment for one subsequent quarter in order to fulfill accountability for costs that may be partially rooted in the past.

Exhibit A-2 illustrates how these concepts are implemented in relation to distinguishing the roles of primary, ancillary, or principal in relation to chronic condition episodes.

- Shown are eight 90-day quarters (1 through 8) with the first four quarters representing the prior year, and quarter 5 through 8 representing a performance year.[13]
- Each set of rows represents a physician (A, B, etc.) who bills for clinically relevant services for the patient with regard to a specific chronic condition.
- The columns represent quarterly periods for that patient in relation to that episode.
- The cells represent the clinician's particular billing patterns and the resulting roles assigned based on the attribution logic.

Exhibit A-2: Illustrations of Clinical Roles Derived from a Chronic Condition Episode

Period	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
Service pattern A	E&M	E&M	non-E&M	E&M	E&M	E&M	E&M	non-E&M
Clinical Role	Supporting	Principal	Principal (warranty)	Supporting	Principal	Principal	Principal	Principal (warranty)
Service pattern B	E&M	non-E&M	none	E&M	none	E&M	E&M	E&M
Clinical Role	Supporting	Supporting	Supporting (warranty)	Supporting	Supporting (warranty)	Supporting	Principal	Principal
Service pattern C	non-E&M	E&M	none	non-E&M	E&M	none	E&M	none
Clinical Role	Supporting	Supporting	Supporting (warranty)	Supporting	Supporting	Supporting (warranty)	Supporting	Supporting (warranty)
Service pattern D	ancillary	non-E&M	none	none	ancillary	none	E&M	none
Clinical Role	Ancillary	Supporting	Supporting (warranty)	none	Ancillary	Ancillary (warranty)	Supporting	Supporting (warranty)

In each of those quarters, the clinician's services for that episode are categorized into ancillary, E&M, or non-E&M. The first rows in the table show a service pattern (A) for a clinician over the span of eight quarters serving a patient for a given chronic condition episode.

- Service pattern A. In the first quarter shown here, this clinician billed clinically relevant services for this patient and chronic condition episode, which included at least one E&M service. Because this is the first indication we have that this clinician is participating in the care of this episode, the clinical role assigned is supporting

[1313] To simplify the illustration, we merge the concepts of calendar quarters within and across performance years for the APM, and 90-day episode-periods, which are linked to service dates affecting the timing of a given patient's episodes. In other words, we assume for simplicity that a patient's chronic condition episode coincides with calendar quarters: January 1; April 1; etc. Relaxing this assumption is not a technical barrier to implementing the APM because EGM includes several methods for summarizing patient-level episodes within calendar periods.

provider. Given that the clinician billed for at least one E&M service again in the second quarter, the clinical role assigned is principal provider. The role of principal provider continues in the third quarter as a "warranty," because the clinician did not bill for any E&M service that quarter. Because this clinician had not provided an E&M service during Q3, and the principal warranty period lasted only through Q3, the occurrence of an E&M service in Q4 reestablishes the supporting provider role. This is elevated to principal provider for the remaining quarters in this illustration by way of E&M services and warranty.

- Service pattern B. This clinician bills for at least one E&M service in Q1, which establishes a supporting provider role. Given only non-E&M services in Q2, the clinician retains the supporting role, which continues by warranty through Q3. The E&M service in Q4 reestablishes a supporting role, which again continues by warranty in Q5. The clinician bills for at least one E&M service during each of the remaining three quarters shown here, which establish supporting followed by principal provider roles in those respective quarters.
- Service pattern C. This clinician shows a billing pattern over the eight quarters that results in a consistent assignment of supporting provider. E&M services are observed occasionally but interspersed with quarters with only non-E&M services, or no professional services at all. The warranty period for supporting providers helps to maintain continuity of role.
- Service pattern D. This clinician shows a billing pattern that includes only ancillary services in some quarters (Q1 and Q5), which lead to an assignment of ancillary provider during those quarters. Because there are no professional services observed for this episode in Q6, and ancillary warranty maintains that assignment during that quarter. The combination of non-E&M services only in Q2, and no services in Q3, leads to an assignment of supporting provider during those quarters. Similarly, the combination of at least one E&M service in Q7, and no services in Q8, lead to the assignment of supporting provider.
- The members and assignments of the team-based care for a patient's chronic condition episode would result from such determinations for each clinician in turn. If the table reflected some of the care for one patient and episode, then for example, the results in Q6 would be one principal provider (A); two supporting providers (B and C); and one ancillary provider (D).
- After determinations are made with respect to each chronic condition episode for a patient, a clinician whose assignment is that of principal provider for any one condition might have that assignment replaced with that of primary provider. That would happen for any clinician with a general specialty who qualifies as principal provider for more than one chronic condition, if and only if those chronic conditions are diverse with respect to clinical domains. For example, a clinician would be

primary provider for a patient (i.e., manages the patient over time) rather than simultaneously principal provider for a combination of ischemic heart disease, hypertension, osteoarthritis, diabetes, and COPD.

- The primary provider for a patient is someone looking across a set of episodes for the patient. Not all Medicare beneficiaries will have a primary provider, or even principal providers, according to these definitions.

Except for the definition of Episodic provider for procedural episodes, the other patient relationship categories involve algorithms that could identify multiple clinicians fitting the category. The graphs shown previously about Supporting and Ancillary providers for procedural episodes illustrate that point. The situation is similar for Primary and Principal providers: empirically, there often is no clear pattern of single clinicians serving consistently or regularly, even if this is considered an ideal state. Over periods such as two years, individual clinicians appear to "come and go," appear once and then either much later or not at all. In other cases, multiple providers may appear often over time.

The discussion here presents a base case for clinical roles leading to fiscal attribution. Clinicians will be accountable for the outcomes of the chronic conditions via their assigned clinical roles. Also, during each quarter for which a chronic condition is an indication for a procedural episode, or gives rise to a sequela (e.g., acute exacerbation), the clinicians' roles for that chronic condition will be used in the fiscal attribution for those acute and procedural episodes.

These rules are subject to reconsideration, debate, modification, and eventual final determination for implementation. Perhaps periodically, the rules and parameters can be refined or reaffirmed. For example, the implied "warranty" for principal, primary, supporting, or ancillary providers could be lengthened.

These observations reinforce the nature of the episode construction for the APM, which is to be highly inclusive. This reflects reality under status quo conditions, and sets the stage for the APM Entity to improve efficiency over time by **avoiding unnecessary and duplicative relevant services**, and to **streamline the composition of the team of caregivers** in order to improve efficiency overall for patients.

The episode framework can provide similar ways of organizing quality information. Outcomes are inherently tied to the patient by episode. Quality process measures are the "responsibility of" certain clinicians, while that implies and corresponds to their respective role in the episode and for the patient. Hence, episodes can be used to link quality outcomes and process measures to resource use, and to enable accountability and analyses that consider the respective levels and trade-offs.

PHYSICIAN-FOCUSED PAYMENT MODEL TECHNICAL ADVISORY COMMITTEE (PTAC)

PRELIMINARY REVIEW TEAM (PRT)

CONFERENCE CALL

Monday, February 27, 2017
10:02 a.m.

PRESENT:

GRACE TERRELL, M.D., PTAC Committee Member
HAROLD MILLER, PTAC Committee Member
BRUCE STEINWALD, PTAC Committee Member
CHRISTOPHER TOMPKINS, Ph.D. Brandeis
JENNIFER PERLOFF, Ph.D. Brandeis
CHUCK HOBSON, M.D., American College of Surgeons
MATT COFFRON, American College of Surgeons
FRANK OPELKA, M.D., American College of Surgeons
VINITA OLLAPALLY, J.D., American College of Surgeons
MARY ELLEN STAHLMAN, ASPE PTAC Staff Director
ANN PAGE, ASPE Designated Federal Official
JANET PAGAN-SUTTON, Ph.D. Social & Scientific Systems, Inc.

P R O C E E D I N G S

[10:02 a.m.]

DR. TERRELL: Hi. This is Grace Terrell. Who else is on the phone?

MR. MILLER: Hi. It's Harold Miller.

MR. STEINWALD: Bruce Steinwald.

MS. PAGE: Ann Page.

DR. PAGAN SUTTON: This is Janet Sutton from SSS.

DR. TERRELL: Who else is on the call?

DR. TOMPKINS: Chris Tompkins from Brandeis.

MR. COFFRON: Matt Coffron.

DR. HOBSON: Sorry. Go ahead, Jen.

DR. PERLOFF: Jennifer from Brandeis.

DR. HOBSON: Chuck Hobson from Brandeis.

MR. COFFRON: Matt Coffron from the College of Surgeons.

DR. OLLAPALLY: Vinita Ollapally, College of Surgeons.

DR. OPELKA: Frank Opelka has joined. College of Surgeons.

DR. TERRELL: Has everybody identified themselves?

MS. PAGE: Grace, this is Ann. I wanted to let everybody know, we are having this transcribed. I think, as we have mentioned, as we the PTAC PRT have mentioned in the past, we need to capture responses to the PRT's questions, which will be posted, and so if it is possible -- I don't want to unduly burdensome the conversation here, but if when people ask questions and comments, if you can just say who is speaking, that will help.

DR. TERRELL: Great. Okay. Well, I am going to go ahead and get started with the phone call this morning. We have another call that the Committee needs to take at 11:15, so in theory, we've got up to an hour and 15 minutes, if need be. But we certainly appreciate having the opportunity to talk with you all about this.

So, for those of you that are not aware, I am Grace Terrell, and I am the chairman of the subcommittee that is actually evaluating the ACS-Brandeis proposal. My two colleagues on the subcommittee are Harold Miller and Bruce Steinwald, who are on the call, and then we have ASPE on the call, who is supporting us with this.

So to give you all just a quick sort of

summary of what's going on so far with the PRT process, we received your application. In fact, it was the first one to come in back in, I believe, December, and we have had several meetings since then, phone call meetings, among those of us that are on the committee, where we fleshed out our initial thoughts on it and then asked some clarifying questions that you all have kindly provided the answers back to us and have met again since then with respect to our thoughts on that.

This morning, we actually also spoke to CMS and CMMI about some questions we had with respect to the process that they had in developing with Brandeis, the grouper that we thought would be helpful in having us understand certain, more technical aspects with respect to the methodology.

So what we're hoping to do today is spend the next hour or so in what we hope will be a useful but somewhat, possibly, clarifying informal conversation in order to sort of clarify some final questions that we have, and if we are able to do so, our hopes are that we will be able to provide our report back to the full committee in time for the April PRT meeting in D.C., to be when the

proposal would go to the full committee for consideration.

So, based on that, we have a series of questions, some of which are just more specific to some of the concerns that we brought up that we are hoping that you'll be able to help us with today. I am going to go ahead, and essentially, I think we can have you all respond to those questions that we sort of come up with and then let the conversation get as informal as we need to after that to continue on.

Is that okay with everybody? Does that sound like a reasonable approach?

PARTICIPANT: Yes, indeed.

DR. TERRELL: So our first question is one that has to do with, as much as possible, can you detail how your proposed payment model actually drives changes in provider behavior. We dug into your answers about the groupers and the risk that individuals would take, but we couldn't get our arms around how that actually created specific changes in the care delivery planned and to what extent would the changes in provider affect quality and cost, not just spending, and having data to

support these changes.

So many of our questions were about more detail as to how you actually think this would actually change behavior with respect to cost and quality. Could you all give us some of your thoughts on that, please?

