The PTAC Preliminary Review Team's Questions on

***Multi-provider, Bundled Episode-of-care Payment Model for Treatment of Chronic Hepatitis C Virus (HCV) using Care Coordination by Employed Physicians in Hospital Outpatient Clinics* Submitted by the New York City Department of Health and Mental Hygiene**

Questions for the Submitter

Responses are italicized

Payment Model

1. The PRT is seeking clarity on certain aspects of the payment methodology. Please describe the following:

    a. The APM Entity.

    The entity includes one or more MIPS-eligible clinicians who are on a participation list and affiliated with a particular hospital-based outpatient clinic.

    b. The flow of funds through the payment model. (A diagram would be desirable).

    Receipt of the bundled payment (as indicated by HCV primary diagnosis with specified CCM code) initiates the episode of care for each patient enrolled in care coordination. The episode of care, including SVR, is expected to last no longer than ten months for Medicare beneficiaries.

    The SVR rate should be calculated for each facility. The SVR rate is the ratio of patients aged 18 years and older with a diagnosis of HCV and enrolled in care coordination who have completed a full course of antiviral treatment with undetectable hepatitis C virus (HCV) ribonucleic acid (RNA) 12 weeks after cessation of treatment. It is calculated using the following steps:

    Step 1. Identify the number of patients enrolled in care coordination to treat HCV. This is the denominator of the SVR rate. This number should match the number of bundled payments the APM entity acquires.

    Step 2. If appropriate, subtract the number of patients who do not start treatment from the number enrolled in care coordination. This is the adjusted denominator. APM entities should only subtract the number of patients ineligible for treatment if they agree (a priori to APM implementation) to return the portion of the bundled payment associated with treatment and SVR follow-up before reconciliation is made.

    Step 3. Count the number of patients enrolled in care coordination who achieved SVR. This is the numerator.

    Step 4. Calculate the SVR rate by dividing the numerator in step 3 by the adjusted denominator in step 2.

    At reconciliation, the SVR rate calculation is compared to a benchmark set by CMS. APM entities with a rate at or above this benchmark receive a bonus for each patient

achieving SVR. Entities with a rate below this benchmark must pay back to CMS a penalty for each patient not achieving SVR. These bonus and penalty amounts are derived by applying one or more shared saving rates (determined by CMS) to the expected total cost of care averted over the life years gained, given the patient's age and disease stage. This flow of funds is also described in a diagram included at the end of this document.

We advise that initial reconciliation occurs starting at the end of the second year in which the APM is implemented (at 24 months). At that time, patients enrolled in care coordination within the first 14 months would be used in the calculation of the SVR rate. Subsequent reconciliations should occur annually. For example, after 36 months of APM implementation, patients enrolled from months 15 – 26 would be used to derive the SVR rate. This lagged timeline is to ensure sufficient time for patients to complete the episode of care, approximately 10 months.

c. Whether the bundled payment includes the following:
    i. Hospital inpatient - *NO*
    ii. Hospital outpatient - *NO*
    iii. Regular fee schedule professional fees - *NO*
    iv. Care coordination fees – *Yes, the bundled payment covers the cost of care coordination activities for the episode of care.*
    v. Post-acute care services (e.g, SNF, home health) - *NO*
    vi. Part B drugs - *NO*
    vii. Part D drugs - *NO*
    viii. Other? - *NO*

d. Which costs are included in the shared savings calculation? Would Medicare recoup the cost of treatment, including drug costs, and the $760 bundled payment before savings are shared?

The shared savings amounts are estimates of the annual total cost of care for Medicare patients with untreated HCV multiplied by life years gained as a result of SVR. As indicated in Table 2 of the proposal, it is expected that five years after HCV treatment, Medicare would recoup slightly more than $30,000 per patient as compared to beneficiaries with untreated HCV infection. This amount does not cover the current full cost of drugs (using the VA price of $45,000).

However, the five-year post-SVR time horizon in Table 2 was dictated by the literature; cost savings associated with SVR were projected out five years post-SVR. Note from the proposal that the differences between the annual total costs of care among those treated using care coordination and those untreated in Table 2 were, at a minimum, $10,000 per year across all post-SVR years. Thus, we suggest that Medicare should recoup all drug costs within seven years after the patient achieves SVR. CMS may ultimately decide to factor this time horizon into determining bonus allocations to maximize the potential for Medicare's total savings.

Our proposal indicated, "for year one of the three-year project, on average, 137 Medicare FFS INSPIRE enrollees experienced a significant 15% reduction in Part B payments." We conducted additional analysis to make a preliminary conclusion as to whether this reduction was sufficient to cover the cost of the care coordination. Among the INSPIRE enrollees, the reduction was $1,872. The reduction among non-INSPIRE enrollees was $20. Thus, before any bonuses are distributed by CMS, ***Medicare has likely recouped approximately twice the episode of care payment.*** *Ongoing economic analysis in the next six months using rigorous matching methods will seek to validate this reduction for the entire INSPIRE Medicare sample.*

Thus, the short-term savings associated with care coordination (as described in Q2.1 of the proposal) should allow Medicare to recoup the entire cost of the bundled payment within the year the services are offered and before any bonuses are paid.

e. The enrollment criteria and how eligible patients would be identified and attributed.

Anyone in the Medicare population who is infected with HCV and in need of additional support to initiate and complete treatment could participate in this model. After diagnosis, the care team will assess for comorbid psychiatric or mental illness, substance use disorders and/or psychosocial barriers such as history of incarceration and marginalized housing. These individuals will be treated with services described under the complex chronic care management (CCM) codes identified in the submitted proposal (see Q3.1 and Appendix A.2). The lower-needs patients may not need HCV treatment with care coordination–supportive services.

f. When the episode begins and ends. Is it a uniform length or variable depending on the patient's participation and response to treatment? Specifically, what happens if a patient's treatment is interrupted or if a patient begins but does not complete treatment? Can the APM Entity receive more than one bundled payment for a patient?

The episode begins when the patient is enrolled in pre-treatment assessment. The episode concludes on one of the following dates:

[1] The date the patient achieves SVR;

[2] The date the patient is deemed ineligible for treatment;

[3] If non-adherent to the treatment, 30 days after the date of the last prescription for HCV medication.

The length of the episode is variable depending on the time required for pre-treatment assessment and the duration of treatment as determined by the physician (12 weeks or 24 weeks). The APM entity may return a portion of the bundled payment for patients who do not start treatment. This amount is approximately $400. There is no option to return a portion of the bundled payment after treatment has started. Patients who receive at least one month of HCV medication will be counted in the SVR rate, regardless of their treatment completion status. If treatment is interrupted due to non-adherence, the patient will need to re-enroll and restart HCV treatment. However, the same APM entity will <u>not</u> receive another bundled payment for this non-

adherent patient should this patient re-enroll. However, if an otherwise adherent patient fails to achieve SVR, the same entity can receive a second bundled payment for a patient who will be re-enrolled beginning with the pre-treatment assessment.

2. If the chronic care management codes under the Medicare Physician Fee Schedule were expanded to complement this kind of initiative (e.g., loosened eligibility, fewer required elements, and greater payment), would a new payment model be necessary?

The chronic care management codes do not allow for higher "up front" payments that recognize the greater costs of pre-treatment activities versus costs of supporting patients while on treatment. However, the structure of the new Collaborative Care Model (CoCM) service codes for behavioral health conditions do differentiate somewhat between first month and subsequent month costs. Our episode-based payment model allows for higher reimbursement early in the care coordination protocol.

Delivery Model

3. Please describe the delivery model as experienced by the following, emphasizing how the experience would be different from prevailing care:

The INSPIRE care coordination delivery model differs from the other care coordination programs, including the prevailing health home model in Medicaid. In the table below, we describe the differences between the two in terms of eligibility, contact, duration, and scope of knowledge required to implement the respective program.

Criterion	***INSPIRE***	***HEALTH HOME***
Eligibility	*hepatitis C*	*2+ chronic conditions (including HCV)*
Contacts	*at least once per week*	*minimum once monthly*
Scope of knowledge	*specialized health promotion, medication prior authorization, pharmacy, medication adherence, substance and alcohol use counseling, healthcare navigation*	*general chronic disease*
Duration	*episodic (maximum of 10 months)*	*continuous/indefinite*

For individuals meeting eligibility for care coordination within health homes, the INSPIRE care delivery model offers a temporary increase in payment to provide more intense, specialized care coordination for the episode of care related to HCV management. The model allows primary care physicians to treat patients in collaboration with liver specialists (hepatologists or gastroenterologists) who work at the "top" of their license by supporting treatment in the primary care environment. Specialists who participate in the INSPIRE model will be able to focus on treating cases of the highest severity. Furthermore, they will be able to work more efficiently as a result of their interactions with primary care physicians and care coordinators. These other providers

will address pre-treatment issues that would likely delay the initiation and/or the progression of treatment. Below we describe the specific stakeholder experiences in the care delivery model.

a. A patient

In prevailing care, a patient is referred to subspecialists with expertise in liver disease. There is no systemic health promotion or psychosocial assessment—this is the responsibility of the liver specialist during brief clinical visits. If the patient has any barriers to care (substance use disorder, mental health disorder, insurance issues, housing issues, language, transportation, cognitive difficulties, low HCV-related knowledge, low motivation, competing priorities), the patient is often referred back to the primary care provider to address these barriers. This often requires multiple appointments at different locations. The patient may be challenged by different physical locations and decreased trust in providers with whom patients are unfamiliar. Treatment by unfamiliar providers may increase the chance that patients will be stigmatized because of co-occurring substance use disorders. The patient must remember to attend scheduled appointments and take medications as prescribed without any reminders or support. If the patient has questions, she must call the specialty clinic directly or wait for the next appointment. There are no peer counselors or peer navigators to counsel patients who are reluctant to address their HCV infection. If a patient is lost to follow-up, there is no systematic tracking or outreach.

In our delivery model, patients will have access to treatment in a variety of settings: primary care medical homes, substance abuse treatment centers, infectious disease clinics, settings which serve marginalized housed individuals, and liver specialist clinics. Where they are treated will be determined by their specific needs, which will be determined with a comprehensive psychosocial evaluation to identify any potential barriers to care, as well as a medical evaluation to determine complexity of liver disease. Barriers will be addressed by non-clinician support staff with whom the patient can develop a trusting relationship. This allows the patient to address issues that will impact HCV management and thus optimize potential for curative treatment. The delivery model staff can assist with navigating multiple locations for clinical management by providing escort services, reminder calls, and rescheduling missed appointments. The patient will be able to call the delivery model staff for any questions related to HCV management. Patients who are lost to follow-up will be systematically tracked, and outreach will be conducted as appropriate.

b. A primary care physician

In prevailing care, the primary care physician (PCP) is rarely involved in managing hepatitis C due to lack of clinic skills and knowledge and insufficient time to manage a patient's multiple medical diagnoses and psychosocial issues. The PCP often refers patients with chronic HCV infection to liver specialists. This requires patients to remember to make the appointment, show up to the appointment, navigate through the clinical visit, and reschedule missed appointments. The PCP often does not know what happens during the specialty visit and has limited capacity to support the treatment plan. If the PCP gains the knowledge and skills to treat HCV infection, there will be little or no

support for addressing psychosocial issues, tracking patient progress, and completing onerous prior authorizations for HCV medication approval. When clinical consultation is required, the PCP will again refer patients to specialists.