DR. TOMPKINS: Sure. I will start. This is Chris Tompkins from Brandeis, and others can jump in, and maybe we can make this somewhat interactive, right?

DR. TERRELL: Yes.

DR. TOMPKINS: Rather than a big question with a big answer, you can start off with a big question. We can give a big answer, and then we can drill down as much as you want to.

DR. TERRELL: Please.

DR. TOMPKINS: Well, let's take three comparators. We have the current fee-for-service system as it is or even as it's amended by MIPS. We will call that the baseline. I think nobody thinks that, necessarily, that's going to drive towards optimality. And then we have two large types of APMs kind of already established and working -- one population-based or ACOs and the

other kind of the acute segments like BPCI.

We think that our model goes, them all, one better at least. I mean, we all, I think, agree that the APM world is an opportunity to set up things that are better than the baseline fee-for-service, but if you think about the ACO world, the population-based, where there the emphasis is on managing patients over time, and then the BPCI world, where you take a segment that has a start and a stop time, in a sense, our model can encompass both of those possibilities.

We're suggesting that it starts off with more of a BPCI style. We did derive this with the College of Surgeons. And if you believe -- so just sort of a rhetorical answer is if you believe that there are opportunities for savings and compared to fee-for-service, we think that our model can, number one, identify them better than the others can and, B, motivate or mobilize people to do something better.

The "identify them better" comes natively, shall we say, from the grouper because instead of, for example, in the ACO world where you're given rules about how beneficiaries are assigned and then

you're given batches of raw data once in a while, what our model does is it organizes all that claims information into clinical context that has meaning that clinicians can understand. It uses the episode framework -- an NQF, for example, has espoused -- and creates context, where now the spending can be interpreted, and the quality of care can be interpreted. And the roles that the various providers are playing with respect to the patients in the episodes can be understood and interpreted, and so we have an information platform that doesn't exist already and doesn't exist anywhere else.

And we think in terms of mobilizing the change, we are putting the accent on team-based care because now that we don't have the obscurity or the anonymity of fee-for-service or the sort of lack of accountability, the information platform organizes that, and now the information about what's going on is available.

Now, the APM world generally talks about more than nominal risk and quality measurement and so forth, and those are very integral to the proposal that we've made. So we contemplate that

APM entities could operate under this advanced APM, where this rich information is provided to them, and then we have team-based care with shared accountability both on the quality side and the cost side. And it's all illuminated. Everybody can see what's happening. They can identify the savings, and the incentives that are now collective and quite different from the raw baseline fee-for-service can mobilize people to act on that information and to generate savings, which I think is a premise of this call, that those savings can exist if people can identify them and then are motivated not towards maintaining or, you know, the fee-for-service world, but actually motivated to change those.

DR. HOBSON: This is Chuck Hobson. I want to give a specific example of the view that Chris Tompkins just outlined.

I am a clinician. I am a surgical intensivist. I work in the VA, where these issues, the issues with the perverse incentives in fee-for-service medicine are much less applicable because of the way that providers work together in an integrated delivery system.

But, for example, the patient who has single-vessel coronary artery disease, in the VA, those patients are treated by the cardiac surgeon or a cardiologist working in concert, whereas in a lot of the fee-for-service world, those patients, if they go to a cardiologist, will be managed by that cardiologist under the fee-for-service incentives. Similarly, that patient, if they end up in the cardiac surgeon, will be managed according to -- or influence, not according to, but influenced by the fee-for-service incentives.

If an incentive world exists where cardiologists, cardiac surgeons, anesthesiologists, intensivists, internists see the opportunity to work together to optimize care for those patients and, thus, receive the financial benefits of providing optimal care in an episode-based accounting system and an episode-based environment, that single-vessel coronary disease patient will be treated by the cardiologist, preferentially, and the multi-vessel coronary artery disease patient will be treated optimally by the cardiac surgeon. And both provider groups in which the risks and sequelae of treating a patient with single-vessel

disease are optimized, and the risks and financial incentives for the multi-vessel disease patient are optimized by those providers working together and redesigning care within their community, within their hospital, within their practice region, provides a care pathway for those patients in -- that is optimized, and it provides financial incentives for this clinical affinity group to provide the best care.

So that's a single clinical example of the world view that Chris Tompkins held.

MR. MILLER: So, Chuck, this is Harold Miller. So just to sort of build on that, so you would argue then that in order for this to work, the clinical affinity group would need to have the cardiologist and the surgeon both included, and that it would need to have both the single-vessel and the multi-vessel patients involved, so that that group could essentially re-sort out what the appropriate pathways for care would be.

And then I guess part two of the question is I wonder if you all have actually looked at your data with that particular clinical scenario in mind to see how often you think that is not happening

today and what the potential impact would be of creating the model.

DR. HOBSON: So I'll answer the first part of the question. I think my colleagues at Brandeis who know the data better than I do may be able to answer the second.

But yes, we would expect clinicians to sort themselves, to organize themselves into natural clinical affinity groups to deal with the problems that they see. There are clinical relationships between cardiologists and cardiac surgeons even in the most atomized fee-for-service regions of this country. I mean, there are referral patterns. There are informal working relationships, but in a world where the incentives are to do the most of whatever they do, there is not the financial incentive to create the kind of care redesign that we are envisioning in the clinical affinity groups with its --

MR. MILLER: Well, I understand that. The question I was asking was that I think one of the things that was a little perplexing to us was the clinical affinity group idea makes a lot of sense, but it seemed when we were asking, "So what's the

minimum composition of the clinical affinity group?" it seemed that there wasn't one. So I was asking, in this particular case, it would seem that in order to be able to achieve the kind of result that you're talking about, you would need to have the cardiologist and the surgeon both involved. It couldn't just be the surgeon and just be the cardiologist.

DR. HOBSON: Absolutely. That's true. Yes.

DR. TOMPKINS: Harold this is Chris.

But there are two ways to answer that, and they're both true. Mathematically, it isn't necessary that all of the providers raise their hand and all the providers wear the same color shirt and all the providers are cheering. Mathematically, we can sort it out to know the difference, so that if one provider is not part of the entity, then that share doesn't go to the entity.

But the care design side of the question, the model isn't just a simple mathematical model. If there were any number of surgical practices that normally use certain facilities and normally came

across their medical colleagues and so forth, the formation of the entity would reflect the willingness, the necessity, and the desire to work together for better care for their patients.

MR. MILLER: Well, I understand that, Chris. The question that Grace is asking was we were trying to get at kind of what exactly is it that you actually expect to be the result of this. What's the change? So what I was saying was in Chuck's example, which is a good example, you would really need to have those folks involved.

I understand the issue that kind of mathematically if some people weren't involved that you could figure out what to do in terms of the allocation, but it wouldn't change necessarily that structure because if mathematically the people -- I mean, whatever, the cardiologist wasn't in the clinical affinity group, then their behavior is really not going to change because they are not being paid differently. So you would really want to have them both in there because the premise is that they both have to essentially change together what they're doing, which again is the whole -- I think the merit of the concept of the clinical

affinity group.

The question was, how does one assure that you don't end up with overly small or clinical affinity groups are ones that are missing key players that are needed to achieve the real result?

DR. TOMPKINS: Well, again --

DR. OPELKA: Harold?

MR. MILLER: Okay. Go ahead, please.

DR. OPELKA: This is Frank Opelka with the American College of Surgeons.

I think that's a really good question. I think what we try to do with this model is to give CMS the ability to create within the model the various aspects of incentives that draw as many of the different groups together who would not necessarily be aligned in a fee-for-service world, and those levers that exist are actually extremely flexible. It could be at the APM entity. It could be at CMS's entity. It could be at how the risk fiscal attribution is assigned in one episode versus another episode. It could vary in regions where there is high variation in the market, where this allows the payer to look at this and say, "We're not getting movement here. Why aren't we

getting movement?" and they've got all the necessary levers to seek the kind of alignment that is optimal for optimal savings.

But if you don't have the full alignment, it doesn't mean you don't appreciate some savings. It just means you might not appreciate the optimal opportunity.

DR. TERRELL: So this leads to our next question. Do you have any providers lined up at this point or provider groups that are ready to participate in this model now?

DR. OPELKA: So we have not been specifically trying to market this. We designed this for CMS -- this is Frank again, by the way -- for CMS to put into an alternative payment model.

We have had some large integrated delivery systems to also run ACOs who recognize this kind of technology would be significantly helpful to them to break down the component parts of their ACO to see how they are at variation and where they would want to put in their efforts to optimize ACO care.

We have gotten permission from CMS to use the Medicare data in those ACOs for this modeling, and we had a breakthrough with one commercial payer

who is very interested in a large market with one of these integrated delivery systems to further make that data available in the ACO environment, to take it to the next level. But those are cautious steps that everyone -- no one wants to invest in all of these activities without really getting kind of the buy-in that CMS is interested. So those are the steps we have today.

But we are getting more and more of the other medical specialties who are coming in trying to figure out the fiscal attribution and the rolling and how the educational framework would roll out for their different specialty areas within the model. There's a high level of interest there.

DR. TERRELL: Okay. You mentioned the large health systems, large integrated system being interested, and one of the things that we wanted some clarification on, simply because this model has -- as opposed to some of the others that have come forth, this one has got the significant breadth of possible influence across specialties and conditions, as it was described. Is there any analysis that's been out there as to how this might involve and impact others, besides physicians, such

as hospitals, skilled nursing facilities, or others with respect to care?

DR. OPELKA: This is Frank again, and others may want to chime in.

We've had several meetings with Premier, who is very interested in the model and sees a real opportunity to play a significant role with all their Premier hospitals, and our discussion with them is that whether it's a small community hospital or a large fully integrated hospital, the hospital could create or partner with the physician community in creating an APM entity. And they could play a very significant role in the risk modeling and the data aggregation and in the ability to get the alignment you need in the specific clinical affinity groups for which those groups, those clinical experts come together to share risk.

DR. TERRELL: So another question we had is related to -- is there any special concerns related to how someone may game the system and how they might be remediated? I mean, this is one of the things that is true in any system is that there may be the ability to game the system. If it's in

the fee-for-service world, it may be providing services that are not necessary. If it's in the world of accountable care, as it's currently construed, sometimes it has to do with falsification of data with respect to risk adjustment or quality measures, et cetera. So because there's a lot of data that is driving this with respect to an information system approach, has there been any work done on your part to think about how people might game the system and how that would be remediated?

DR. TOMPKINS: Well, I remember I was lecturing a roomful of surgeons many months ago, and one of them finally said, "No one has ever done this before. I feel like I'm the subject of an x-ray machine."

Sort of another anecdotal way to answer this, I remember talking about health plan incentives back in the 1980s. It was a meeting at CMS, and somebody finally said, "Okay. We can all agree that 2 percent of the population is crooks, but that doesn't mean we have to treat everybody as if everybody is a crook."

DR. TERRELL: No, you don't. The question

just becomes -- sometimes it makes a great deal of difference in terms of the ability to get acceptance of it --

DR. OPELKA: Right.

DR. TERRELL: -- or that it doesn't get overregulated. The last thing we want is a really promising idea that the crooks mess up for everybody else, so that is part of --

DR. TOMPKINS: Well, maybe interactively, we can talk about some of those ways to gaming, but I would just say this. I mean, in general, if you think of the way MACRA frames the upcoming reimbursement world, where there's MIPS and there's the APM, if you're really trying to get away with something, I don't think you would step into this bright light. That's sort of what I meant.

DR. TERRELL: Okay.

DR. TOMPKINS: The information system that runs under this APM looks at every dollar for every episode, at every patient, and every provider who participates, and it's not the kind of environment that somebody would be attracted to if you're trying to individually game the system. So that's one way to cut your question is whether it's

individuals who are trying to do something or get away with something or whether it's the entity itself because, again, with the collective incentives for shared accountability, with a lot of illumination at the entity level, and everybody has a stake in what everybody else is doing, this model kind of like really revs up peer review and shared awareness and so forth.

Now, I suppose we could theorize about an entity that's organized in order to try to do all that and game the system at the same time, but, I mean, whenever you step away from fee-for-service, you're stepping into a place where you're making estimates, and you're comparing actuals to estimates. And you're relying on the integrity of the data that people are reporting and that you're making inferences about, so yes. I mean, if we said -- if everybody adopted a completely different coding system that didn't affect clinical reality, would that affect the way that the information is set up and how to interpret it? Yes, it would.

I don't know if you want to get to it, but later in your questions, you talked about avoiding high-need patients and so forth --

DR. TERRELL: Yeah.

DR. TOMPKINS: -- and then the consequences. You said increasing --

MR. STEINWALD: This is Bruce Steinwald.

I'd like to go back to what you said about hospitals and institutional providers for a second. You mentioned Premier and their interest. My question has to do maybe with the whole of institutional providers and the consequences of success of the model on their bottom lines.

Since so much of the expected savings come from the reduction of the inpatient hospital and emergency rooms and maybe home health and others, how do you see the model working when the institutional providers are not a party to the model and, in fact, they're the ones that are being most affected, and yet they're not necessarily participants in the model?

DR. OPELKA: So --

DR. TOMPKINS: Go ahead, Frank.

DR. OPELKA: Could we just be clear? When you say institutional providers, I can think of a couple different ways to define that. It could be all those physicians who are employed by a health

system, or it just could be the anesthesia, radiologist, pathologist, and so it would help if I understood what your reference is.

MR. STEINWALD: Well, let's just take, for example, a hospital that does not have employed physicians but whose physicians comprise a clinical affinity group, and they implement the model, and they obtain savings through the reduced use of the hospital's resources, and yet the hospital is not a participant either in the savings or in any other fashion in the exercise or model.

DR. OPELKA: Well, first of all, the goal is that we're reducing the waste that's in the system. So if there is wasteful care that comes from any source, whether it's a hospital or home health or skilled nursing or clinical services, we're trying to reduce the waste and optimize care in the process. So somebody is going to feel they're going to have to change their business model if they're relying on resources that are generated from wasteful services. So that hospital, if that is the instance, would be faced with reviewing what its lines of services are, and if those lines of services are excessive, how are

they going to adjust their business model to be a sustainable enterprise once those wasteful services are removed?

Partnering with clinicians, we think is actually going to happen. Because of the levels of risks that are involved, physicians have trouble -- are facing significant risk-based capital needs if they're going to go at risk, and they don't always have all the informatics. And they also don't tend to have all the common linkages for the entire clinical affinity group, particularly in a setting where those clinicians are independent practitioners working with a hospital in a community.

So we think that there are incentives that try to bring alignment, but where you don't have alignment and you do have savings, if those are wasteful savings, that is what the model is intended to do.

MR. MILLER: Frank, it's Harold Miller.

Just to sort of pick up on that, though, I think one of the challenges is that you're providing information about spending based on current payment rates for things, but there isn't -

- inherently, because you don't have it, you don't have information on cost. And one of the challenges the hospitals will face is that there may be wasteful utilization, people are getting cardiac testing or surgical procedures or whatever that aren't necessary, but the hospital still has to be able to cover the cost, its cost for the patients who do need it, which will generate some level of savings, but it may not be the amount of savings that are achieved by simply reducing the spending at the current spending rates, because the average cost may go up.

And one of the difficulties that physicians have faced in a lot of these models is that they don't really have good information because they needed to get it from the hospital in terms of what those costs are, and there has been a lot of problems in a lot of the bundled payment models in terms of lack of trust about that, because the hospital says, "Well, guess what? Our costs went up somehow, and the savings that we anticipated really didn't materialize," and there is no real basis for the physicians to be able to determine that.

So I think one of the things that will come up in the implementation of it -- it's just a challenge; it's not something that your model, per se, can solve -- is that the savings will be coming by reducing cost, but someone has to actually understand what those costs are and what the new costs will be at the newer lower volume levels.

DR. OPELKA: I think that's right, Harold. I don't think we disagree. I think that is a challenge, and the indirect costs that hospitals bear are real, and we recognize that. As those direct costs go away, those indirects get redistributed, and as they do, all of that needs to be relooked at, right?

MR. MILLER: Right. And it may take time to do that.

I think Bruce's question was there didn't seem to be in any of the materials that we got any recognition of that. There was no discussion of it. There was no explanation as to how it would be addressed. There was no explanation of how -- if, in fact, an alternative service that's currently not payable by Medicare.

So let's suppose that some new, more

intensive, home-based rehab program would be developed. That might actually lead people to -- patients to be able to go home sooner, wouldn't have to go to a SNF or whatever, but it would require costs, and those costs wouldn't be reimbursable. There was no discussion as to how that would actually happen.

I mean, I can imagine, as you can, how that might take place, but the issue would be it's not really addressed in there, and it's not clear. One of the concerns overall, I think, is going to be for all of these models, since you have basically a retrospective model, would be if, in fact, somebody really innovates, develops a new kind of service to implement through this model, they could potentially be paid for it retrospectively in the short run, but there's going to have to be some way of tracking that service, so that whenever you decide how to reprice the episode down the road, you haven't lost the information about the fact that there's some whole new service being developed under the model -- or being delivered under the model that isn't being reported and isn't counting as spending right now, but it is

critical to being able to achieve the savings that are being achieved.

DR. OPELKA: Well, I'm going to be very brief, and perhaps Chris may want to jump in on this because we have talked about this in the evolution of this model. We don't think this model stands alone for all time. If it does what we expect it would do and you race to the bottom, so to speak, we would envision that this model can become supportive in a prospective environment and move to that transition. It is not limited to case rates and episodes. It can move to conditions. It can move to conditions summing up to a bigger top health payment, but let me stop there because those are discussions Chris and I have had with the team.

DR. TOMPKINS: Well, Harold, your point is well taken. If it's considered -- if this model really is sort of a Petri dish for tremendous innovation that involves the formation of programs and currently non-covered services and so forth, then we would want to capture that. In the information stream, we'd want to capture that.

So I would say that to the extent that CMS overlays the basic model itself with information

feeds, close monitoring, detailed evaluation and so forth, you'd want to capture those lessons, and you'd want to replicate those lessons. And the way to replicate it using the same engine would be to identify those services, quantify their input value, and cover them in the future. As long as you're tracking those things -- and maybe some sort of data collection protocol would be worthwhile to be implemented with this model in order for that very purpose -- then that would illuminate the future, in a sense, and allow Medicare to adjust the way it pays for things in even the fee-for-service retrospective model or turning a corner, as Frank started to allude to, other ways to add to the budget, so to speak, on the expectation that those services are appropriate and ought to be recognized as legitimate costs that help to arrive at the optimal solution.

MR. MILLER: Just to be clear, you have not really anticipated and have not planned at this point to be able to create any mechanism for capturing that information right now as part of the model.

DR. TOMPKINS: Correct. I mean, we

actually -- well, no. That's right. We've talked about it. It's not part of our written proposal.

In terms of going from design to pre-implementation to implementation, such a data protocol, I can see where it could fit, and it could certainly be added on without subtracting anything else for the model.

DR. TERRELL: We are at 10:39. I'm going to keep moving through some of the questions that we had sort of thought about ahead of time, just so that we get through those, and then we could open it up for more conversation.

I don't know if any of you had in front of you, some of your prepared answers. Some of these were very specific questions we had. One was on page 15 of the most recent set of proposals. We gave an example related to colectomy, and there was some interest in understanding why the surgeon received the smallest payment because we were trying to understand and walk through the model. Do any of you have that in front of you?

MR. MILLER: It looks like you were dismissing the actual surgical fee, but I wasn't quite clear what was going on there.

DR. OPELKA: I don't have the model in front of me that you're referring to. This is Frank again.

The surgeon's fee is not dismissed. I think this was the savings model?

DR. TERRELL: Yes.

DR. OPELKA: And the surgeon's fiscal attribution is 40 percent, and they would be eligible for 40 percent of the savings model or 40 percent of the loss, if that were the case, to the APM entity, which is the risk-bearing entity. How the APM entity reconciles with the surgeon is a separate piece of all this, but the surgeon's fees, anesthesia fees, all the physician fees are separately paid, and then this reconciliation is the retrospective reconciliation based on the savings or the loss. And the surgeon in the colectomy model has the highest percentage of risk. Anesthesia has the second highest.

MR. MILLER: What we had been hoping to get, which I don't think we still got, was a worked-out example showing how you would imagine that working for an example.

I mean, there was a table in here that had

kind of what the current payments were for a colectomy episode inside, basically, an overall management of by a gastroenterologist and a primary care physicians and what their current payments were, but there wasn't an example showing how you would actually -- then what the change in care might be, what that would actually -- what the 40 percent would represent, how people would actually come out of it.

We were trying to divine as much as we could from what we got, and when we were looking at it, we were then a little bit confused by the table. That was the one Grace was referring to on page 15, which listed all of the current payments for them. There was no actual surgeon. The surgical fee was not there, and we were just a little confused as to whether that was just an error or whether or not that was trying to tell us something that we didn't understand.

DR. PERLOFF: So, Frank, I can help, and I can also send around the table. On page 15, this is something we called the "provider vignette." So we were trying to think of different ways to display information. This is focused on as you're

talking about the patient relationship categories and how providers and episodes sort of link to each other, and so this is real data-based findings. And it's showing all of the services that occurred in the course of this episode and which one sort of landed with which provider, so just context.

Frank, I don't know if that helps you remember what the table is, but I can send it around to folks.

MR. MILLER: And the specific issue was, if you look in the middle of that table where it says episodic physician general surgery, it lists what's basically an E&M payment, but there's no actual surgical fee, which would be significant compared to all of the other payments here. Again, it may simply be that that line got dropped, but we weren't sure exactly why, whether that was supposed to have been dropped or whether it was just an error.

DR. PERLOFF: No. So our code service type "PX def" is procedure definitive, and that's actually the surgical fee. The way the data is rolled and summarized, you can't actually see that it's in the line, so it's --

MR. MILLER: But it shows $108 payment.

DR. PERLOFF: Shows payment. Maybe I'm looking at the wrong -- oh, oh. That $108 payment.

MR. MILLER: I would hope that the surgeon got a little bit more than $108 to do the colectomy.

DR. TOMPKINS: So this is what we envisioned the surgeon gets under the APM, Harold. No. I'm sorry.

MR. MILLER: Well, that was the question, Chris. That was exactly the question, right? It was so, you know, did Frank decide to take a very big discount to make the episode work here.

DR. TOMPKINS: On the one hand, it's great credit to look at this so closely in that way. The table could be expanded, I think, to have more than $108. I don't know why -- it's an artifact. I don't know what it's from. So you're pointing it out, it's a good point.