In the delivery model, PCPs can gain knowledge and skills to treat chronic HCV infection by working directly with a multidisciplinary team via tele-mentoring. In the tele-mentoring sessions, PCPs can discuss complicated patients in real-time without sending the patient to another clinic location. They will have direct support from care coordinators for prior authorizations, patient referrals for mental health and substance use disorders, health promotion, and tracking outcomes. PCPs will see improved show rates and more consistent rescheduling of missed appointments with the support of the care team. They can spend more time with patients discussing medical issues.

c. A hepatologist or other gastroenterologist

In the prevailing model, liver disease specialists are referred patients with chronic HCV infection. These patients often have multiple medical and psychosocial comorbidities that liver specialists are not trained to address. To address these issues, they must collaborate with other providers. Often, this means referring the patient back to primary care or other specialists in a series of appointments. The specialists are often the only source of HCV management, even for patients without advanced liver disease. Because of the improved efficacy and tolerability of current HCV treatment, a greater number of patients are now eligible for treatment. This has resulted in access problems and longer waiting periods for next available appointments. The specialist's office must provide internal support for the prior authorization process and education of the patient.

In the delivery model, liver disease specialists will see a greater proportion of patients with chronic HCV infection who have advanced liver disease or other medical complexity because simple HCV patients will have access to treatment with their PCP. This allows the liver specialist to treat the most complicated patients who may require other services including endoscopy or transplant evaluation. The liver specialists, like the PCPs, would have increased support for prior authorization, health promotion, and psychosocial issues, thus allowing more time for clinical care.

4. Under the delivery model, what is the interaction between the hepatologist or other gastroenterologist, primary care physician, other clinical specialists, and care coordinator?

Specialists, PCPs, and care coordinators interact via in-person meetings, emails, and tele-mentoring sessions. This allows for open, multidisciplinary discussion related to treatment issues and specific patients. "Specialists" includes hepatologists, gastroenterologists, infectious disease providers, addiction specialists, psychiatrists, psychologists, social workers, and HIV specialists. Specialists can provide clinical expertise for patients with medical complexity that cannot be managed by the PCP alone. ***Advised by the specialists, the clinicians can work with care coordinators to implement the treatment plans developed by the multi-disciplinary team.***

5. What are the qualifications of the care coordinator?

The education level preferred for care coordinators is a Bachelor's degree with a focus in public health, biology, psychology, and/or education. Applicants must have a minimum of three years of work experience, preferably in a community health role. Coordinators must possess interpersonal and communication skills, as well as knowledge of hepatitis treatment, community resources, and fluency with medical terminology. They must possess knowledge and experience with personal computers; have excellent decision-making skills, the ability to manage multiple projects, time management and organizational skills. They must possess the ability to communicate orally and in writing and, in some cases, be bilingual (English and Spanish).

6. The proposal states, "For NYC specifically, it is unlikely that the 40–50 hepatologists currently practicing could manage and treat all new patients with chronic HCV infection." How would the model address this? In your answer, please describe the following:

    a. Whether the model assumes that hepatologists or other gastroenterologists may not be involved in a patient's care.

    b. Whether there is a specific role for hepatologists or other gastroenterologists in mentoring/oversight of the care delivered.

    c. How much of the care of HCV patients is being currently managed by these specialists and whether the patients these specialists manage differ from those being managed by other providers.

The model will directly address the difficulties with adequate access to curative treatment by expanding the number of clinical sites and providers with the knowledge, skills, and support to manage chronic hepatitis C infection. Without the model, PCPs would rarely treat hepatitis C because of the following barriers: time consuming prior authorizations for medication, lack of clinical support for complicated patients, lack of support from mental health and substance abuse providers, and lack of time for health education. The model provides support to overcome these barriers, thus allowing PCPs to treat HCV infection. This allows more patients to have access to treatment. Liver specialists will still be involved in the treatment of patients with complicated liver disease and to support PCPs as needed.

7. Please provide more detail on how patients would be better managed under the delivery model? In your answer, please describe:

    a. Any agreed-upon clinical protocols, guidelines, or care pathways that participating providers would follow.

    Care coordinators adhere to specific guidelines in their implementation of the INSPIRE delivery model. A table of the protocol is provided at the end of the document (Appendix 2).

    b. How patients would be aided in overcoming obstacles to treatment (e.g., patient cost sharing for medical services and prescription drugs).

    Care managers assist patients in obtaining access to pharmaceutical company-sponsored patient assistance programs if they are eligible. The amount of cost-sharing will depend on the Part D plan that the patient is enrolled in.

c. Whether and how screening according to clinical guidelines is incentivized.

    i. What happens to patients who are screened and are found to have HCV but decline to enroll in the model? Are their outcomes tracked? Is this cohort followed in any way and are they reached back out to at a later date (e.g., after an HCV-related complication) to see if they can be enrolled?

Patients who decline enrollment do not receive treatment using care coordination. Their outcomes are not tracked. Patients who decline enrollment or are lost to follow-up are contacted again by the care coordinators at a later date and encouraged to enroll.

8. Please clarify why the model targets employed physicians at hospital-based outpatient clinics. What are the advantages from a care delivery and/or payment methodology perspective?

The clinical sites we partnered with have strong HCV experience and primary care practices. An advantage of implementing this model in hospital-based outpatient clinics is the ability for care coordinators to make referrals to other diagnostic and treatment services within the same facility. At Montefiore, many of the providers work in community health centers or Federally Qualified Health Centers (FQHCs), which are relatively geographically distant from specialty sites. Patients prefer to access care in their neighborhoods and will not travel to distant specialty sites. In addition, our model requires an investment to set up the care coordination infrastructure. From a care delivery perspective, it is likely that only larger institutions, such as hospital-based outpatient clinics, FQHCs, and community health centers will have the capacity to create and sustain such an initiative.

From a payment model perspective, the division of labor between PCPs and specialists will vary. This variation cannot be predicted in any way that allows transparent separation of bonuses or paybacks by job category. Having shared savings distributed centrally and then passed through to salaried staff based on contributions to the effort fosters institutional flexibility.

9. How is mild to moderate fibrosis determined? Histologic examination?

Well-validated methods for fibrosis assessment have been established. These include invasive (liver biopsy, now rarely used) and non-invasive methods. In our model, any one of these modalities may be used to determine fibrosis. Currently, noninvasive methods to estimate hepatitis fibrosis are most commonly used and these methods include indirect biomarkers, direct biomarkers, and imaging modalities. Examples of indirect biomarkers include the Aspartate Aminotransferase-to-Platelet ratio index (APRI), FIB-4, FibroIndex, Forns Index, HepaScore (or FibroScore), FibroSure / FibroTest-ActiTest. Direct biomarker examples include FIBROSpect II. Imaging modalities include hepatic ultrasound, transient ultrasound elastography (transient elastography and shear wave elastography) and magnetic resonance elastography. If noninvasive methods provide a clear-cut assessment of hepatic fibrosis then further assessment with liver biopsy may not be needed.

10. The proposal highlights the impact of the care delivery intervention on emergency department (ED) visit rates. Please clarify the following:

a. Were ED visits the result of HCV complications or other conditions?

Our data evaluated any/all ED visits and did not look at ED visits specific to HCV complications.

b. Did the reasons for ED visits change post-enrollment?

Further inspection of the Medicaid claims data is ongoing. By our July 19 call with the PRT, we expect to be able to identify diagnoses associated with ED visits via examination of the following CPT codes:

- *99281 (CPT G0380) ED visit for minor severity condition*
- *99282 (CPT G0381) ED visit for low-to-moderate severity condition*
- *99283 (CPT G0382) ED visit for moderate severity condition*
- *99284 (CPT G0383) ED visit for moderate-high severity condition*
- *99285 (CPT G0384) ED visit for high severity condition and pose an immediate significant threat to life or physiologic function*

c. The mechanisms through which ED visits are reduced.

Better and consistent engagement in outpatient care leads to reduced ED utilization.

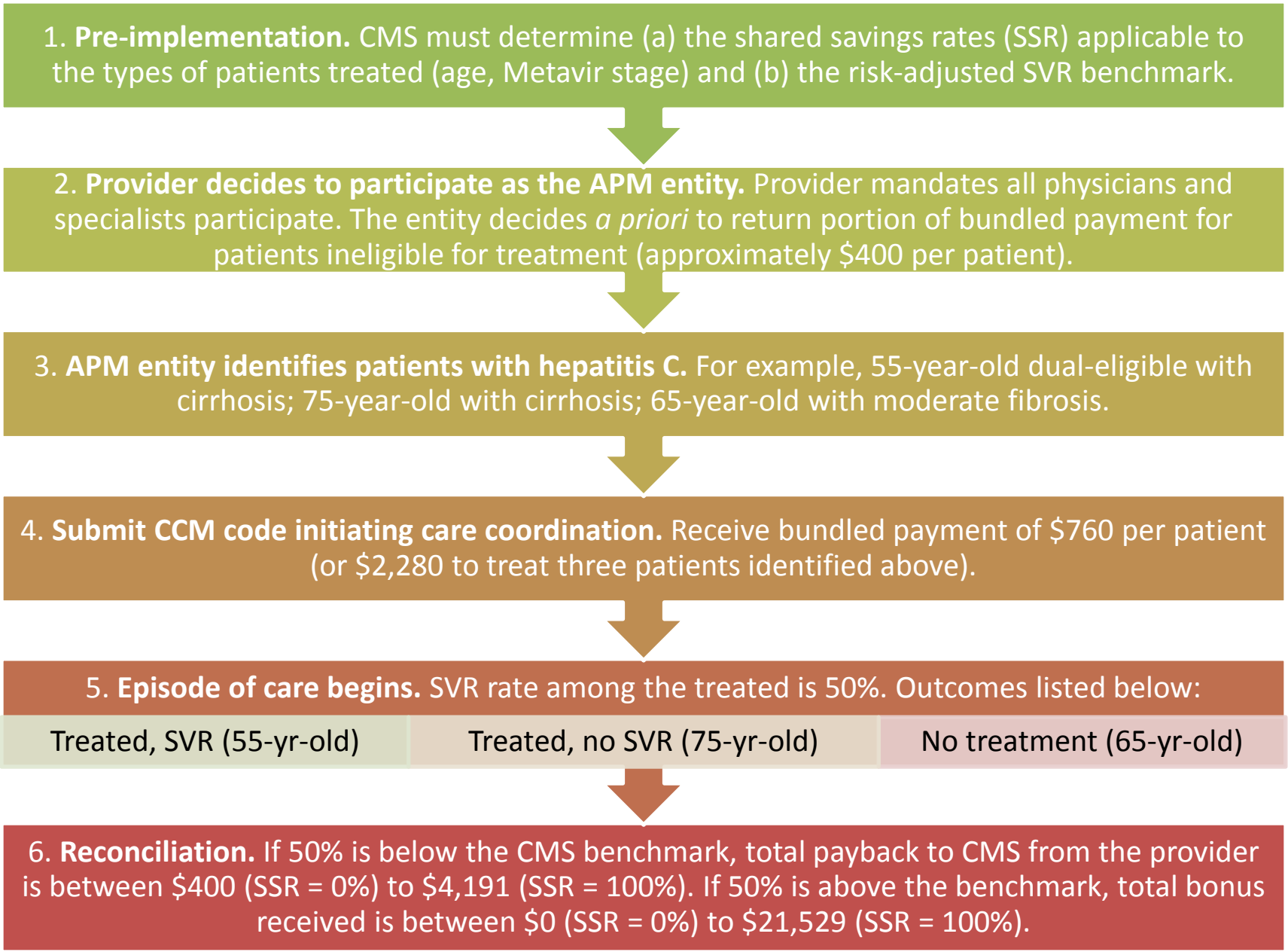
d. Is the delivery model aimed at better management of HCV or better management of a high-need, multi-morbidity patient population (signaled by HCV)?

This delivery model addresses both by offering appropriate management of comorbidities so that HCV treatment can be successful, as demonstrated by achieving SVR. Specifically, the model provides patients with resources to better understand the progression of their disease, available treatments, and the opportunity to engage in treatment and be cured. At the same time, the model provides more intense services to high-need patients with multiple comorbidities to facilitate focus on HCV treatment.

Other

11. From a data standpoint, describe how patients would be tracked and how performance would be monitored. Is the model scalable in this respect?

As part of the care delivery protocol within Project INSPIRE, care coordinators had to "maintain a thorough database of patient progress and treatment outcomes" (see the table in Appendix 2). However, use of Certified Electronic Health Record Technology will be mandatory for the 2018 performance period under MACRA. Therefore, we recommended that coordinators have access to the electronic health record (EHR) system to ensure that appropriate diagnoses (using ICD codes), procedures (using CPT codes) and other notes regarding care coordination services are recorded and accurately reflected in the EHR. This modifiable access allows PCPs and specialists the ability to easily review their patients' progression through the care coordination protocol in relation to their treatment milestones, without having to access a separate database of information.


1. **Pre-implementation.** CMS must determine (a) the shared savings rates (SSR) applicable to the types of patients treated (age, Metavir stage) and (b) the risk-adjusted SVR benchmark.
2. **Provider decides to participate as the APM entity.** Provider mandates all physicians and specialists participate. The entity decides *a priori* to return portion of bundled payment for patients ineligible for treatment (approximately $400 per patient).
3. **APM entity identifies patients with hepatitis C.** For example, 55-year-old dual-eligible with cirrhosis; 75-year-old with cirrhosis; 65-year-old with moderate fibrosis.
4. **Submit CCM code initiating care coordination.** Receive bundled payment of $760 per patient (or $2,280 to treat three patients identified above).
5. **Episode of care begins.** SVR rate among the treated is 50%. Outcomes listed below:
Treated, SVR (55-yr-old)
Treated, no SVR (75-yr-old)
No treatment (65-yr-old)
6. **Reconciliation.** If 50% is below the CMS benchmark, total payback to CMS from the provider is between $400 (SSR = 0%) to $4,191 (SSR = 100%). If 50% is above the benchmark, total bonus received is between $0 (SSR = 0%) to $21,529 (SSR = 100%).

Appendix 2. Care coordination intervention components

Effort	***Protocol***	***Performance Standard***
25%	*Provide hepatitis related education and information to patients.*	*Be readily available and accessible to all patients referred for hepatitis C pre- and post-test counseling and treatment.* *Develop and maintain a learning library for patients that includes multilingual materials.* *Ensure educational materials are readily available in the clinic.*
20%	*Liaison to guide patients who are receiving HCV treatment, including clarifying information and answering questions regarding disease pathology, hepatitis C treatment evaluation, eligibility for treatment, psychiatric consultations, and managing co-morbidity.*	*Maintain a caseload of 100 active patients receiving treatment.*
15%	*Track interventions and outcomes.*	*Maintain a thorough database of patient progress and treatment outcomes. This database should be accurate and up-to-date.*
15%	*Assist patients in arriving on time and prepared for scheduled appointments.*	*Measured by no-show rates; number of patients arriving unprepared.*
10%	*Recruit, train, and lead a group of hepatitis C peer educators.*	*Peer educators are recruited, appropriately trained, and effectively directed to participate in Project INSPIRE activities.*
5%	*Develop relationships with providers, manage interventions and outcomes.*	*Facilitate interactions between healthcare staff and providers.* *Educate providers as to the patient educator's role in order to maximize the efficiency of care delivery.*
5%	*Build relationships with other patient educators.*	*Establish contacts and maintain relationships with them via weekly meeting, email, and phone contact.*

November 2, 2017

Thank you for your inquiry regarding our proposed use of chronic care management (CCM) codes in the Project INSPIRE alternative advanced payment model (APM) for treatment of hepatitis C (HCV). We did consider the CCM codes as a way to initiate the one-time, bundled payment of $760 for the episode of care. However, these codes were newly available when we submitted our proposal, and we have since noted some significant limitations with them that could potentially preclude patient enrollment if our APM were recommended.

One limitation is that Medicare does not allow the CCM service codes to be billed during the same service period as home health care supervision (HCPCS G0181) or ESRD services (CPT 90951-90970). A substantial portion of our participants were eligible for one or more of these services. Thus, adopting a CCM code may be too restrictive for full-scale APM enrollment. Furthermore, the documentation requirements are specific and can be too demanding (especially for specialists) for the time-limited nature of our intervention, which is largely focused on cure as opposed to long-term disease management. Finally, our intervention occurred in hospital-based outpatient settings; we had limited experience with CCM codes, which are intended for community-based physician practice settings.

In looking for codes that would support an episode of care we have considered the Oncology Care Model and other similar models. We are starting to explore the Evaluation and Management (E&M) codes, including G0463 (hospital outpatient clinic visit for assessment and management of a patient) for payment under the outpatient prospective payment system (OPPS) for outpatient hospital clinic visits. The 2018 monthly payment rate for this service is $109.58.[1] However, this amount is insufficient to cover the most important components of our phase I intervention: the weighted per-month average is $178, 60% higher than what is currently reimbursed.

This research has led us to consider use of the less restrictive G0463 E&M code with a type of bill (TOB) coding modification. In particular, we think the introduction of a new modifier for the third digit of this code (as opposed to a new CPT code entirely) could be used to indicate our one-time only claim. Institutional providers could then submit on an outpatient claim (UB-04/CMS-1450) using the above mentioned E&M code with HCV listed as the primary diagnosis with a TOB modifier indicating a one-time claim. This billing mechanism would initiate the full bundled payment of $760 and thus pay for the episode of care coordination services. Once the bundled payment is given using this billing framework, it will be easy to identify and track APM enrollees so that payment reconciliation can be made.

We hope this response is helpful and would appreciate any recommendation or guidance that you might have. Please let us know if you have any additional questions and we look forward to seeing and responding to the report from the Preliminary Review Team as soon as that is available.

Best regards,

Project INSPIRE

[1] See 2018 NPRM OPPS Claims Accounting

December 8, 2017

Physician-Focused Payment Model Technical Advisory Committee
C/o U.S. DHHS Asst. Secretary for Planning and Evaluation
Office of Health Policy
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Response to PRT – [Multi-provider, bundled episode-of-care payment model for treatment of chronic hepatitis C virus (HCV)]

Dear Committee Members,

On behalf of Project INSPIRE and the submitting organization, the New York City Department of Health and Mental Hygiene (DOHMH), we are writing to express our thanks for the Preliminary Review Team (PRT) Report dated November 15, 2017. The PRT report articulates key issues that we need to clarify about the INSPIRE model and we appreciate the thorough review.

To elaborate on our previous submission, Project INSPIRE is a collaboration between the DOHMH and two clinical partners that aims to deliver an innovative model of care and treatment of hepatitis C (HCV) for patients with multiple co-morbidities. The core of this model is the provision of an integrated care approach led by a liver disease specialist. The specialist meets regularly with HCV "champions" from primary care, addiction medicine, and infectious disease in-person or via webinar and teleconferences. These tele-mentoring forums allow for HCV care to be expanded into clinics that have not traditionally treated HCV. This care delivery model creates opportunities for primary care physicians (PCPs) to learn how to treat HCV while remaining connected to a liver disease expert to support, mentor and accept referrals for more complex patients with advanced liver disease.

As the 2017 Report for the National Academies of Science, Engineering and Medicine states, unrestricted treatment of hepatitis C is necessary to eliminate the disease as a public health problem by 2030[i]. Given the highly effective treatments available and the large burden of HCV in the United States—2.7 million with chronic hepatitis C[ii]— we feel strongly that now is the time to move forward on this proposal. Furthermore, the model supports HCV elimination efforts across the country by incentivizing providers to screen and treat those at greatest risk of infection, including 'Baby Boomers' (those born between 1945-1965), a sizable portion of the Medicare population.

PROJECT INSPIRE
coordinating HEP C care

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Weill Cornell Medical College
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healthfirst
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Visiting Nurse Service of New York VNSNY CHOICE Health Plans
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Mount Sinai
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The proposed INSPIRE advanced alternative payment model (APM) is designed to support a more efficient and effective approach to hepatitis C care and treatment by allowing specialists to work at the highest level of their training. An interdisciplinary team of physicians forms the core of the intervention. The team is led by specialists who provide mentorship and training to non-specialists about treatment of HCV and comorbidities. Trainings are administered via weekly tele-mentoring, which also enables rapid access to specialist care for persons with advanced liver disease. To manage prevalent co-morbidities in this complex population clinical providers work with care coordinators to address these conditions throughout HCV care. Care coordinators serve in an important supportive capacity that enhances the physicians' ability to treat as many patients as possible by addressing barriers that prevent patients from progressing through care. The bundled payment would support tele-mentoring and care coordination, both critical elements to achieving cure — sustained virologic response (SVR) in a population with complex needs. The potential bonuses reflected in the APM will reward specialists and physicians for continued participation in this collaborative, more efficient approach to care.

Additional evaluation of INSPIRE outcomes is now available, including results on short-term cost savings, derivation of a risk-adjusted SVR benchmark, and a simulation of the payment model with two-sided risk. The complete methods and results from this evaluation are included as an appendix to this response. Below, we use the results from this additional evaluation to briefly address the four criteria that the PRT found our proposal did not meet:

Criterion #1 Scope

a. **Risk adjustment for patient case mix**: The SVR quality outcome has been risk-adjusted to account for patients with mental health diagnosis and those treated in primary care clinics. This downward adjustment indicates an SVR benchmark rate of 80%. However, the model is flexible to accommodate further risk adjustment that accounts for a more (or less) complicated patient mix.
b. **Reimbursement using chronic care management (CCM) codes**: Reimbursement under the Physician Fee Schedule and the Outpatient Prospective Payment System does not support the INSPIRE intervention as designed, namely by lacking support for tele-mentoring to provide the team-based training necessary to expand HCV treatment into primary care settings. Providers would lose an average of $98 per patient in phase I. To avoid this loss, our recommendation is the bundled payment approach. In addition to care coordination services, our bundled payment design is intended to support this tele-mentoring, which is not otherwise included as a billable service within the CMS' definition of telehealth.

Criterion #3 Payment Methodology

c. **Precedent for bonuses**: We recognize the concern that a shared savings model based on future medical cost savings associated with this curative treatment requires projecting benefits in a manner that may not have a clear precedent. However, such an approach to estimating future savings is implicit in Medicare's value-based insurance design and Part D enhanced medication therapy management models. Furthermore, these savings calculations reflect the major recent advances in pharmacotherapy for HCV; achieving

SVR slows progression of disease and liver complications by more than 80%[iii,iv], with some patients even experiencing regression of liver cirrhosis after therapy[v,vi] .
In our proposal, the estimate of future cost savings is based only on the presence of cirrhosis and age; these data are easily extractable from a claim form. The table of savings we have provided for each disease stage and age category is transparent and based on published data sources. The savings are calculated using only medical costs for HCV-related disease avoided due to cure and do not attribute any economic value to the life years gained; they are not 'lifetime savings,' as expressed by the PRT. To ensure that the savings estimates are conservative, they have also been revised downward to account for the fact that additional years of life saved do result in additional medical care costs to Medicare for other diseases.

d. **Risk adjustment of bundled payment**: We have conducted further cost analysis for the INSPIRE intervention and identified that a pared down version of the INSPIRE model costs $670 per episode. This condensed version excludes some health promotion, appointment reminder, and follow-up activities, which may not be needed for less complex patients. As with the original bundle, these estimates can be geographically adjusted to reflect local economic conditions.
e. **Patient eligibility and attribution**: All Medicare beneficiaries would be eligible. Dual eligible beneficiaries could receive the full bundled payment of $760 and the full set of INSPIRE services. A reduced amount of approximately $670 could be available for non-dual eligible patients. This approach reduces the reliance on only 'physician-determined attribution,' a concern raised by the PRT and, could be implemented by using an existing Evaluation & Management code with a type of bill coding modification(s) to indicate into which bundle a beneficiary would be enrolled for reconciliation purposes.