The purpose of the table was to show a tracing of the way in which these various providers were involved with a patient --

MR. MILLER: Right. And that was helpful. I would just say what we were trying to get was one

really complete example to make sure that we understood what you were thinking of the same way you were thinking of it. I mean a complete example that basically said, "Here's what's happening today," similar to the example Chuck gave earlier, but with colectomy or whatever. Here is what is happening today. Here is what we might imagine happening tomorrow under this model. Here is what might change in terms of maybe the surgery isn't done. Maybe the complications get reduced, maybe whatever, and then here is how the payment would -- what would happen under the payment model to everyone, given that particular scenario about the change and the way care was being delivered. We were really honestly, desperately trying to get a completely worked out example like that, and we just never got one. And this was the closest we got, and then we didn't even understand what the data was saying.

DR. TOMPKINS: Right.

MR. MILLER: So it would be really, helpful, I would just say, if you could really give us an example like that. We understand it's just an example. I mean, it's just a hypothetical, but

it would be really helpful to see a realistic hypothetical as to what kind of a care change you might imagine happening and how you would see that all playing out in the model, and ultimately, it gets to some of the issues, like what Bruce was raising earlier. If in fact if the savings opportunity is that the patient doesn't get the colectomy at all or some proportion of the patients don't get a colectomy at all, where does the savings come from? Well, a lot of it presumably comes from the hospital because even though the surgeon gets paid more than $108, the hospital gets paid a lot more than $108. And that would potentially sort of -- if you don't care about the hospital, it could be a lot of money for everybody, from the PCP to the gastroenterologist to the surgeon to the nurse anesthetist or whatever. But the issue would be, well, that wouldn't make the hospital very happy. So how that might work out in practice would be really useful to see how you thought that through.

DR. TOMPKINS: And somewhere in there --

MR. MILLER: Grace, am I characterizing accurately what we had hoped to get?

DR. TERRELL: Yes. I think that from our point of view, getting a -- the way you started this conversation is exactly what we hoped, which is that there will be a model out there that can be broadly applied to many specialties that would allow an alternative payment model that would incentivize appropriate behavior.

And because this particular proposal has such potential breadth relative to some of the others that we're getting so far, we really believe it's important to understand at a very granular level for a particular example exactly how this would work, because we need to make sure we understand it, because understanding it for 102 different episodes and chronic diseases and 62 specialties or whatever may not be possible unless we understand a really, really, at a granular level, good example.

Now, having said that, we understand that we put limitations such as your application could only be 20 pages, and then we added back some clarifying questions. So part of what we're doing in our own process is understanding how we can best evaluate these things, and we believe that for this

particular proposal, having a very detailed granular example is to do exactly what you said, which is if I'm a clinician, what is going to basically -- in this model, the payment methodology associated with the bundled process, change my behavior such that I want to work in teams, and that good things happen for patients by virtue of improving the cost and quality. So that's what we're trying to get at.

It's really important. You guys are doing some very important work.

MR. MILLER: And let me just add one more feature to it, which is, Chris, you started out basically saying it was improving on the BPCI as well as ACOs, et cetera, but it would really be important to understand an example, which I think you have here, the page 15 example, that shows how this would be different than BPCI, because -- and, again, back to the earlier points, at least the way you've answered the questions, it seems -- you tell me if I'm wrong -- it seems as though the model could be activated by CMS, but the only people who would sign up might be the surgeon and the anesthesiologist, who would simply figure out how

to reduce post-acute care utilization. In those circumstances, it really wouldn't seem to be any different than BPCI.

If, in fact, the gastroenterologist and the PCPs and everybody else signed up and said, "Okay. We're really going to figure out how to manage patients at risk of colon cancer more effectively," et cetera, et cetera, et cetera, that would be very different, but we need to sort of see how that might actually work, or if you have something in the middle that says we're going to start doing hip surgeries in an ambulatory surgery center or something like that, which also isn't contemplated under BPCI, how would that all work out? So that's kind of what we were trying to do because one of our criteria -- no, it's not one of -- it's one of the CMS criteria in the regulations is that this has to expand the CMS portfolio. So understanding clearly when and how this is different than their existing episode models is going to be essential to us in terms of being able to evaluate that criteria properly.

DR. TOMPKINS: Yeah. Well, okay. So a couple things, maybe several. First of all, it's

not just one person raising his hand and another person raising her hand and let's wing it. The formation of the entity would have to make sense. The model itself begins by respecting the work of the individual specialist, and that work is conveyed to the entity because those providers were involved with those patients. So there is a natural bringing, to the entity, the work of the clinicians, and we talked about that earlier in the call about how that might come about.

One of the ways that this contrasts with BPCI -- and, Harold, I remember -- I don't know how many years ago. I think it was when we first met. You provided a slide presentation to a small group of us about how bad quality is incentivized, talking about the upgrade in the DRGs and so forth when complications arise.

MR. MILLER: Oh, yeah. It's still there. It still exists.

DR. TOMPKINS: One of the things that is very different about our model as compared to BPCI is that it doesn't trigger on DRGs. So, as you would be the first to appreciate, given so many years ago you had that insight, that we would

trigger on the definitive surgery --

MR. MILLER: Yes, yes.

DR. TOMPKINS: -- or we would trigger on the reason, the original condition for the -- and if things go awry and somebody ends up in the ICU and somebody ends up respiratory failure and all the rest, the model calls those sequelae extra costs, and the entity is not just given a pass for that.

So from a logical standpoint, it's a better starting point than BPCI, and it creates incentives that BPCI can't imagine, because under our model, people would know whether the patient was part of their entity or not.

MR. MILLER: Chris, that would be a wonderful example to see you work out because it's not clear. I mean, we're kind of all talking at a very high level here. The model somehow captures that, and I understand that in theory, it captures it, but how it actually would work -- and so the patient ends up there getting a colectomy. They end up becoming septic, and they end up on a trach or whatever. You're absolutely right. That would sort of bump them out of the episode in BPCI. But

how would that work here, I think it would be very useful to see because then that would help all of the members of the PTAC say, "Oh, that is actually very different," and, "Oh, it actually would seem to create a different structure."

But without an example or two of that -- and that's why we asked to sort of pick one. So colectomy could well be the one, or maybe you pick something else, but you could actually give several examples of here's two or three different kinds of clinical improvements. One might be reducing infection rates, one might be reducing post-acute care, one might be avoiding the colectomy altogether, and then saying here's how the model would work in all of those things, which would then help to show the power of it.

DR. TOMPKINS: Okay. We could do that.

PRT MEMBER: So if we could get that, I think it's going to be very, very helpful.

I'm going to give another example. It's the last thing we hadn't sort of -- I think if it was written down ahead of time, and then we'll maybe get at how that would be helpful to get in more detail.

So on page 24, you explain that there is a wide variation in expenditures by episode, and you provide a supporting table showing a large gap between the 25th and 75th percentiles for certain procedures. Then you have a second table showing the average observed and average expected cost for an episode, giving the patient's demographic and risk profile.

But one of the things that wasn't entirely clear to us is how much of the variation demonstrated in the first table is accounted for by differences in the patient demographics and the risk as opposed to just unexplained variation and cost, if you will. This is the type of detail.

I think because, as we said before, this is broad and could be a very big deal for many, many clinicians, we're really wanting the type of detail where we can get into this in a great deal of understanding, so that we can make sure that we're appropriately responding to your proposal.

DR. TOMPKINS: Okay. I think this could be another request, right?

DR. TERRELL: Yes.

DR. TOMPKINS: You are framing this

possibly as another request for additional information from us, and if so, then let me see if I can repeat what you're asking. What you're saying is if you show the cost distribution for the type of episode according to the provider averages, then the provider at the 25th percentile might be quite a bit lower than the provider of the 75th percentile, and the way you interpret that difference would be very different if the 25th percentile provider was exactly as expected and the 75th percentile was exactly as expected, because most or all the difference was actually explainable by patient risk factors.

DR. TERRELL: Yep.

DR. TOMPKINS: Was that your point?

DR. TERRELL: Yeah, that was our point, so how much of the variation in what you are showing us is actually related to just unexplained variation in behaviors and providers.

DR. TOMPKINS: If we framed the dependent variable, such as the difference between the actual and expected, summarize at the provider level, and then show the distribution of that dependent variable.

DR. TERRELL: Yep.

MR. MILLER: Well, I would just say again it would be probably most helpful to do it in the context -- if you want to provide more, that's fine, but to do it in the context of the example we were talking about.

DR. TERRELL: Yep.

MR. MILLER: So if, in fact, you said we're -- again, up to you, but if you're doing this kind of colectomy, colon cancer screening, or whatever you want to call the example, then say let's look at the variation there. You could actually say, given the kind of data you have, something about what you actually think is causing the variation. So what is it that makes some colectomies only 16,000 and some 36,000? Is that, in fact, intra-hospital complications? Is that post-acute care differences? Whatever that is, and then, again, to Grace's point, how much of that is explained? Because when you go from the first table to the second table on page 24, you would kind -- I mean, the model, in a sense, probably is designed to have the same average expected as the same average observed. The key issue is really

kind of how much of the total variation gets removed by the model, and how much is left as unexplained variation. And what's the nature of that unexplained variation? What's causing it?

DR. TOMPKINS: I'm just taking notes.

DR. TERRELL: Sure.

MR. MILLER: No, that's fine.

DR. TERRELL: Yeah.

MR. MILLER: One other suggestion -- it's really in response to your earlier question -- it's back to this issue of who is in the clinical affinity group -- would be that it would be -- I think if you can detail the example and multiple examples of where the clinical improvement opportunities might be, it would then potentially help to clarify to say that, well, if only the following people participated in the clinical affinity group, then you'd be able to get this particular opportunity for savings built in. If more people participated and you sort of went further upstream, you could get these additional opportunities, and then that would help to clarify what those opportunities are, because I think, to me, if you do want to recruit people to

participate, they are going to have to understand the "What's in it for me?" So what's in it for me, the PCP, to be part of this clinical affinity group for colon cancer screening or whatever it is as opposed to what's in it for the surgeon? And I think those are the kind of things that would be helpful to see that in a couple of different examples, some examples for the same basic concept.

DR. TERRELL: Are you all understanding what we're asking, do you think?

DR. TOMPKINS: Yes.

DR. TERRELL: Okay.

DR. PERLOFF: This is Jen with a clarifying question. To show both, it sounds like it's sort of a case study or a narrative and also the empirical part as well, how the dollars would fall out.

DR. TERRELL: Yes.

DR. PERLOFF: Okay.

MR. MILLER: Well, I guess, again, I would just say if you have some real data based on your analyses to support it, that would be certainly desirable, but even if it's just a hypothetical example worked through -- because I think those are

two different concepts. One is in the hypothetical example of there's a clinical improvement opportunity, how would the model work, is one kind of thing that we want to make sure we understand. The second issue is, based on your data analyses, what do you seem to see as being the clinical improvement opportunities out there, so that it would be clear, for example, that the opportunities are more than just reducing post-acute care use, which one would argue is already being captured by some of the existing CMS models.

But, Chris, to your earlier point, it clearly doesn't capture the DRG bump-up issue inside the model, and if you'd be able to clarify if you have any data as to how often you think that may be happening, that would help to say here's something that if you did this rather than BPCI, what some of the potential opportunities would be.

DR. OPELKA: This is Frank.

I mean, we can answer all of these questions. In fact, we've been asked many of these questions by the many, many specialties who are anxious and willing to participate. I think you're going to find that there are a million scenarios,

and colectomy will have several hundred. And there are many opportunities that have not been leveraged because the clinical teams haven't been incentivized to leverage them.

Classic example we give all the time is we know from a quality standpoint that tobacco cessation prior to surgery has an enormous impact on reducing sequelae and other resources needed to deal with those sequelae, and yet there's no coordinated incentive plan that pulls all that together.