Criterion #6 Ability to be evaluated

f. **Shared savings**: We have proposed a two-sided risk model. However, this payment model is flexible enough to implement with conservative upside risk only to gauge overall cost-neutrality of the intervention to Medicare in initial implementation efforts.
g. **APM validation**: The PRT noted that validating our proposed APM would take a lifetime perspective. We do not think this is necessary. The shared savings and payback rates can be assigned (and changed) by CMS. Furthermore these rates can be designated such that Medicare recoups any distributed bonuses within a one- or two-year time horizon. This approach allows for model validation within a timeframe that is comparable to other implemented or proposed APMs.
h. **Recommendations on reconciliation**: As noted in our response to the PRT (dated July 10, 2017), we advise that initial reconciliation occurs starting at the end of the second year in which the APM is implemented (at 24 months). At that time, patients enrolled in either INSPIRE bundle within the first 14 months would be used in the calculation of the SVR rate. One bonus or payback amount will be established for each facility participating in the APM, based on comparison to the benchmark and an evaluation of the savings/payback rates set by CMS. Subsequent reconciliations should occur annually.

Criterion #7 Integration and care coordination

i. **Comorbidities**: Care coordinators provide care navigation, medication adherence support, health promotion sessions, appointment reminders and referrals for support services. Care coordinators foster better provider communication, reduce missed appointments and loss to follow-up, and are directly associated with improved clinical outcomes like cure. The health promotion modules administered by the care coordinators address health behavior change related to alcohol and substance abuse, diet, exercise, and liver health. Furthermore, care coordinators offer support and linkage to care for comorbidities, such as HIV, diabetes and kidney disease. This aspect of the intervention focused on co-morbidities is expected to have the beneficial impact on reduced utilization of the emergency department for primary care and averting the need for future inpatient admissions.

j. **Continuity of care**: The team of clinical providers includes primary care, addiction medicine, infectious disease, and liver specialists working together to provide care. The inclusion of tele-mentoring and inter-disciplinary case conferencing creates a team approach between primary care and hepatology, allowing prompt identification and referral of complex patients with advanced liver disease to liver disease specialists. The tele-mentoring provided as part of this bundled design is a collaborative approach to training PCPs, intended to improve their ability to treat chronic diseases with the support of care coordinators. The call for specialist support of PCPs has been a recurring theme in the U.S. healthcare system for years. The INSPIRE payment model incorporates this support, while offering the perfect opportunity to leverage the application of tele-mentoring to multi-morbidity more generally by including other specialists as trainers.

Thank you for the opportunity to provide additional information to the PTAC. We look forward to discussing this proposal with you in detail during the full PTAC meeting on Monday, December 18, 2017.

Best regards,

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Appendix

Evaluation of Project INSPIRE: Methods and Results

As indicated in our original proposal, we have conducted extensive evaluation of the proposed Project INSPIRE alternative payment model (APM). The additional analyses include the following:

(a) A Medicare cost savings analysis;
(b) Bayesian analysis to identify the risk-adjusted SVR rate;
(c) and a cohort simulation of the proposed APM

Below, we further described these methodologies and the results. We believe the PTAC will find these analyses very informative to their ongoing evaluation and in-person deliberations of the model's merits as a value-based alternative to supporting care coordination for treatment of hepatitis C.

Medicare cost savings analysis

Objective: This evaluation is a longitudinal analysis of the cost savings associated with the INSPIRE intervention. We considered how Medicare payments were potentially impacted for beneficiaries who received INSPIRE services. Our goal with this approach was to identify whether the short-term cost savings would cover the bundled payment, which we have identified as $760 per episode of care.

Methods: This analytical approach first consisted of identifying the episode of care for all Medicare enrollees within INSPIRE. The episode of care was defined as the enrollment date through the estimated date of SVR for patients completing treatment. The estimated date of SVR was calculated as 90 days post-treatment completion for SVR at 12 weeks or 180 days post-treatment completion for SVR at 24 weeks. For patients not initiating treatment, the episode of care was defined as the enrollment date through the recorded discharge date.

We next identified all monthly payments from the inpatient, outpatient, carrier and skilled nursing facility claims files. Eligibility for Medicare was assessed from the Master Beneficiary Summary File. We specified inclusion criteria that beneficiaries had to be eligible for both Part A and Part B and meet a minimum eligibility duration of six continuous months before (pre-) and after (post-) INSPIRE enrollment. Part D data were not available for 2016 and thus Part D claims were not included. Dual eligibility was assessed and classified using the Medicare dual status indicator. Enrollees with dual eligibility were identified as (1) qualified Medicare beneficiaries with full Medicaid coverage (including prescription), (2) specified low-income Medicare beneficiaries with full Medicaid, or (3) other dual eligible with full Medicaid coverage. Where possible, additional analyses considered a longer post-intervention period, constrained to claims through December 2016.

We used fixed effects panel regressions with autoregressive error structure to predict Medicare payments in the pre- and post-INSPIRE periods. A fixed-effects, parametric regression model appropriate to panel data was fit using the within regression estimator.[1] The fixed-effects model is

$$y_{it}^{s} = a + x_{1,it}^{s}\beta_1^{s} + x_{2,it}^{s}\beta_2^{s} + v_i + e_{it} \qquad [1]$$

where y_{it}^{s} represents the total fee-for-service payments for enrollee *i* (*i* = 1, …, *n*) in month *t* (*t* = 0 denotes the initial pre-intervention month) of enrollment period *s* (where *s* = 1 for pre-intervention, *s* = 2 for the intervention, and *s* = 3 for post-intervention period), $x_{1,it}^{s}$ denotes the month of observation, $x_{2,it}^{s}$ refers to the total number of paid claims per month, v_i denotes the fixed effect, and e_{it} is the error.

The derivation of the fixed effects model is shown next. It follows from Eq. [1] that

$$\overline{y_i} = a + \overline{x_{1,i}}\beta_1 + \overline{x_{2,i}}\beta_2 + v_i + \overline{e_i} \qquad [2]$$

where $\overline{y_i}$, $\overline{x_{1,i}}$, $\overline{x_{2,i}}$, $\overline{w_i}$ and $\overline{e_i}$ are the averages of y_{it}, $x_{1,it}$, $x_{2,it}$, and e_{it} within *i*, that is for each individual enrollee. Subtracting Eq. [2] from Eq. [1], we obtain

$$y_{it} - \overline{y_i} = \left(x_{1,it} - \overline{x_{1,i}}\right)\beta_1 + \left(x_{2,it} - \overline{x_{2,i}}\right)\beta_2 + \left(e_{it} - \overline{e_i}\right) \qquad [3]$$

As written, $\hat{\beta}_1$ and $\hat{\beta}_2$ are the fixed-effects estimators for the regression model. From Eq. [1], it also follows that

$$\overline{\overline{y}} = a + \overline{\overline{x_1}}\beta_1 + \overline{\overline{w_2}}\beta_2 + \bar{v} + \bar{\bar{e}} \qquad [4]$$

where $\overline{\overline{y}}$, $\overline{\overline{x_1}}$, $\overline{\overline{x_2}}$, $\overline{\overline{w}}$, $\bar{v}$ and $\bar{\bar{e}}$ are the grand averages of y_{it}, $x_{1,it}$, $x_{2,it}$, v_i and e_{it}. Summing Eq. [3] and Eq. [4], we obtain the following:

$$y_{it} - \overline{y_i} + \overline{\overline{y}} = a + \left(x_{1,it} - \overline{x_{1,i}} + \overline{\overline{x}}\right)\beta_1 + \left(x_{2,it} - \overline{x_{2,i}} + \overline{\overline{x}}\right)\beta_2 + \left(e_{it} - \overline{e_i} + \bar{v} + \bar{\bar{e}}\right). \qquad [5]$$

The left-side variable is the enrollee-month observation minus the within-enrollee mean and the grand mean added. The covariates on the right side are similarly defined. Eq. [5] was estimated with clustered standard errors.

Using the Eq. [5], three scenarios were analyzed. These scenarios are identified in Figure 1.

[1] Greene, W. H. (2000), Econometric Analysis, 4th Edition, Upper Saddle River, NJ: Prentice Hall.

Figure 1. Scenarios used for cost savings analysis

Scenario #1	Scenario #2	Scenario #3
Predict all PMPM costs using only pre-intervention months (i.e., as if INSPIRE never happened)	Scenario #1, but predict intervention and post-intervention costs using INSPIRE months	Scenario #2, but predict post-intervention PMPM costs using post-intervention months

Scenario #1 modeled the per member per month (PMPM) Medicare payments using only data from the pre-intervention period. We then used this abbreviated model to predict the payment outcomes for both the intervention and the post-intervention periods. This scenario describes the payment outcomes under the assumption that the INSPIRE intervention never occurred. Scenario #2 expanded Scenario #1 by including the intervention period. In this scenario, we used payment data from the intervention period to predict post-intervention payment outcomes. This scenario assumed the impact of intervention after discharge or the SVR date was equivalent to the impact of the intervention itself. Scenario #3 removed this assumption by allowing for potential waning of the intervention's effects.

Cost savings were defined as the difference in PMPM payments between Scenario #3 and Scenario #1 and aggregated over all relevant months.

Results: We identified 143 Medicare beneficiaries that met our inclusion criteria, covering 2,101 months of pre- and post-intervention claims data. This set of beneficiaries had a median INSPIRE enrollment of seven months. For only 19 months (<1%) were these 143 INSPIRE enrollees dual-eligible according to our definition. For these 143 beneficiaries, the total estimated cost of the intervention using the proposed $760 bundled payment was $108,680.

Figure 2 shows the results of our regressions models. Using six months pre- and post-intervention data, savings are almost 40% of the care coordination investment. However, using all available months of post-intervention claims (2,694 months), however, suggests sufficient savings may be achieved. The total savings were $108,706.

Figure 2. Cost savings results by scenario

	Scenario #1	Scenario #3	Cost savings
6 months pre/post	$629,761	$589,601	$40,160
6 months pre/post + additional months	$900,303	$791,597	$108,706

Conclusions: There is evidence to suggest that within one year after the intervention, Medicare will be able to re-coup the investment.

Bayesian analysis to identify the risk-adjusted SVR rate

Objective: Our proposed APM is a performance-based, facility-specific model. Facilities will submit the bundled payment request as well as receive bonus or engage in payback based on achieving a sufficiently high benchmark SVR rate. To make this work, we pursued Bayesian analysis techniques to generate an optimal risk-adjusted model that accomplishes two objectives: (1) identifies an SVR benchmark rate on which bonuses or paybacks would be based, and (2) predicts a SVR probability distribution for each clinic in INSPIRE. The results of the latter objective serve as inputs for the third analysis, in which we fully simulate the APM.

Methods: The Bayesian analysis consists of a hierarchical model with case mix adjustment. The case mix model is how we risk adjust for variability in SVR outcomes at the individual level. The data generating process that updates our likelihood of observing an SVR outcome is a multivariable, mixed effects logistic model accommodating a random intercept.[2]
This methodology mirrors that of Ten Have & Localio (1999).[3] We assume I clusters, indexed as clinics $i = 1, 2, \ldots, I$ participating in Project INSPIRE, each of which consists of J_i patient observations, indexed by $j = 1, 2, \ldots, J_i$. We let Y_{ij} be the binary SVR response for the j^{th} observation of the i^{th} cluster: $Y_{ij} = 1$ if observation j of cluster i achieves SVR, and 0 otherwise for all i and j. We also define z_{ij} to be the observed covariate vector, including the intercept and within- and between-cluster covariates, corresponding to the fixed effects for the j^{th} observation of the i^{th} cluster. We consider two risk adjustment covariates that accounts for both baseline patient-level health attributes and clinic-level characteristics: whether the patient had at least one mental health condition (i.e., the within-cluster covariate), and whether the clinic is a specialist office versus primary care provider (i.e., the between-cluster covariate). In the future, other adjustments would likely need to be added.