We envision that this kind of model can put together PCP and anesthesia team with a reference from the surgeon to optimize perioperative tobacco use and reduce subsequent sequelae related to tobacco, and that is broad-reaching across numerous different types of patients.

There's nothing in the current environment that incentivizes those kinds of activities under its hypertension management, COPD management, diabetes management, and this is just the surgical environment care coordinating with the primary care environment, now in a shared savings model and in a

shared quality metrics model where the measures are on the patient, and so the team is being measured to cooperate.

MR. MILLER: Well, I would say, Frank --

DR. OPELKA: The incentives are in play, and how those markets are going to respond to those incentives are going to vary all across the country. So we can speculate and give you a hypothetical and walk you through how it plays out, but there are many different ways --

MR. MILLER: We understand that.

DR. OPELKA: -- it plays out.

MR. MILLER: We are looking for some hypotheticals for some things like that. So that would be a good example.

The question is we have to have some way of being able to say, "Yes. In fact, this model would, in fact, incentivize that," rather than just saying it would, to be able to show that it would. We recognize there may be a million opportunities out there, but just pick two or three good ones and show that and then say, "And guess what? Those are only just two or three examples."

We understand that whatever you pick is

not going to represent the whole universe, and we're not going to say we don't think those three things you picked are important enough. What we're trying to understand is how in any given example of an improvement opportunity, the model would work, so that we can clearly say, "Yes, the model actually does, in fact, enable, encourage, whatever, that particular kind of an improvement." That's what we're trying to get at.

DR. OPELKA: I'm clear on that. I just want everyone on your end to realize these hypotheticals are that speculative, and we've already created it and modeled it, and we have an idea about it, but it by no means is reality. Until we get out there and see the behavior, we're not going to know whether we have the right incentive to move the behavior.

DR. TOMPKINS: We think that this is a conversation that will be happening with many of the models because people are just in this state of innovation right now where they've got some really good ideas, but you're exactly right. Because the payment system hasn't been out there to allow all the innovation to happen, it's hard to actually

imagine all the potential that's out there.

But we need something that's concrete enough that there can be an aha, if you will, at a level that people see those possibilities, and for us, we think that needs to be sort of a walked-out concrete example: Here is the way the money flows. Here is the way people's behavior changes because of this new incentive. Does that make sense to you?

MR. MILLER: The distinction, I guess, I would make, Frank, is that some of the other proposals that we're getting -- I mean, it's not that there is anything right about this or wrong, but those other proposals are very focused on a specific thing. They're saying, "Here is the opportunity. Here is the improvement thing that we are trying to do. Here is the barrier in the current payment system, and here is how the alternative payment model specifically will remove that barrier to enable us to do this thing. It's not kind of a vague incentive notion. It's basically they are identifying those kinds of improvements. So we want to be able to see, in fact, whether how this model would do similar kinds

of things, if you have a specific improvement opportunity identified.

DR. OPELKA: I'm good. I appreciate that. I think those are all helpful, and we can give you some hypotheticals.

DR. TERRELL: Good.

It's 11:07. We've got about eight more minutes, so I'm going to just open it up for any -- Bruce, you've asked one question. I've sort of gone through the list we had, and Harold has provided some detail. Are there things that others on the phone either from ASPE or otherwise or from Brandeis or ACS wants to get clarification on?

MR. STEINWALD: This is Bruce.

I have no more questions, Grace.

DR. TERRELL: Okay.

MS. PAGE: Grace, this is Ann.

I do have one. This is ASPE. I would like you to talk a little bit about a link between the grouper and the quality measures. So, in several of the questions we've asked and then we've seen your responses, you have linked these two things together somewhat. We understand the freedom that you want to afford CMS to take the

grouper and use it and modify it and implement it.

But then there was this sentence in one of the responses about development costs and maintenance costs for performance measurement requires resources, and it was unclear whether you were seeing the quality measurement piece that might be derived from the grouper as separate from the grouper software and were you wanting to have different treatment of those two parts.

DR. OPELKA: So this is Frank again.

The quality measurement is for the most part separate. It is a measurement system we've introduced to CMS -- I guess it was almost a year ago -- that we think is more patient-centric. It is based on what we refer to as the phases of care, and in this instance for us, the surgical phases of care. And there are high-value process measures that we link to PROs.

There were some questions about appropriateness measures, and to the extent those high-value process measures are patient goals related to PRO in terms of achieving those goals, we get, I think, some baseline levels of appropriateness. But formal appropriateness

science is much more complicated, and if that was the goal, it's going to take resources to develop those richer appropriateness measures.

I think this first round of PROs linked to high-value process measures tied to patient goals will give you a new look at appropriateness that we have only seen in a few instances of care, and we're working with all the specialties right now to set up meetings to explain how to walk through this and for them to develop their own version of phases of care measures with high-value process linked to PROs. So that's the basis of this.

MS. PAGE: So the quality measures, then, would not rely on the grouper software for their calculation, but the calculation would come through sort of a separate analysis of claims or other data sources?

DR. OPELKA: Yes. We're envisioning for these episodes that we put forward that they are part of a registry-based system that provides the current thresholds for the different four levels.

MS. PAGE: Thank you.

MR. MILLER: Grace, this is Harold. One more question I had, if you don't mind.

Frank and Chris, could you just say a word about how you came up with the percentage allocations amongst the clinicians and how you would see those potentially being updated or evolved over time? Because I understand that you sort of said that you came up with them and nobody has objected to them, but you didn't explain how you came up with them, and you didn't explain how they might evolve over time.

DR. OPELKA: Well, I'll take the first half, and Chris may want to comment.

Inferentially, just looking at the clinical courses of care, we assigned these risks in alignment with the CMS five categories of attribution, which have been subsequently minimally modified by CMS.

We've had conversations with the AMA as a larger convener of the rest of medicine to talk about how to actually govern these attributions over time, because we think we'll learn more, and we'll learn from the different markets. We don't have the kind of hard data that actually gives us a clean enough picture, and we also think that if the model does what we believe it will do that these

attributions should shift and change. So it needs ongoing processes for governing the fiscal attributions beyond our initial starting point, just put a stake in the ground and say, "Inferentially, we'll begin here, but we recognize this will move, and it ought to be more broadly managed cooperatively between the government and an entity like the AMA."

MR. MILLER: Well, fair point, and I understand where the categories came from. I just wanted -- so where -- take 40 percent surgeon. Where does 40 percent come from? How did you come up with that number? Throw at a dartboard or some methodology?

DR. OPELKA: Chris, do you want to jump in here?

DR. TOMPKINS: Well, I don't have much to say because I'm tempted to say dartboard.

No, it's not algorithmically driven, if that's what you mean. It wasn't like let's apply this --

MR. MILLER: So you're saying it was judgment on the part of all of you? Kind of in thinking about it, that sort of felt right?

DR. TOMPKINS: Yeah. I mean, I don't object to that characterization, but, Frank, if you wanted to say something --

DR. OPELKA: Yeah. I think everyone realized there was a starting point, and of course, whenever I first show this to surgeons, they say, "Well, why aren't I 90 percent?" Then when I tell them about the downside risk, they want to know why they're not 30 percent, so --

MR. MILLER: And the PCPs want 90 percent unless there's a downside risk problem.

DR. TERRELL: I'm shocked. I'm shocked at this.

DR. OPELKA: Yeah.

DR. TOMPKINS: It's a zero-sum game, and it's a question of influence and judgment.

MR. MILLER: Okay. Well, that's all I wanted to try to understand was kind of was this just a -- because, I mean, if it is, in fact, kind of initial judgment, then updating it over time, the process becomes more important to think about that, because you don't know whether it will actually turn out to be the right basis. But if there were some data that said whatever, that we've

attributed 40 percent of the sequelae to surgeons based on our methodology and whatever, that would be a more quantitative thing. But you're saying you didn't do that, which is okay.

DR. TERRELL: Okay. So we are going to have to get off the phone now, but I thank you for your kind attention this morning.

I think what we're left with right now is that we're hoping to have this ready for the April meeting. There's some time limitations on us where we have to -- actually, what is it? Ten days or two weeks that we actually have to get the report out in public prior to the meeting. So there is going to be the need for you all to give the specific example that we've asked for, if you can and will, back to us by a particular date, so we can then evaluate and get that done.

MR. MILLER: And if you can't do that, that's up to you. I mean, we would just then have to delay the process of finalizing our action on it, so it's entirely up to you as to whether you want to try to stick with that time table or not.

DR. TERRELL: Yeah. We're just trying to --

DR. TOMPKINS: We are going to go to work on this, so tell us what the date is. I mean, you're not going to mind if you get it this week. On a day-by-day basis, is there any strong preference or sort of like critical juncture where it's no longer useful?

DR. TERRELL: I don't think that's the case other than just we won't prepare our final report.

DR. TOMPKINS: No, I mean without slowing down your timetable is my question. If we had it for you today, it wouldn't slow down your time table.

MR. MILLER: Oh, no. No. I mean, I think this week, anytime this week would be fine.

DR. TERRELL: Yes, this week would work.

DR. TOMPKINS: Okay. All right. That's what I was wondering. Good. Very good.

DR. TERRELL: All right. Well, thanks, everybody, and for those of you that we have been talking all morning long to different folks, I'll talk to you again in a minute on another line. Thank you.

[Whereupon, at 11:16 a.m., the conference

call concluded.]

Supplemental Material on the ACS-Brandeis model

I. Development of Innovative Services

An assumption of the ACS-Brandeis model is that successful APM entities would be motivated to implement innovative services that would reduce costs, increase quality, or improve patient experience, yet might not be payable by CMS under prevailing fee schedules. Instead, an entity could pay for those services (e.g. coordination of care, care management, social services, home visits, and so on) out of current or expected (future) savings. Hopefully and eventually, this is not a sustainable payment model because an expected product of success would be that waste is squeezed out of the expected cost or price of each episode.

There are several ways to think about this question. One way is to help CMS identify high-value services and build them into their fee-for-service (FFS) framework for all providers. Another way of thinking about this question is as an evaluation question. An evaluator might ask, "What are the non-reimbursable services that successful APM entities provide and how can those services be rapidly disseminated in a learning collaborative?" Additionally, our model could identify innovative quality improving or cost-reducing services, with the goal of eventually building the cost of those services into a fairer, stable price for the episode based on excellent care.

The ACS-Brandeis model is built on the CMS FFS chassis of bill payment. Therefore, CMS does not routinely collect information on services that are not payable. However, CMS does collect non-billable information on quality of care. It is possible that a condition of participation for this model could be to require APM entities to report on innovative services as described above, and potentially on internal evaluations with respect to ROI. CMS could then use this information to consider adding such services to the baseline prices.

II. Steady State versus Start-up

When a model as comprehensive as the ACS-Brandeis model initiates, it will evolve. We envision the model gives CMS the necessary levers needed to attract entry or start-up enterprises into APM entities to assume levels of risk and evolve their ability to manage the risks. We also believe the model offers an opportunity for phased participation of the various physician types and specialties. Risk aversion will keep some adopters out of the risk pool until they are more comfortable with the risk management. We also feel that the episode based quality framework can make quality improvements both more apparent and understandable to providers and patients.

As these evolutions continue, we would move to promote more comprehensive adoption and move from retrospective payment models to prospective payments. In the steady state, virtually all Medicare services, beneficiaries, and providers could be included within a coherent system that tracks and reconciles all accounting, and links clinical information with cost to drive a fully

empirical value-based payment system. The ACS-Brandeis model can support that vision of the steady state, and facilitate a stepwise approach to getting there.