We let π_{ij} denote the probability of $Y_{ij} = 1$ and τ_i identify the i^{th} cluster random effect. The variance of τ_i is a measure of how much the clinics vary in the SVR outcome. The conditional distribution for Y_{ij} is Bernoulli(π_{ij}), with the following logistic model specified for π_{ij}:

$$\log\left(\frac{\pi_{ij}}{1-\pi_{ij}}\right) = \sum \tau_{0i} + \beta z_{ij}, \qquad [6]$$

where β is a vector of an intercept parameter and log odds ratios corresponding to unit changes in the elements of the covariate vector z_{ij} among observations within a cluster, τ_{0i} ($i = 1, 2, \ldots, I$) is a standard normal random variable with designated mean and variance, $\sum$ is the variance matrix, consisting of one nonnegative element σ_0. The product, $\sigma_0\tau_{0i}$, represents the departure in

[2] Note that a fixed effects model (such as that used by CMS to profile facilities in their Dialysis Facility Reports) would contain an estimate for each clinic using dummy variables. The purpose of their more complex model is to adjust for the potential correlations between unobserved and observed covariates.
[3] Ten Have, T. R., & Localio, A. R. (1999). Empirical Bayes estimation of random effects parameters in mixed effects logistic regression models. *Biometrics*, *55*(4), 1022-1029.

the clinic-level odds of SVR from the average for all clinics in Project INSPIRE. In this basic random effects model with an intercept-only probability distribution, the unobserved/omitted covariates in z_{ij} are assumed to be uncorrelated with the included covariates. Equation [6] assumes conditional independence among the elements of $\mathbf{Y}_i = (Y_{i1,\ldots,}Y_{iJ_i})$, given τ_i.

The posterior distribution summarizes the information in the data, *x*, together with the information in the prior distribution, $f(\theta)$. It summarizes what is known about the parameter of interest θ after the data are collected. To obtain the posterior belief distribution, $f(\theta|x)$, using Bayes Theorem, we multiply the prior belief with a likelihood function. Notationally, this is represented as the following:

$$f(\theta|x) \propto \frac{f(x|\theta) \times f(\theta)}{\int f(x|\theta) \times f(\theta) d\theta}$$

This likelihood of observing the INSPIRE data given θ is multiplied to our probability density function of the prior distribution to get an overall posterior distribution of the SVR outcome:

$$f(\theta|x) \propto \underbrace{\theta^x(1-\theta)^{(N-x)}}_{observe} \times \underbrace{\theta^{\alpha-1} \cdot (1-\theta)^{\beta-1}}_{prior\ belief}$$

We present results using a Bayesian approach based on 3,000 iterations after a 3,000 iteration burn-in period. The Bayesian approach was implemented assuming the following priors: (1) a vague inverse gamma hyper-prior for σ_0 with mean of 0.001 and variance of 0.001, (2) vague independent univariate normal priors for the fixed effects parameters, each with mean 0 and variance 100, (3) informative, independent univariate normal non-conjugate beta prior for the intercept with shape parameters $\alpha = 4100$ and $\beta = 400$,[4] and (4) a normal prior for the random effects parameter τ_{0i} with mean drawn from the set [0.60, 0.99] and variance σ_0^2. These priors reflect a mean probability of SVR to be 0.91, which corresponds to real-life SVR outcomes using the new direct acting antiviral therapies.[5]

We identify the prior (i.e., the mean value of τ_{0i}) that maximizes the log marginal likelihood that our model represents the INSPIRE intervention. Bayes Factor was used to compare models with difference mean values of τ_{0i}.[6] Additionally, Gelman-Rubin statistic was used to assess convergence of the final model.[7] Graphical summaries of convergence included trace plots, autocorrelation plots, and various distributional plots. The outputs of these analyses include (1) a

[4] Note that $\mu = {}^{\alpha}/_{(\alpha+\beta)}$ and $\sigma = {}^{\alpha\beta}/_{(\alpha+\beta)^2(\alpha+\beta+1)}$.

[5] Su, F., Beste, L. A., Green, P. K., Berry, K., & Ioannou, G. N. (2017). Direct-acting antivirals are effective for chronic hepatitis C treatment in elderly patients: a real-world study of 17,487 patients. *European journal of gastroenterology & hepatology*, *29*(6), 686-693.

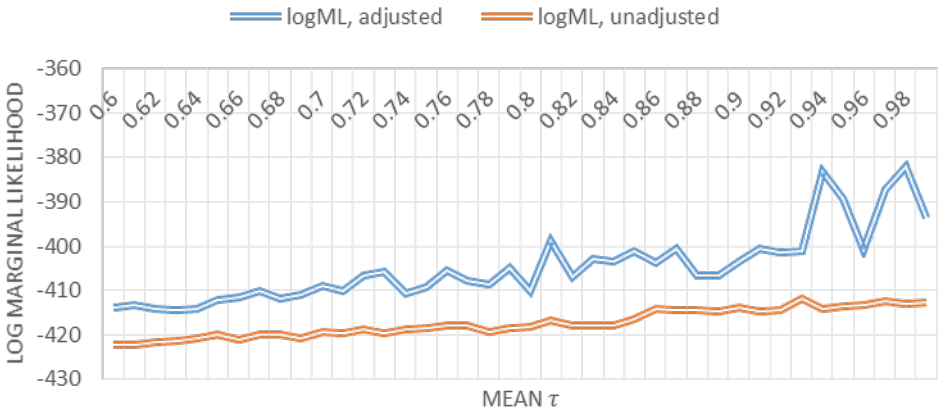
[6] Kass, R. E., & Raftery, A. E. (1995). Bayes factors. *Journal of the American statistical association*, *90*(430), 773-795.

[7] Gelman, A., and D. B. Rubin. 1992. Inference from Iterative Simulation Using Multiple Sequences. *Statistical Science 7*: 457–511.

recommendation for the risk-adjusted SVR benchmark, and (2) a series of posterior SVR distributions for all clinics associated with Project INSPIRE to be used in the cohort simulation.

Results: We first present the results of the risk-adjusted SVR benchmark. Figure 3 displays the log marginal likelihood values for the random effects parameter τ_{0i} with mean drawn from the set [0.60, 0.99]. Models without risk adjustment are indicated by the orange line; models with risk adjusted are indicated by the blue line. The SVR probability with the largest likelihood was 0.81; this represents the optimal Bayesian model. This SVR probability was adjusted for the presence of a mental health condition and also being treated within a non-specialist clinic. All adjusted models (blue) fit the data significantly better for every specified prior for the random effect, as demonstrated by the larger likelihood values**, thereby demonstrating the importance of risk adjustment**. For enrollees without a mental health condition who were treated in specialist clinics, the SVR rate matched published studies (θ = 0.90). Our Bayesian model therefore indicates downward adjustment in the benchmark SVR rate (90% to ~80%) to accommodate for more complex patients treated in primary care settings. However, further risk adjustment should provide additional clarification on the most appropriate benchmark for APM implementation.

Figure 3. **Risk-adjusted** SVR benchmark results. Note the convergence issues for mean values of $\tau > 0.93$, as there were no INSPIRE facilities with SVR rates above this threshold.



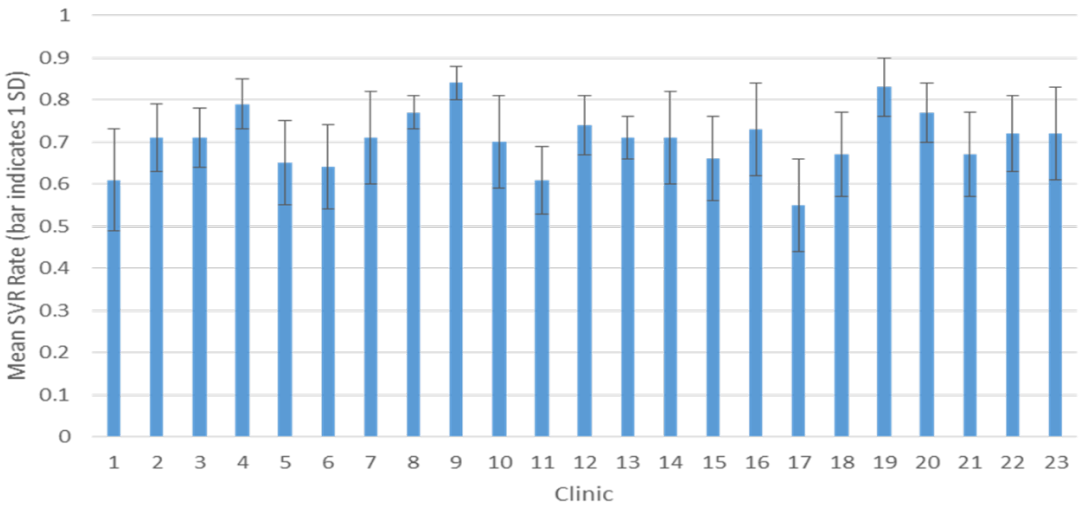
We next present the post-estimation results of the posterior distributions for the SVR rate for all clinics in INSPIRE. These distributions were generated using the optimal Bayesian model. Note the larger bars indicate clinics treating fewer patients. Clinics 8 and 9 treated one-third of all INSPIRE enrollees. These distributions were applied to the cohort simulation.

Conclusions: For INSPIRE APM implementation, a risk-adjusted SVR benchmark of 0.81 is recommended. However, additional risk adjustment may modify this probability.

Cohort simulation of the proposed APM

Objective: The final analysis included a payment model simulation of the payment outcomes for the Medicare beneficiaries in INSPIRE. As described above, we incorporated each facility's risk-adjusted SVR rate distribution from the Bayesian analysis (see Figure 4) into the simulation. We then assessed the complete payment outcomes, factoring in the bundled payment and potential bonuses and paybacks under a specified set of parameters, including the benchmark SVR rate of 0.81 and shared savings percentage (varied from 2% to 10%). We aggregated these outcomes across hospital site to determine the average episode of care payment.

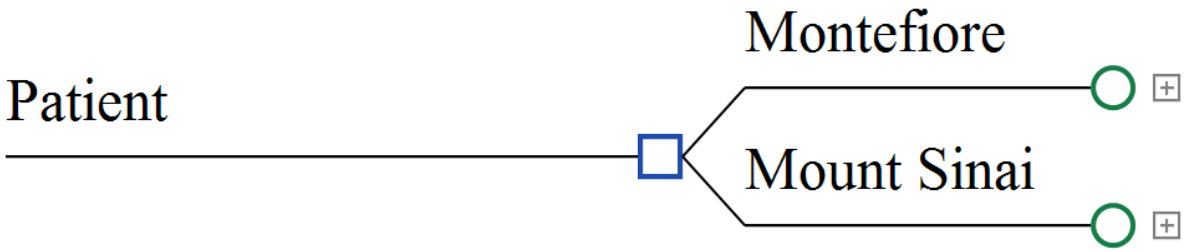
Figure 4. Posterior SVR distributions for 23 clinics associated with Project INSPIRE.



Methods: Decision analysis is an objective, explicit method that uses diagrams to represent specific decision problems. Decision analysis is used when the outcomes of decisions are not certain, but the probabilities of different outcomes are known. It is a method of structuring different treatment options in order to calculate which of the strategies is best in light of our probability set. Figure 5 identifies the decision tree.

In the current INSPIRE APM simulation, the "trees" extending from each hospital node comprise the clinics of the provider. From those nodes, we insert branches identifying the age categories and cirrhotic status of all patients in the INSPIRE cohort. Also included are the probabilities associated with each of these characteristics. The final node for each path through the tree describes the associated clinic-specific SVR rates and the costs associated with either achieving or not achieving the SVR outcome.

Figure 5. Cohort simulation model for the INSPIRE APM (Note the hospital partners were Montefiore Medical Center and Mount Sinai Health System)



All risk-related reconciliations are made in comparison to the SVR benchmark rate. When the risk-adjusted benchmark SVR rate (identified in the Bayesian analysis) is achieved at a clinic site, the clinic receives a bonus payment for every patient with a documented SVR. This bonus payment is calculated as the bonus SSR multiplied by the estimated total costs of care averted over the expected life years gained as a result of SVR. The estimated total costs of care are identified using the patient's age and Metavir stage (see Table 2).

There is no other adjustment made to the reimbursement total for patients not achieving SVR within clinics that have otherwise achieved the benchmark rate. When the risk-adjusted SVR benchmark is not achieved, the clinic must engage in payback for every patient without a documented SVR. The payback to Medicare is calculated as the payback SSR multiplied by the estimated total costs of care not averted over the additional life years not acquired. Note in our analyses, we only consider scenarios where the bonus SSR equals the payback SSR. This financing design is intended to promote the importance of SVR documentation as a way to reduce the uncertainty to Medicare solvency with respect to the future cost burden of liver disease.

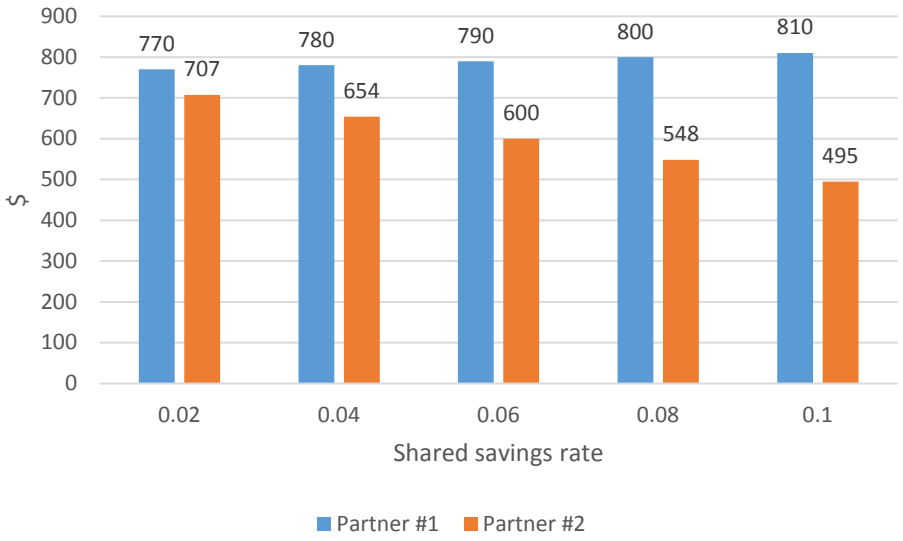
Achieving SVR slows progression and liver complications by more than 90%.[8,9] In addition, some patients experience regression of liver fibrosis after therapy.[10] However, upon limited-scale testing of the INSPIRE APM, CMS may wish to apply probabilities to the bonus table calculations that reflect a more nuanced view of regression likelihood. We do not advocate this approach, as it reduces the APM's transparency and could, in fact, lead to adverse patient selection by providers.

Results: Figure 5 shows the simulated outcomes for the INSPIRE APM over a range of shared savings rate (SSR) possibilities. Notably the rates were equivalent for bonuses and paybacks. That is, at an SSR = 0.02, on average hospital partner #1 received the entire bundled payment

[8] Bruno, S., Zuin, M., Crosignani, A., Rossi, S., Zadra, F., Roffi, L., ... & Almasio, P. L. (2009). Predicting mortality risk in patients with compensated HCV-induced cirrhosis: a long-term prospective study. *The American journal of gastroenterology*, *104*(5), 1147-1158.
[9] Hagan, L. M., Yang, Z., Ehteshami, M., & Schinazi, R. F. (2013). All-oral, interferon-free treatment for chronic hepatitis C: cost-effectiveness analyses. *Journal of viral hepatitis*, *20*(12), 847-857.
[10] D'ambrosio, R., Aghemo, A., Rumi, M. G., Ronchi, G., Donato, M. F., Paradis, V., ... & Bedossa, P. (2012). A morphometric and immunohistochemical study to assess the benefit of a sustained virological response in hepatitis C virus patients with cirrhosis. *Hepatology*, *56*(2), 532-543.

after adjusting for performance with respect to the SVR benchmark of 0.81. On the other hand, hospital partner #2 received 93% of the $760. As we increase the SSR, the disparity between the providers grows.

Figure 5. Average episode of care reimbursements over range of shared savings and payback rates, by hospital partner (using 0.81 as the SVR benchmark)



It is straightforward to adjust the SSRs by altering the set of values that would apply to bonuses and paybacks. For example, a SSR for potential bonuses of 2%, but lower for paybacks (e.g., 1%). The results of these additional simulations are not presented here. The choice of SSR makes the INSPIRE APM flexible and well-poised to accommodate changes in hepatitis C prevalence based on nationwide elimination efforts currently taking place.

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[i] National Academies of Sciences, Engineering, and Medicine. A national strategy for the elimination of hepatitis B and C: Phase two report. National Academies Press; 2017 Jun 30.

[ii] Denniston, M. M., Jiles, R. B., Drobeniuc, J., Klevens, R. M., Ward, J. W., McQuillan, G. M., & Holmberg, S. D. (2014). Chronic hepatitis C virus infection in the United States, national health and nutrition examination survey 2003 to 2010. *Annals of internal medicine*, *160*(5), 293-300.

[iii] Ng, V., & Saab, S. (2011). Effects of a sustained virologic response on outcomes of patients with chronic hepatitis C. *Clinical Gastroenterology and Hepatology*, *9*(11), 923-930.

[iv] Morgan, R. L., Baack, B., Smith, B. D., Yartel, A., Pitasi, M., & Falck-Ytter, Y. (2013). Eradication of Hepatitis C Virus Infection and the Development of Hepatocellular CarcinomaA Meta-analysis of Observational Studies. *Annals of internal medicine*, *158*(5_Part_1), 329-337.

[v] Pol, S., Carnot, F., Nalpas, B., Lagneau, J. L., Fontaine, H., Serpaggi, J., ... & Bréchot, C. (2004). Reversibility of hepatitis C virus-related cirrhosis. *Human pathology*, *35*(1), 107-112.

[vi] Serpaggi, J., Carnot, F., Nalpas, B., Canioni, D., Guéchot, J., Lebray, P., ... & Pol, S. (2006). Direct and indirect evidence for the reversibility of cirrhosis. *Human pathology*, *37*(12), 1519-1526.

PHYSICIAN-FOCUSED PAYMENT MODEL TECHNICAL ADVISORY COMMITTEE (PTAC)

PRELIMINARY REVIEW TEAM (PRT)

CONFERENCE CALL

Call with the Proposal Submitter/
New York City Department of Health and Mental Hygiene (NYC DOHMH)

Wednesday, July 19, 2017
Noon

PRESENT:

ROBERT BERENSON, MD, PTAC Committee Member
JEFFREY BAILET, MD, PTAC Committee Chair
GRACE TERRELL, MD, MMM, PTAC Committee Member

MARY ELLEN STAHLMAN, PTAC Staff Director, Office of Assistant Secretary for Planning and Evaluation (ASPE)
SARAH SELENICH, MPP, ASPE
JANET PAGAN-SUTTON, PhD, Social & Scientific Systems, Inc. (SSS)

MARIE BRESNAHAN, MPH, NYC DOHMH
KYLE FLUEGGE, PhD, MPH, NYC DOHMH
ANN WINTERS, MD, Project INSPIRE, NYC DOHMH
RASHI KUMAR, MUP, Healthfirst
ALAIN LITWIN, MD, Montefiore Medical Center
SHUCHIN SHUKLA, MD, Montefiore Medical Center
JEFFREY WEISS, PhD, Mount Sinai Medical Center

P R O C E E D I N G S

[12:01 p.m.]

MS. BRESNAHAN: So, again, this is Marie Bresnahan from the Department of Health. I've been the Project INSPIRE (Innovate and Network to Stop HCV and Prevent complications via Integrating care, Responding to needs, and Engaging patients and providers) Director. I'm joined by Kyle Fluegge. He’s our Health Economist, and Ann Winters is our Medical Director.

And we're a partnership with two major medical centers here in New York City, Montefiore and Mount Sinai. So from Montefiore, we have Dr. Alain Litwin and Dr. Shuchin Shukla on the line, and from Mount Sinai, we have Jeff Weiss on the line, Dr. Jeff Weiss. And then our partnership includes two managed care organizations. One of them, the largest that's been working with us, is Healthfirst, and we have Rashi Kumar joining us.

Did I miss anyone from our team?

[No response.]

MS. BRESNAHAN: Okay.

MS. SELENICH: And, Marie, I would just ask -- so since this conversation is being

transcribed, I would ask that could you send me a list -- this is Sarah -- I guess to the PTAC mailbox, with the names of anyone that's on the call that is going to be speaking, just so that we get the proper spelling?

MS. BRESNAHAN: Yes. I'll do that as soon as we get off the phone.

MS. SELENICH: Great. Thank you.

And then just so -- again, just a reminder, this call is being transcribed, and for the reporter's benefit, please try to remember to state your name before questions and comments.

And then, Bob, I'll turn it over to you and let the PRT members introduce themselves.

DR. BERENSON: Thank you for participating with us today.

I am Dr. Bob Berenson. I am the Chair of this little subcommittee called the PRT.

As it happens, I am a graduate of Mount Sinai and was an intern at Montefiore.

MS. BRESNAHAN: Oh, great. Welcome.

DR. BERENSON: I don't consider -- let me just say I don't consider that either a positive or a negative bias, so that it was a long time ago,

with a lot of water under -- under the bridge since then. But I know something about delivering health care in New York City.

So I am a -- I was a practicing internist for 20 years and then became a policy wonk and currently a fellow at the Urban Institute and have -- have been at CMS (Centers for Medicare and Medicaid Services) in charge of Payment Policy in the Clinton administration.

Grace, why don't you go next?

DR. TERRELL: Good afternoon. I'm Grace Terrell. I'm a practicing internist still at Cornerstone Health Care, which is a multi-specialty medical practice in North Carolina that I was the CEO of --

MS. SELENICH: Grace, we're having trouble hearing you.

DR. TERRELL: Okay.

MS. SELENICH: Sorry.

Do you have a lot of background noise?

DR. TERRELL: Yes. I'm in a meeting. Can you hear me now, better?

MS. SELENICH: Yeah, that's better.

DR. TERRELL: Okay. I'm Grace Terrell.

I'm a practicing internist at a multi-specialty medical practice in North Carolina called Cornerstone Health Care, where I was the CEO (chief executive officer) for 17 years, also have been the CEO of a population health management company called CHESS (Cornerstone Health Enablement Strategic Solutions), and I'm currently the CEO of a company called Envision Genomics, which is doing care model redesign and genomic testing for patients with rare and undiagnosed disorders.

DR. BERENSON: Jeff?

DR. BAILET: Yep. And so I'm Jeff Bailet, Dr. Jeff Bailet. I'm an ENT (ear, nose, and throat) surgeon by training. I recently stopped practicing, was formerly the president of Aurora Medical Group, a 2,000-physician practice in Wisconsin and an integrated delivery system, and as of January became the executive vice president for Healthcare Quality and Affordability for Blue Shield of California.