For example, consider the clinical domain of gastroenterology, which includes the gastrointestinal (GI) system and its disorders. Figure 1 shows procedural episodes that pertain to that clinical affinity group (CAG). A surgical practice along with anesthesia and key supporting and ancillary providers could manage these procedures within the context of an APM entity that did not necessarily engage the broader team of clinicians who may know the patient. For example, the Principal Shares can be calculated and set aside for now, or set to blank (as depicted), and reallocated to the Episodic or other categories. Either option allows for CMS to start-up the model without requiring full coverage.

Figure 2 continues to illustrate the implementation pathway using examples of acute conditions that reflect the clinical work of GI specialists. The ACS-Brandeis model can include acute conditions such as common indications for procedural episodes, frequent reasons for hospitalization or acute exacerbations of chronic conditions. An APM entity that engaged general surgeons and gastroenterology could manage acute episodes in this clinical domain as Episodic providers and supporting team, without necessarily including "the whole team" participating in the patient's care. As before, the longer-term primary and principal roles can be added as implementation proceeds toward the steady state. Figure 2 illustrates optional reweighting and reallocation of the fiscal attribution along these lines.

Figure 3 gets one step closer to the steady state by adding chronic condition episodes and establishing the role of Principal provider (medical specialist) who manages the GI condition(s) over time. As condition episodes are added to the entity's episode library, the medical specialists (e.g., gastroenterologists) would easily meet MACRA thresholds for qualifying as QPs. Including conditions from among all of the clinical domains also would allow generalists to qualify easily for QP status in the ACS-Brandeis model.

Thus, generally as the episodes available to entities grow in number, the conceptual advantages of the ACS-Brandeis model continue to blossom, including shared accountability in patient-centered, team-based care; and fulfillment of thresholds for being QPs in the APM. EGM can manage the contemporaneous and nested episodes for precise accountability across the clinical spectrum.

Figure 1: Procedural Episodes Pertaining to GI (an example of one TIN selected from claims data)

	All Episodes	Total Shares	Episodic Shares	Principal Shares	Supporting Shares	Ancillary Shares	Sum of Actual	Sum of Expected	Net Savings
Colonoscopy	8,029	6,055	3,595		850	1,609	$ 5,491,255.82	$ 5,169,323.16	$ (321,932.66)
EGD endoscopy	5,906	3,618	1,750		752	1,115	$ 3,915,063.04	$ 3,997,562.12	$ 82,499.08
Colectomy	478	291	126		77	88	$ 5,164,963.76	$ 5,364,642.66	$ 199,678.90
Cholecystectomy	431	263	100		86	77	$ 1,948,601.57	$ 1,988,356.25	$ 39,754.68
all procedural episodes									**TBD**

Figure 2: Acute Condition Episodes Pertaining to GI (an example of one TIN selected from claims data)

	All Episodes	Total Shares	Episodic Shares	Principal Shares	Supporting Shares	Ancillary Shares	Sum of Actual	Sum of Expected	Net Savings
lower gi bleeding	831	647	449		180	18	$ 458,387.40	$ 616,216.35	$ 157,828.95
intestinal obstruction	537	430	244		116	71	$ 1,553,235.72	$ 1,492,069.39	$ (61,166.33)
c-difficile colitis	444	310	172		87	52	$ 688,926.58	$ 684,294.26	$ (4,632.32)
gastroenteritis	329	279	210		63	6	$ 292,760.75	$ 283,738.57	$ (9,022.17)
diverticulitis of colon	297	194	94		50	50	$ 660,927.00	$ 626,733.37	$ (34,193.63)
pancreatitis acute	197	152	96		45	11	$ 359,624.06	$ 397,819.75	$ 38,195.69
peritonitis	169	143	88		44	11	$ 211,736.67	$ 186,979.21	$ (24,757.46)
upper gi bleeding	141	120	94		23	3	$ 200,272.68	$ 227,395.93	$ 27,123.25
biliary tract disease nos	136	108	70		28	10	$ 132,893.85	$ 106,381.28	$ (26,512.57)
gastrostomy complications	67	57	29		28	0	$ 126,710.49	$ 127,120.44	$ 409.94
biliary tract obstruction not	60	48	29		14	5	$ 59,940.02	$ 39,454.31	$ (20,485.71)
appendicitis	52	38	15		12	10	$ 223,812.68	$ 238,850.30	$ 15,037.62
colostomy/enterostomy	46	39	26		10	4	$ 140,414.36	$ 138,594.68	$ (1,819.68)
complications GI other	40	36	28		7	1	$ 56,354.87	$ 77,787.03	$ 21,432.16
cholecystitis (acute)	40	27	14		10	4	$ 6,107.55	$ 6,986.43	$ 878.88
anal/rectal abscess	37	25	14		10	2	$ 64,352.05	$ 48,395.97	$ (15,956.08)
vascular insuff intestines	27	25	14		8	2	$ 143,594.42	$ 67,149.87	$ (76,444.55)
anal/rectal ulcer fistula	20	16	13		2	0	$ 6,274.78	$ 14,901.73	$ 8,626.94
esophagus foreign body	8	4	3		1	0	$ 2,398.42	$ 7,855.50	$ 5,457.08
all acute condition episodes									**TBD**

Figure 3: Chronic Condition Episodes Pertaining to GI (an example of one TIN selected from claims data)

	All Episodes	Total Shares	Episodic Shares	Principal Shares	Supporting Shares	Ancillary Shares	Sum of Actual	Sum of Expected	Net Savings
esophagitis (chronic)	2,952	2,646		2,429	158	59	$ 194,736.00	$ 362,700.95	$ 167,964.95
colorectal neoplasm malignant	1,897	1,290		521	239	531	$ 3,464,405.78	$ 4,140,864.58	$ 676,458.80
cirrhosis other	1,028	797		484	143	170	$ 379,486.47	$ 224,087.44	$ (155,399.04)
hepatitis c (chronic)	837	681		568	91	22	$ 128,030.32	$ 186,745.02	$ 58,714.70
metastatic neoplasm to gi organs	758	466		140	81	246	$ 728,379.69	$ 543,091.93	$ (185,287.76)
hepatobiliary neoplasm malignant	754	447		157	131	159	$ 1,679,077.97	$ 1,045,907.99	$ (633,169.99)
irritable bowel and related	583	539		513	24	2	$ 67,434.84	$ 53,918.07	$ (13,516.77)
enteritis	546	460		400	47	12	$ 210,852.31	$ 208,336.44	$ (2,515.87)
pancreatic neoplasm malignant	470	280		129	74	77	$ 1,243,765.65	$ 1,273,401.71	$ 29,636.06
liver disease chronic other	460	419		335	44	39	$ 127,956.64	$ 78,370.53	$ (49,586.11)
esophagus neoplasm malignant	349	206		119	47	40	$ 443,762.85	$ 601,863.63	$ 158,100.79
inflamm bowel ds ulcerative colitis	345	310		288	19	2	$ 72,928.30	$ 87,521.46	$ 14,593.16
pancreatitis chronic	267	225		186	22	17	$ 68,208.49	$ 94,563.82	$ 26,355.33
hepatitis other	266	242		196	24	21	$ 50,996.44	$ 25,752.45	$ (25,243.99)
hernia other nec/nos	254	223		167	51	6	$ 413,922.91	$ 423,512.18	$ 9,589.27
cirrhosis etoh	223	192		155	25	12	$ 185,019.78	$ 154,260.42	$ (30,759.36)
inguinal hernia	207	174		140	26	7	$ 163,407.68	$ 169,713.80	$ 6,306.12
colorectal neoplasm benign	190	181		169	7	5	$ 53,469.76	$ 79,266.41	$ 25,796.65
other gi neopasm malignant	182	130		42	19	70	$ 76,958.46	$ 71,737.86	$ (5,220.60)
hernia other umbilical ventral	180	140		89	34	18	$ 214,381.66	$ 137,931.14	$ (76,450.51)
gallbladder stones	165	137		81	17	38	$ 63,856.55	$ 64,311.19	$ 454.64
hepatitis b (chronic)	153	130		113	10	8	$ 15,356.09	$ 23,775.44	$ 8,419.35
stomach neoplasm malignant	140	81		32	19	30	$ 343,004.92	$ 271,067.98	$ (71,936.94)
vascular insuff intestines chronic	138	124		101	15	8	$ 235,726.45	$ 319,022.95	$ 83,296.50
cholecystitis (chronic)	129	101		51	21	30	$ 871,720.54	$ 1,059,915.60	$ 188,195.06
cirrhosis billiary	129	103		87	11	4	$ 22,499.02	$ 10,652.54	$ (11,846.49)
liver disease nec	126	101		49	20	32	$ 140,264.44	$ 64,347.35	$ (75,917.10)
hernia diaphragmatic	125	104		66	13	25	$ 129,759.98	$ 57,938.77	$ (71,821.21)
all chronic condition									**TBD**

I. Illustrative Case Study

The ACS-Brandeis model is intended to take advantage of the clinical efforts of care that are currently reimbursed in FFS silos and, instead, push for team-based incentives that more closely mirrors the clinical intent of care. The model attempts to achieve this by defining an episode with its cost and measuring quality across that episode framework at the patient level with shared accountability with upside and downside risk. To illustrate this let's look at two scenarios.

Figure 4 shows compares scenarios for managing a CABG episode. The beneficiary in the illustration has diabetes and ischemic heart disease and is undergoing a CABG. Scenario 1 features a cardiac Clinical Affinity Group (CAG, the medical team in a service line of care) that has extensive experience with patients that have hypertension, diabetes and chronic kidney disease. As a result, they take a number of steps to avoid acute kidney injury during and after the surgery. Scenario 2 represents typical care, with providers working in traditional silos, often in different TINs, and includes costs associated with a kidney injury.

Scenario 1: The episode begins with a referral to the surgeon and a surgical evaluation of the patient. The referring physician may be in the CAG or may be referring to the CAG. Once the patient has been identified as a surgical patient, the surgeon consults with the anesthesiologist prior to the surgery to review comorbidities. In this discussion, they determine that acute kidney injury is a possibility during the surgery and implement a series of activities to reduce this risk. The pre-operative consultation is a new, non-reimbursable service, but key to the beneficiary's outcome.

During the surgery, the team implements a new screening test for early detection of acute kidney injury. A positive finding prompts the anesthesiologist to institute more aggressive monitoring, some changes in the cardiac perfusion, and convinces the surgeon to shorten the pump run by foregoing a bypass that was not considered necessary but could have been done if the risk was low. The screening test for acute kidney injury is likely reimbursable. In the ICU the higher level of hemodynamic monitoring is continued, and nephrotoxic medications are absolutely avoided. After discharge to the floor the patient is pushed toward early ambulation with the help of a physical therapy consult. This is not a directly reimbursable service, but a low cost way to avoid or reduce post-operative institutional costs. The CAG has implemented a number of step to promote physical activity and reduce loss of muscle tone during recovery, including the use of cardiac rehabilitation post-surgery. Before discharge to home the surgeon consults a nephrologist within the CAG to optimized care of the patient with a now resolving acute kidney injury.