I am really looking forward to this conversation and appreciate all the efforts of your team to develop this proposal and submit it for our consideration.

Thank you, guys.

MS. BRESNAHAN: Thank you. So nice to meet you all on the phone here.

DR. BERENSON: So, I guess I'm sort of organizing the discussion. Sarah sent ahead some bullets on topics we wanted to talk about. We're not going to necessarily be limited to those topics, but we wanted to give you a heads-up.

Your response to our questions were quite helpful, and I learned -- I learned a lot more about what you're planning on, et cetera, than came across in the initial proposal, which was, I guess, time-limited -- I mean space-limited, so that you can't say everything. But that was helpful.

But as we talk about these particular topics, let me just do a sort of -- it may well be that you've addressed this to some extent in your -- in your responses to our questions already, but please indulge us because it's not always that easy to sort of completely absorb and understand the responses. So if, in fact, you can refer us to where you sort of dealt with something, that would be helpful, whether that's in the original proposal or in the response to the questions.

Some of the questions we've sent you now are -- you've addressed to some extent in your responses to the questions we sent you, but we felt the need to explore some of these in a little more depth.

So that's what we're hoping to do in an hour or less, is to talk about some of these issues, so we have a better understanding of what you're trying to achieve and then sort of the mechanics of how you want to achieve it.

I would like to start actually -- so is everybody on the same page? Do we all know what we're doing here?

MS. BRESNAHAN: Yes.

DR. BERENSON: Okay. I assume in the absence of any negative comments -- and we are being recorded, so that we can go -- we have found it very helpful to go back over a transcript to actually capture the -- what the person was really saying as opposed to what we thought, as opposed to what seems to happen in national policy, but that's a whole different story.

I'd like to go out of order and just understand the status of your Innovation Award. I

know that you refer to that a fair amount, the timing, when results will be available --

MS. BRESNAHAN: Yes.

DR. BERENSON: -- and the relationship between that activity and coming forward with a proposal for a payment model. If somebody would get us started by talking about that.

MS. BRESNAHAN: Yes. I'll jump in on that. This is Marie Bresnahan.

We were a Health Care Innovation Award Round Two, which is -- which was for three years, and it's scheduled to end. Well, all the care coordination services end on August 31st, so next month.

We do have a six-month, no-cost extension to complete some of our analyses, so that we'll be working on the -- looking at our cohort for cost utilization and clinical outcomes over the next six months.

DR. BERENSON: So let me just ask how that works. You do your own self-analysis rather than there being an external evaluation that CMMI (Center for Medicare & Medicaid Innovation) is responsible for? You do your own?

MS. BRESNAHAN: It's both. CMMI has engaged Mathematica to do some external evaluation, but we've been -- we have a really very exhaustive dataset that we've been collecting from the clinical partners. They submit that to us monthly. We are then able to look at trends, what's happening with this population, what results we're seeing.

And then here at the Health Department, we have access to New York State Medicaid data, as well as through a data-sharing agreement, we have access to Medicare data as well so that we can look at cost and utilization issues.

DR. BERENSON: So we're within months of having your self-evaluation, some significant findings. Right?

MS. BRESNAHAN: Yeah. We already have written the paper that's on our Year One outcome, so it doesn't include our entire cohort.

DR. BERENSON: Yeah. So I guess one question I have is why not wait for the full analysis in terms of the timing of this proposal so that we have some more real numbers to deal with in terms of savings, in terms of quality improvement,

et cetera, rather than -- I mean, what's your thinking about proceeding when you did, as opposed to waiting until the final analysis is done?

[Unintelligible]

[PARTICIPANT]: So we recognize how valuable this intervention has been to the clinical site, and I think they can also speak about this. But -- so from the beginning, you know, knowing that this is a time-limited grant, we've been starting to look at ways that we could develop payment models. So our payer partners have been looking at their data, and our clinical partners have been working with the payment models -- I'm sorry -- the payer partners to look at their possible future relationship, so looking at our Medicaid and Medicaid managed care organizations and how they may want to pay for this care coordination. So, you know, we really have been looking at sustainability from the very beginning of this, and so that's why, you know, as we had some data that we could start to look at, we wanted to start this process.

I'm not sure if -- Alain or Jeff or Shuchin, if you want to add sort of why now, why we

want to start looking at this as soon as possible.

DR. LITWIN: Sure. This is Alain.

You know, so a large dataset as [unintelligible] programs or studies go, you know, at the end will be several thousand, but even in the interim -- correct me if I'm wrong -- was up about a thousand patients. Is that correct?

MS. BRESNAHAN: That's right.

DR. LITWIN: Yeah. And so that's a quite significant sample size, and given the kind of sense of urgency that we have been facing, you know, working with this issue for nearly 20 years, and what we're seeing is that over the next five to 10 years, more and more patients are developing cirrhosis, if they don't already have it, and liver cancer and dying and, you know, needing transplants. And so, the idea is really to get some important data out there as soon as possible and to try to be able to replicate this model before further morbidity and mortality take place because it's really --

DR. BERENSON: So you think you have enough data now to know how to price the care coordination activity and -- et cetera, and the --

MS. BRESNAHAN: Oh, yeah.

DR. BERENSON: So you didn't really need to wait is basically what you're saying?

MS. BRESNAHAN: No, we did. We conducted a cost analysis with our partner, Cornell. Weill Cornell Medical Center supported us in that work, and the cost analysis on the intervention itself, we had done a preliminary round in the early part of Year Two or the latter part of Year One of our award. And we didn't feel we were at steady-state, where the care coordinators would really be able to -- you know, had a full caseload and were well trained on how to implement this model. So we redid that the middle of Year Two, and we felt confident we were at steady-state at that point. And that's the big -- that's what we used to calculate the cost related to care coordination services.

DR. BERENSON: Okay. Any other questions, Grace or Jeff, about -- about that topic?

[No response.]

DR. BERENSON: Let's move on, then, to the top bullet. There are a few questions we have regarding the relationship between treating

hepatitis C and patients' comorbidities, social factors, et cetera. I'll start and then turn it over to my colleagues.

We've actually done a run in which it looks like Medicare beneficiaries with hepatitis C are remarkably in Medicare because they are under-65 disabled rather than aged in -- you know, typical 65-and-over Medicare patients. Could you say something about your population, what their sort of underlying reason for being Medicare, if they are, in fact, SSI disabled, and what that means in terms of management of their hepatitis C? Are you aware? I mean, is that the findings you have that they are largely younger people with disabilities?

MS. BRESNAHAN: And --

DR. FLUEGGE: Largely, yes. This is Kyle.

The majority are dual-eligible individuals --

DR. BERENSON: Yeah.

DR. FLUEGGE: -- with the comorbidities that you mentioned.

MS. BRESNAHAN: Dr. Litwin, would you like to speak to the kinds of comorbidities you're

seeing?

DR. LITWIN: Sure. There's a variety of substance abuse comorbidities, psychiatric comorbidities, including severe psychiatric illness. There's, you know, disabilities in terms of some patients being wheelchair-bound, seizure disorders, kind of a number of conditions that may be related to drug use, as well as a lot of the kind of common chronic illnesses of diabetes and heart disease, lung disease, COPD (chronic obstructive pulmonary disease) and so forth related to smoking. There's a lot of co-occurring, obviously, tobacco use disorder.

Shuchin, Jeff, am I missing some things here?

DR. BERENSON: But it is right that your population is largely under 65 with these [unintelligible] problems?

DR. LITWIN: Yes. That's a correct statement. We do have some over 65, but the majority would be under 65.

DR. BERENSON: And one basic question -- and then I definitely will turn to my colleagues -- is whether the -- I mean, you presented in your

original proposal some information about reduction in ED (emergency department) use. I mean, is the reduction related to hepatitis C, or is it related to the fact that with care coordination, you are heading off ED use for a whole range of the comorbidities that patients will often rely on the ED for? I mean, where are you having impact? Do you know that at this point? Is it on complications of liver disease, or is it on these other -- these other comorbidities that your patients have?

DR. FLUEGGE: So we looked at -- this is Kyle again. So we looked at ED visit use among the [unintelligible] -- [audio break].

DR. BERENSON: We've lost contact.

DR. BAILET: Hello?

MS. SELENICH: This is Sarah. I'm still here. Did we -- did we just lose contact with Marie and her group?

DR. LITWIN: This is Alain. I'm still present.

Shuchin, are you there?

DR. SHUKLA: Yeah, I'm there. It looks like we just lost the DOH (Department of Health).

DR. WEISS: Yeah. This is Jeff. I'm still here.

DR. LITWIN: Great.

MS. SELENICH: And do we still have the transcriptionist?

COURT REPORTER: Yes.

MS. SELENICH: Okay.

DR. BERENSON: So we've been forgetting to announce who we are, so I'd like to remind people. But who was just speaking, and are you back?

MS. SELENICH: Not yet. I'll send a quick email.

COURT REPORTER: In the meantime, Dr. -- is it Litwin and Shuchin? Can you guys spell your name for me, please?

DR. LITWIN: Sure. My first name is A-L-A-I-N, and my last name is L-I-T-W-I-N.

DR. SHUKLA: And this is Shuchin Shukla. It's spelled S-H-U-C-H-I-N; last name, S-H-U-K-L-A.

COURT REPORTER: Thank you.

DR. BERENSON: So it sounds like whoever was speaking is now back, is that correct, before you got cut off somehow?

[No response.]

DR. BERENSON: No?

MS. SELENICH: [unintelligible] we lost another person.

DR. WEISS: Yeah. No, Jeff Weiss. I'm still here.

DR. BERENSON: Okay. Well, I wasn't going on here without them coming on.

DR. WEISS: Yeah. The city -- the city got cut off. That's Marie, Ann Winters, and Kyle were probably all together.

MS. SELENICH: Okay.

DR. BERENSON: I see. So we were talking about where the impact is. Does anybody else want to try to tackle that one?

DR. BAILET: Yeah. So, Bob -- Bob, this is Jeff. If we could back up just a bit.

DR. BERENSON: Mm-hmm.

DR. BAILET: The economics of the model are driven to a large part by savings from ER (emergency room) utilization, and it would help me understand what brings these patients to the ER. It was sort of where Bob was going, but are there some unique characteristics about this particular population in your facilities versus other

hepatitis C populations across the country that are unique because it's New York and it's the city?

DR. LITWIN: I would think this is generalizable to any urban area and beyond. I mean, you know, I think in the urban areas, the epidemic is a little more mature in terms of all -- you know, we do have young people but also a lot of older patients and many with advanced liver disease. You know, nearly 50 percent of our patients had either Stage III or IV liver disease, so advanced liver disease. Whereas, in some of the suburban rural areas, it's more younger patients with this opioid epidemic wave that's hitting America. But -- but I think the problems are very similar. I don't think it's specific at all to New York City.

In terms of the problems -- you know, the INSPIRE model, there's multiple health promotion modules that work on kind of the hepatitis C specifically and liver health and treatment and prevention after treatment, but also on substance use issues and healthy living and identifying and screening, using various means of substance use disorders or mental health comorbidities and

referring to resources that are available in the health care systems in the federally qualified health care centers and other settings. And that's one of the big advantages of the intervention is that it's kind of a hook. People are very interested in the hepatitis C treatment. If it's tangible, there's a chance for cure. The word is out, but it also allows -- it provides us time as providers to work with our patients and engage them and to help impress upon them the importance of taking care of their whole body, of total health and not just the hepatitis C. In some cases, it's the hook, which is quite the opposite from the interferon era, you know, when it was very difficult to engage patients, but it really is a good conduit to overall care.

I don't know, Shuchin and Jeff, if you wanted to piggy-back on that.