Scenario 2: The episode begins with a referral to the surgeon and a surgical evaluation of the patient. The risk of kidney injury is not a particular focus of the clinicians involved in the case. The surgery proceeds uneventfully, with standard hemodynamic monitoring, and the surgeon decides to do all possible bypasses and the patient has a long pump run. The patient is transferred to the ICU post-operatively and is given both acetaminophen and ketorolac for pain relief. On postoperative day 1 the patient develops stage 3 acute kidney injury that progresses to renal failure and the need for temporary dialysis. This requires more testing, invasive procedures within the ICU, specialty consultation, and both a longer ICU length of stay and a longer total hospital length of stay which is reflected in the final DRG which is 'with MCC'. This beneficiary

is discharged to a skilled nursing facility given the need to monitor and treat the kidney injury as well as get the patient physically able to function independently at home. During the post-operative period, one of the medical specialists seeing this patient orders angiography, a potentially low value test, and which exacerbates the acute kidney injury. Given lack of a referral, the beneficiary does not go to cardiac rehabilitation. Given ongoing issues related to the cardiovascular disease and acute kidney injury, this patient is readmitted twice from the skilled nursing facility.

As shown in the table, the cost profile of these two cases is quite different. The costs shown here are derived from claims-based clinical vignettes from 2014. Figure 5 shows how the dollars for this single episode would be distributed to the team based on role. The third panel plays out an extreme scenario where all of the patient for one APM entity are scenario 1 patients and the second practice only has scenario 2 patients. This shows that the APM entity is successful in the model through the accumulation of high quality, efficient care. The scenario 2 APM entity is not successful under status quo conditions, although the losses are capped in the model.

These two scenarios focus specifically on the surgical procedure episode. However, within the ACS-Brandeis APM, the CAG can be expanded to include medical specialists and cover chronic conditions like hypertension, IHD, diabetes and kidney disease. In this more inclusive group, the benefits of aggressive management of the hypertension can also contribute to better surgical outcomes and fewer acute exacerbations for the beneficiary. In fact, over time, the CAG may come to specialize in patients with this particular mix of co-morbidities, working out communication pathways, primary and secondary prevention protocols and the appropriate mix of new technologies to optimize care for this and similar populations of patients at the condition episode level. By optimizing the care of the hypertensive and diabetic patient, this CAG does not just optimize the patients who eventually present for CABG and optimize their perioperative care, but reduces the development of chronic kidney disease and cardiovascular disease so that there is less chance that they need the surgery in the first place.

In the scenarios shown, the clinicians within the APM entity may vary. If the surgeon and anesthesiologist are the only two participating in the APM entity, for example, a larger portion of the savings will still accrue to the APM entity. Supporting and ancillary providers will continue to be paid their share outside of the APM entity. This does not dilute the gains of the surgeon and anesthesiologist, but does make it harder at the APM entity level to accumulate larger enough gains to support more significant care redesign activities. This creates an incentive to include key provider specialties inside the CAG, potentially buying some services, such as imaging, outside of the CAG. The benefits of a comprehensive CAG get even larger at the condition episode level where the group can adjust and optimize team size, reduce the use of low value services and increase the use of high value, sometime non-reimbursable services, internalize the financial benefits of avoiding surgery, or changing the site of surgery among other things.

These scenarios do not explicitly focus on the differences between the ACS-Brandeis APM and BPCI, but can be used to highlight some key differences. In the second scenario, for example, if the surgery had major complications the patient may have ended up on a ventilator and a different DRG, which would have bumped the case out of BPCI. Nesting the CABG within the related condition episodes allows for broader participation of medical specialists and can results in savings for events like avoided or delayed surgery. The ACS-Brandeis model can also

internalize the benefits of better post-operative management through the condition episodes. For example, the post-operative visit with a nephrologist may be cost increasing within the 90-day CABG window, but much more cost decreasing for the CABG and chronic kidney disease episodes. The examples also focus on complex patients with a mix of cardiac and kidney disease, requiring coordination across medical specialists. The ACS-Brandeis model, because it is designed to address multiple services that make up a large proportion of any clinician's work, is better able to address and capitalize care redesign that cuts across departments and even organizations by allowing clinicians to focus on common clusters of episodes, not just one episode type at a time.

Figure 4: Illustrate Scenarios for Managing CABG

CABG Procedure Episode			**Scenario 1**	**Scenario 2**	**Comments - what makes scenario 1 and 2 different?**
Service	Service Type	Provider Role	No kidney injury	Kidney injury	
Referral from Primary Care to Surgeon	e&m	Primary	72.77	72.77	
Surgical evaluation of the patient	e&m	Episodic	142.22	142.22	
Surgeon & anesthesiologist meet to plan approach	---	Episodic and Supporting	Y	N	Non-billable care coordination
Pre-op testing	text/lab	Ancillary	78	78	
Pre-operative imaging	img	Ancillary	84	84	
Surgery	pxdef	Episodic	2,500	2,500	
Supporting procedures	pxsup	Supporting	2,320	3,230	More unanticipated problems during the surgery
Testing for early identification of kidney injury	text/lab	Ancillary	153		New test for early detection of kidney injury
Surgical ICU	e&m	Supporting	750	750	
Post-op testing	text/lab	Ancillary	78	250	More post-operative testing given complications during and after surgery
Early ambulation/PT while INP	---	Supporting	Y	N	Early ambulation to reduce muscle loss
Post-operative imaging	img	Ancillary		250	More post-operative testing given complications related to kidney injury
Inpatient facility charges	INST	INSTITUTIONAL	20,000	22,000	Higher DRG and greater facility changes
Skilled nursing facility	INST	INSTITUTIONAL		3,200	Need skilled nursing rather than home with support
Home health	hh	INSTITUTIONAL	1,200		Home health for 2 weeks rather than skilled nursing facility stay
Angiography (low value test)	text/lab	Ancillary		148	Low value test
Follow up - primary care	e&m	Principal	84	84	
Follow up - nephrologist	e&m	Principal	125		Including a medical specialist on the team to monitor kidney health
Cardiac rehabilitation	therapy	Supporting	623		Cost effective rehabilitation to improve function in frail elders
Readmission	INST	INSTITUTIONAL		5,423	Readmissions due to complications
TOTAL (observed)			28,210	38,212	

Figure 5: An Example of Reconciliation

Expected Cost: $35,250	**Scenario 1**	**Scenario 2**
Savings/Loss (observed-expected)	7,040	-2,962
Quality Score	Excellent	Unacceptable
Primary (10%)	489	-296
Principal (15%)	734	-444
Episodic (40%)	1,956	-1,185
Supporting (30%)	1,467	-889
Ancillary (5%)	245	-148
Cap on Risk	15% Upside	8% Downside
Reconciled Savings/Loss	5,287	-2,820
Maximum risk		
Primary (10%)	529	-282
Principal (15%)	793	-423
Episodic (40%)	2,115	-1128
Supporting (30%)	1,586	-846
Ancillary (5%)	264	-141
Expected Cost: $35,250		
APM Entity Cases: 250	**Scenario 1**	**Scenario 2**
Expected Cost	8,812,500	8,812,500
Observed Cost	7,052,498	9,552,998
Over/Under	1,760,003	-740,498
Variation in participating providers	**CABG Revenue**	**CABG Revenu**
Principal and episodic in APM Entity	672,375	-407,274
Principal, episodic and half the supporting in APM Entity	855,750	-518,348
All providers in APM	1,760,003	-740,498

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April 7, 2017

Physician-Focused Payment Model Technical Advisory Committee
C/o U.S. DHHS Asst. Sec. of Planning and Evaluation Office of Health Policy
200 Independence Avenue S.W.
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Dear Members of the Physician-Focused Payment Model Technical Advisory Committee (PTAC),

The ACS-Brandeis Advanced Alternative Payment Model (A-APM) project team appreciates the opportunity to share our reaction to the Preliminary Review Team's (PRT) report. The PTAC has been given a difficult task to digest and evaluate multiple diverse proposals, each with its own context. We recognize the complexity of developing a review process that could evaluate many different approaches. The general PTAC criteria are likely well-suited for a range of simpler models; however, we believe that a few sub-criteria were applied in the preliminary review to the disadvantage of our unique APM. These sub-criteria include a requirement to predetermine and prescribe care redesign for every type of episode in advance; reward or punish quality performance in the model potentially without regard to financial performance; establish empirical benchmarks for quality metrics before launching a test of the model; any of which would lead the PRT to favor narrowly focused models over the comprehensive ACS-Brandeis model. It is our hope that the responses and clarifications in this letter will enrich the PTAC deliberations, and allow for the PTAC to recommend the ACS-Brandeis A-APM proposal for implementation or staged, limited-scale testing.

Most models that have been submitted to date are limited in scope and targeted to a defined specialty, patient population, condition or procedure, and are therefore well-suited for a narrow review. In contrast, the ACS-Brandeis proposal sets forth a comprehensive yet clinically precise model that is ambitious in scope, encompassing a broad range of providers and payers. The ACS-Brandeis model is also flexible by design, and provides entities and participating physicians with new tools and incentives to find innovative ways to improve care pathways and

reduce unwarranted variation. The quality framework included in the model sets a high bar. It uses the quality measurement design in existing approved APM models as a minimum quality baseline, and proceeds to incorporate measures tied directly to the care delivered and to meaningful patient-reported outcomes to ensure that quality is maintained or improved (and therefore patients are protected) while striving for efficiency.

Our model will provide CMS and other payers with an adaptable framework that begins with an initial set of well-developed episodes, with a planned transition to larger sets of interrelated episodes that represent disease-specific and population-based care.

The PRT states two of the ten criteria did not meet the standard they wished to see for the model. Those two criteria were #2. Quality and Cost and #4. Value over Volume. Our responses to the PRT perspectives are below:

Criterion 2. Quality and Cost

a. PRT critiqued our proposal for a lack of explicit plans for improving quality and reducing costs for each episode. We believe this conclusion by the PRT stems from an apparent presumption of the preliminary reviewers that care redesign must precede and dictate modifications to the payment system. The PRT report states, "…the submitter did not provide adequate information describing (1) the ways in which care delivery would change in order to improve quality and/or reduce costs and (2) the reasons those changes could not occur under current payment systems." (PRT Report, page 6)

   Other models could focus on a single episode and require a prescriptive care pathway or a cookbook approach to value optimization within that episode. However, the ACS-Brandeis model does not begin with predetermined care redesign, or formulate in advance the strategies or mechanisms of change. We designed the model to allow providers and provider groups to find their own way towards high quality and high value care. The model can provide opportunities for numerous specialties, in diverse settings, to participate in an APM.

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b. Instead of laying out a prescriptive care pathway, the ACS-Brandeis model provides new incentives for the delivery team to evaluate each episode-of-care individually for variation in quality or cost and then drive innovation, acknowledging that care redesign is fundamentally local and context specific. Participating providers and entities will be provided with tools and data to enable them to identify unwarranted variation and target it. We wish to drive value from multiple directions, and not create restrictive pathways or a single distinct formula. We propose to provide the care delivery team with reports detailing variation in care, to which they can apply clinical logic for appropriate and efficient care. We are concerned that there may be a presumption on the part of the preliminary reviewers that a quality measurement framework comparable to MIPS (and more stringent than those of certain existing CMS models) is not acceptable for the APM, or that the APM is not the appropriate context for advancing the science of quality performance metrics. We disagree, and believe that not only will the proposed model protect patients by assuring quality, it will be an important impetus to further the accuracy and validity of quality measurement in health care.

   It is important to clarify that the ACS-Brandeis model provides CMMI with two distinct quality frameworks to choose from for each episode: the Episode-based Quality Category, and the All Patient-based Quality Category. Both quality categories require an outcome measure if available. We strongly believe that both categories are comparable to, or exceed, the requirements of MIPS and existing CMS APMs.

   CMMI may elect to accept the episode-based measure framework, and/or the all-patient MIPS specialty measure sets approved by CMS, possibly allowing clinicians to select which measure set applies best to their local situation. It is our preference that entities use the Episode-based Quality Category and the associated measure framework, which is tied to the specific episodes of care provided. That approach would help to galvanize the model with respect to shared accountability in team-based care, and for evaluating cost and quality simultaneously within the same clinical episode context. However, due to the fact that quality measures and patient-reported outcomes (PROs) may not be available immediately for all episodes, we have provided the All-patient

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Quality Category as an alternative for those who unable to use the Episode-based Quality Category, in order to be more inclusive for all interested parties.

CMS appears to share our interest in measuring quality and cost over a defined episode. For example, Deputy Administrator for Innovation and Quality, Patrick Conway, MD, promoted the episode-based measure framework and PROs in his address to an AMA APM workshop on March 20, 2017. Our model aligns with his efforts to promote this measurement environment to the physician community. In our episodes, we propose high-value process measures and PROs because they capture what is truly important to patients. We rely less on typical clinical outcomes because of their inferior statistical reliability to discern differences in care due to large confidence intervals and small effect sizes. We prefer our PROs to be episode-specific and linked to key processes of care, such as functional and pain assessments matched to treatment goals.

ACS has proposed to CMS' CCSQ a set of measures in an episode-based measure framework with inclusion of PROs. CCSQ sought inclusion of the ACS measure sets in the MIPS program and asked us to introduce these measures to the NQF MAP in 2017, a request that has been fulfilled. We have also noted the PRO developmental work currently underway uses the CMS-endorsed Surgical CAHPS instrument as a resource for the PRO questions. These questions have been adopted by CMS and are psychometrically sound.

In their report, "…the PRT concludes that the proposal contains insufficient information to assure that there would be adequate quality protections to offset the financial incentives for lower spending in the wide range of conditions and procedures proposed." (PRT Report, page 7) Our conclusion differs from the PRT report. Our measures serve as new and innovative episode-specific measure sets. These measures represent the assurance needed to secure quality in an episode-based APM by exceeding the level of measurement in the MIPS program.

As noted above, we have included in our proposal an alternative measurement system, which can be used as a flexible part of implementation especially

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when episode-based measures are awaiting CMS approval. The All Patient-based Quality Category uses the CCSQ-approved MIPS measures or specialty measure sets. These measures can be used at the individual provider level although they are not necessarily episode-specific. So, at a minimum, this measure set provides the APM proposal with a MIPS-comparable set of measures. We prefer the episode-based measure framework over the MIPS measures because they are episode-specific and are intended to foster shared accountability.

Criterion 4. Value over Volume

a. The PRT report asserts that "…there are insufficient mechanisms in the model to…encourage or reward quality even with no change in spending, which are essential elements of a truly value-based approach." (PRT Report, page 10) Separately, the PRT report concluded unanimously that our proposal met the high-priority Criterion 3: Payment Methodology.

   Our proposed payment method follows a standard template commonly referred to as the "benchmark" approach, which defines risk and accountability in terms of shared savings and losses in reference to specific benchmarks. Whether the benchmarks refer to episodes (or bundles as in CJR), or to expenditures per beneficiary (e.g., ACOs), this approach does not reward or punish quality outcomes separately and without regard to the financial outcomes. If a site or entity breaks-even at reconciliation, there are no further rewards (no positive savings to share) or penalties (no losses to extract).

   There is at least one template, often called discounted price (e.g., the BPCI demonstration), that does adjust the target price according to observed levels of quality, which in turn affects the financial reconciliation. However, that example does not support an evaluation criterion that defines such *a priori* adjustments as "essential elements of a truly value-based approach."

   Although the initial transition phase of quality measurement would be largely reporting-based (as in other CMS models), we fully intend that the model move to performance-based measurement once benchmarks can be

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established. Furthermore, participants with lower achievement in relation to quality standards would have lesser upside potential and greater downside risk.

The model effectively prohibits participating providers from benefiting financially from reductions in care that lead to poor performance in quality. In fact, quality performance influences reimbursement in both upside and downside risk. In the instance of losses, the quality score influences the level of risk associated with the loss. Unacceptable quality scores result in assumption of greater downside financial risk. Excellence in quality reduces or eliminates any losses. Thus, we disagree with the PRT and believe quality influences both the upside benefits and the downside losses.

b. The PRT raises legitimate concerns over assessing the appropriateness of surgical procedures. In most cases, these measures simply do not exist, are the most complex measures to create, and will take considerable investment for their development. Patient risk factors, clinical options and complexity, neural networks and machine learning all offer promise to enhance the opportunity for appropriateness measures.

   However, we believe these measures are beyond the scope of this proposal and their absence should not preclude initial implementation of the model. These represent future work and would easily fit into the quality and value matrix. We would welcome inclusion of suitable appropriateness measures in the Episode-based Quality Category of any particular episode for which evaluation of appropriateness has attained this level of sophistication. A benefit to basing the APM and performance measurement on the episode framework is that it facilitates logical linking of cost and clinical data, including potentially indicators of appropriateness. Furthermore, as the PRT noted, our larger framework nests procedures within condition episodes, providing for risk arrangements that encompass metrics related to the value of all treatment pathways within a condition, including but not limited to surgery.

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Until such time as these measures are developed and become available, the Episode-based Quality framework can serve as a proxy for appropriateness measures through linked dyads of high-value process measures related to goals of care paired with related PROs which catalog the effectiveness of care toward achieving the goals. For example, a goal of care to reduce pain or improve function will pair with a PRO that measures the degree of reduction in pain or return of function.

The model also calls for assessment of variation in volume of services relative to patient needs and quality scores. Reducing unwarranted care as noted above is a foundational component to promoting value and reducing volume. In this context, maintaining or improving quality adds to the value. Where quality is worse there is a loss in value that will generate losses. Prime areas of focus are assessments of the use of various services relative to an episode of care. These include redundant or overuse of diagnostic services, labs, imaging or consultations and greater use of home and community based care.

The PRT report states that: "Initial implementation is proposed to focus on 75 procedures in 10 clinical areas involving 75 separate medical specialties. Expansion into acute and chronic conditions increases the scope of the model to potentially impact $1.5 trillion in Medicare expenditures annually, with the potential for over half of all clinicians in the country to have greater than 75% of their professional fees covered by this methodology." That captures our vision. The steady state will involve passing the tipping point toward a new value-proposition encompassing clinicians' full body of work, as well as transforming organizational cultures and community standards of practice. We recognize that staged implementation and stepwise expansion is prudent, but our model anticipates scaling over time to achieve the wide application noted above. Substituting a narrowly constrained APM or APMs, that would fill only a small portion of the APM void faced by surgeons and other specialists, would terminally limit the APM program.

In conclusion, we believe that the PRT has accurately pointed out that the APM will require substantive inputs from CMS for its implementation. Each of the rules we have applied in building the model will require review and input from CMS' implementation team. We believe the model reaches the PTAC's criteria for

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consideration as a model worthy of pilot-testing or phased-implementation with refinements toward expansion and wider implementation, and we seek to continue our work with CMMI. We encourage PTAC to help move this project forward.

Sincerely,

David B. Hoyt, MD, FACS
Executive Director

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Testing the ACS-Brandeis Advanced APM

MACRA is modifying how Medicare will pay physicians for the remainder of their careers. MACRA represents a once-in-a-generation opportunity to transform the healthcare system by leveraging decisions and efforts led by physicians, other clinicians, and their respective practice environments. Does MACRA expect the system to "turn on a dime," or "change overnight?" No. MACRA allows for transition phases, interim policies, and appropriate testing and development. However, MACRA sets forth a clear vision for healthcare purchasing by Medicare and other payers to reflect a clear value proposition, with an explicit time line for the process of transformation.

Towards this end, we recommend testing and implementing by phase the ACS-Brandeis model which would lead predictably to a national model that entails reconciliation by design across all entities. This stands in contrast to alternatives that would have any number of clinical domains and specialties "reinvent" logic and develop fiscal models that won't mesh regionally or nationally.

A clear value proposition is a tall order. It requires valid and consistent tracking of inputs affecting value, most importantly, the benefits achieved in relation to spending. This is done, in part, by leveraging the Episode Grouper for Medicare (EGM). More specifically:

- The ACS-Brandeis model offers an unprecedented opportunity to establish measures, incentives, and accountability for such a value proposition.
- The ACS-Brandeis model would allow CMS and other payers to track virtually every dollar spent and every dollar saved, attribute every one of those dollars to the clinicians and entities participating in patient care, and to link patient-related outcomes or other quality indicators in every case within a common episode framework.
- The ACS-Brandeis model is designed to operate at a national scale, allowing all of the clinical domains and specialties to manage within a coherent framework guided by a consistent clinical logic and system of fiscal accountability.

Since this model is new and potentially far reaching, CMS will need to articulate phases of implementation that define the scope of supported activities; i.e., the episode libraries and their corresponding quality metrics. CMS will need to specify criteria for entities to participate, such as corporate governance and minimum case volumes. Clinicians, organizations of practice, facilities and conveners will need to huddle and consider their best options, and then formulate a response to the relevant RFA.

With that in mind, here are options that may guide staged implementation of the ACS-Brandeis model:

1) **Participation.** It is unknown at this time how many and which entities would enter risk arrangements under the ACS-Brandeis model, the terms and conditions for which do not yet exist. Similar to the BPCI demonstration, CMS could issue an RFA that describes the scope and logic of the model, provides for data support, and elicits applications to participate.

A possible scenario would be:

a. Round I: Issue an RFA for all interested stakeholders (January 2108)
b. Select a pre-implementation set of potential entities that would use data reports to support efforts to submit a complete application to participate. The reports could be customized to reflect the anticipated "identity" of the entity, such as lists of TINs, NPIs, and facilities.
c. From among those potential entities that wish to complete the application process to become advanced-APM entities, CMS could select the right number and mix of entities to begin testing operational phases of the model.
d. Successful applicants would enter 5-year agreements that begin with initial episode libraries, which could be expanded as CMS brings more episodes into the model. Sufficient duration of the contract is important to create a sense of financial continuity, encouraging innovation and investment. (October 2018)
e. Round II: re-open the process for a second round of applications. Repeat steps above for this second round. (January 2019)

2) **Information protocols.** The ACS-Brandeis model is intended to increase greatly the utility of information that supports improvement.
    a. EGM is able to convey all services and their costs assigned to each episode, which can be summarized to any level of aggregation while preserving the ability to drill down to each service and each dollar.
    b. Participants in the first round can form a learning network that includes consideration of the optimal timing and levels of detail included in information reports and/or distribution of grouped claims (i.e., claims data with embedded episode information). These are a source of cost-driver information that is not available in any other APM.
    c. Participants in early rounds will be responsible for reporting quality metrics attached to episodes in their respective libraries. That will involve certain preparation, logistics, and QC. Merging the quality and cost information for entities will test the systems for reconciliation after performance periods.

3) **Beta test results.** Running the model for the first round of entities will constitute a beta test of the model, including behavioral responses and feedback from entities. Other potential advanced APMs have had the advantage of formal demonstrations operating for several years. The results will be the first glimpse of the model's effectiveness.
    a. It will be important to see which episodes were selected by entities, and why.
    b. Results by episode can be assessed, which can inform learning networks as well as episode specifications.