DR. SHUKLA: Yeah. I would also make the comment -- this is Shuchin, by the way. I would make the comment that a lot of what drives patients to the ER are a lot of things that could be handled by a primary care provider, but, you know, as a family doc, I see all the time patients that go to

the ER for minor complaints, the way it may be side effects of medications or ailments that are easily treated. But to call a clinic to get in touch with your primary care provider is usually an arduous process.

And, I mean, I don't even know if you guys have the same experience I do when I try to get my primary care provider on the line. It's pretty hard. Whereas, in our model, the -- all of the patients have one care coordinator's phone number that is theirs to call, and they can directly reach that care coordinator, whether it's related to physical complaints or just questions about medications. So I think that drives a lot of the decrease in ER utilization.

I can't speak to the data, and hopefully, we'll have Kyle and the DOH back.

MS. BRESNAHAN: Yeah. We're back. Sorry about that.

DR. SHUKLA: Oh, great.

MS. BRESNAHAN: Yeah. We got disconnected.

DR. BERENSON: So if you guys could actually -- your DOH folks could actually also try

to address this, we're interested in what's producing the reduction in ED use. Is it related to liver disease, per se, or is it all of the comorbidities and other factors that are going on? Do you know what the reduction is due to?

DR. FLUEGGE: This is Kyle.

I don't know how much of what I was previously saying, how much of that was --

DR. BERENSON: Very little.

DR. FLUEGGE: Okay. So I'll just repeat it all.

So we noticed -- we looked at the diagnoses related to ED visits in our -- in a sample that we identified in our original proposal, and the shift seems to be from a pre-enrollment diagnoses related to drug addiction and abuse and with enrollment in INSPIRE that there was a transition to more diagnoses related to diabetes. And as we go forward, we expect that the impact of the intervention after discharge has occurred that the patients will be well on their way to handling, addressing issues related to diabetes or other chronic conditions in the outpatient setting, especially for the Medicaid dual-eligible

population.

But that we haven't -- we haven't confirmed that in the post-discharge period yet. We just looked at pre-enrollment and then INSPIRE enrollment.

DR. BERENSON: Jeff, does that respond to your question?

DR. BAILET: Yes, it does, and I guess I don't want to make an assumption, but one of your elements of your care model is behavioral health, inter -- you know, multidisciplinary team that has a behavioral health component. And my assumption -- and you can validate it for me -- is that the behavioral health component is really helping to drive these patients to take accountability for their overall health to curb some of the unhealthy lifestyle behaviors and pursuits and also get them plugged into a care delivery program, either a medical home or through the FQHC (Federally Qualified Health Center) or other venues, which gets them out of the ED, which tends to be a default for this population. Is that -- are those assumptions accurate?

MS. BRESNAHAN: Yes. I think maybe, Jeff

Weiss, you could speak to that, and I can just add because I was on the phone this morning with care coordinators, and they were telling me that the patients feel so much better after being cured for hepatitis C, that I'm quite sure that's an incentive to help them eat right and exercise and get other things going on in their life to a better extent, because they frankly just feel so much better.

And maybe, Jeff, you could add to that.

DR. WEISS: Sure. This is Jeff Weiss.

So my role on INSPIRE was the behavioral health lead at Mount Sinai's site. Jeff Weiss. J-E-F-F-R-E-Y, W-E-I-S-S.

So the care coordinators do a thorough psychosocial assessment of the patients they're enrolling in Project INSPIRE when they first meet them, and, you know, the -- probably the most frequent areas of psychosocial needs are in terms of active substance use and untreated psychiatric disorders. And a great deal of the work that the care coordinators do is to find the appropriate referral source for those patients, whether it be, you know, substance use treatment, psychiatric

treatment, or some dual-diagnosis program addressing both issues, and then work very intensively with the patient to make sure they follow through, make the initial appointment, and, you know, continue in treatment.

So I think your, you know, hypothesis is certainly in line with our understanding of one of the, you know, dominant ways that Project INSPIRE is helping patients. You know, from our perspective, it's also, you know, really driven by helping them prepare for hepatitis C treatments and ensuring that they have the best possible chance of succeeding on treatment, but obviously, at the same time, what's occurring is that their unmet psychiatric needs and their ongoing substance use is being addressed.

DR. BAILET: Thank you.

DR. BERENSON: Thank you.

Grace, do you want to ask about the severe cirrhosis and transplantation issue?

DR. TERRELL: Yes, I do want to ask about that.

So one of the things that we were interested in understanding more about was where

these patients that have a potential need to go to liver transplant because of severe disease, what sort of things, mechanisms, do you have in place to address that with respect to the [unintelligible], follow-ups, or other ways where you're integrating the care for something that may be much more intense in terms of their chronic needs than in some of the other patients in terms of their acuity of needs?

PARTICIPANT: Do you mean from the program perspective or from the payment model perspective?

DR. TERRELL: From the program perspective.

DR. BERENSON: And related to that, does the payment model actually even address those patients, or is the payment directed towards lower acuity -- earlier-stage liver disease? And it was very helpful, by the way, to learn, because my knowledge is outdated, that you don't need liver biopsies anymore, that there are all these noninvasive ways to establish fibrosis.

But so we're interested in what you're doing in delivery, but also does the payment model even address this -- these patients?

[PARTICIPANT]: Well, the model in general for INSPIRE was designed to move clinical care for hepatitis C out of specialty clinics and into primary care or substance abuse treatment programs, infectious disease clinics, into settings where the patients are.

So the patients with severe cirrhosis or in need of liver transplants would likely stay with the specialist in the liver or GI (gastrointestinal) clinics where they are.

I know Dr. Litwin, I'm sure, could speak a little bit more to that.

DR. LITWIN: Yes. Well, I think the tele-mentoring component of the program really helps to address kind of the fragmentation of care. It brings the primary care providers and specialists together, and so primary care providers are able to correctly and accurately stage patients first to determine whether or not they have cirrhosis or not and then whether or not they're decompensated.

And so, in many cases, they're not in specialty care yet, but because of this program, they're able to get into specialty care. The primary care provider is able -- who have that

trusted relationship, is able to impart the reasons why this specialty care follow-up is important and really, you know, be able to expedite evaluation for a transplant.

On the other hand, if someone is -- has advanced fibrosis or cirrhosis and is not decompensated, does not have ascites, has not had a bleed yet, is not encephalopathic, then they can be treated in the primary care in tandem with the specialist. So it really, you know, does help to get people moving to the proper place if they need specialty care and need a transplant.

And also, with the screening, we understand it's a viral disease, and we can cure that, but it's also a liver disease. And even people that have been cured in terms of the virus still can develop liver cancer, and so being able to refer people in a timely fashion who develop liver cancer based on screenings, either through ultrasound or MRIs (magnetic resonance imagings), you know, at the regular intervals can really get people in for the care that they need. So that's something that the care coordinators have been able to address as well, be able to make the linkage,

not just the mental health care and substance abuse, but the specialty, hepatology care as needed.

DR. TERRELL: Do you have any tracking functions for those patients or a registry where you're looking at those that might require a different level of care because of -- because of the intensity of their disease?

DR. LITWIN: Locally, we certainly keep track of the patients. That is a minority of patients, and that's the goal, is to prevent these complications. But, yes, absolutely, we track those that have -- and through our EMRs (electronic medical records) and so forth, track patients that are kind of most in need of urgent specialty care.

There is a phenomenon in which we get people evaluated, but they're not candidates for transplant because of issues around psychosocial issues or ongoing alcohol and addiction disorders. In that case, the patient may end up being treated, would benefit either by the primary care provider, especially, but really in tandem, because all that can be done is medical treatment, and transplant is not an option.

DR. TERRELL: Thank you.

DR. BERENSON: This is, I think, a good segue, unless anybody else wants to talk about more issues around comorbidities to the delivery system and the role of the primary care physician, the care coordinator. And we didn't see much mention of PharmDs (Doctor of Pharmacy). We've talked to some other programs that rely a lot on not -- rely not on physicians to manage the drugs, which we understand can be challenging, but rather PharmDs to be a primary part of the team.

So if you could just talk about sort of the roles of the various clinicians or health professionals in your delivery?

PARTICIPANT: Sure. I can start in broad brush and then let our clinical partners weigh in. That the physicians evaluate and determine which treatment option is recommended, and then the care coordinators support the development of the prior authorization paperwork to actually obtain the medication. They provide health promotion medication, adherence counseling, and all kinds of other support to really help the patient get through to treatment completion.

In INSPIRE, we have some specialty pharmacies that have worked with our -- with this population to help get medications approved and into the hands of the patients. Both of our clinical sites have pharmacies on site, so they can talk about the role of -- if whether they've had any PharmDs specifically involved.

DR. LITWIN: So, at Montefiore, just very briefly, we do have a PharmD on our team, a multidisciplinary team kind of as part of our tele-mentoring and so forth, and for any patient, because drug-drug interactions can be an issue if there's multiple comorbidities and multiple medications, there will be an assessment that can be done by the PharmD independently.

Providers have gotten very good because of the education and so forth and standardized tools to understand all the drug-drug interactions that may -- especially in the coinfection and so forth, but there is another level of kind of scrutiny there that is available through kind of formal consultation with our partnering PharmD.

DR. BERENSON: But, basically, you're -- with mentoring, the primary care docs develop the

expertise to actually manage drug-and-drug interactions, complications, things like that?

DR. LITWIN: Yes, absolutely, because it's really the same types of, you know, PPIs (proton pump inhibitors) and certain drugs that are -- you can't use at all or things that work with a P450 system and so forth. So, yes, there is a great level of expertise there, but there's ongoing mentoring if there's any new issues or new black box warnings that come out and so forth. But we certainly acknowledge the integral importance of PharmDs as well in that, you know, it is a team.

DR. BERENSON: And the care coordinators, what are their qualifications, and are there -- what makes them care coordinators for hepatitis C as opposed to care coordinators for any number of chronic conditions that lots of folks are beginning to employ care coordinators for? Is there something unique about this condition that calls for special qualifications or special education?

MS. BRESNAHAN: I can speak to that. Maybe, Jeff, you'd like to join as well. That, basically, the job description requires a bachelor's degree because we do -- we need -- we

want qualified people that can talk to the doctors, talk to the patients, kind of translate some of the information from the physicians for the patients, making sure patients understand what's going on. But we've also recruited people who are, in many cases, from the community and who are bilingual and speak English and Spanish and can also then speak in a language that's most comfortable for the patient, and then we train them on hep C (hepatitis C) when they start. And there's a variety of training platforms that are available to let people understand this, the hep C itself, but then I think that both sites have been very good at recruiting care coordinators that are just really willing and able to work with a population like this.

DR. BERENSON: Are those care coordinators also coordinating other conditions, so other than hepatitis C, which again, as I suggested, seems to be a developing trend to have care coordinators for patients with congestive heart failure or for diabetes, et cetera, or are they dedicated to hepatitis C?

DR. WEISS: So this is Jeff Weiss at Mount Sinai.

The care coordinators are specifically dedicated to hepatitis C, and I think there are specific training needs and tasks that the hepatitis C care coordinators get involved with that are distinct from the work of other care coordinators working in the primary care setting.

One area in particular is the prior authorization process, which the care coordinators are not responsible for, but at times are very central to facilitating and navigating and ensuring that there's no breakdown in that process. So that is, you know, often a crucial step after the patient has been medically evaluated and working toward initiating hepatitis C treatment where, frankly, a lot of time and staff effort needs to go into it. There's a lot of communication back and forth between the medical facility and the specialty pharmacy and great potential for things to fall through the cracks, processes to get delayed and broken down. So that's really a specific area where the hepatitis C care coordinators have specific expertise.

And, you know, I think throughout medicine and even in the primary care setting, hepatitis C

is moving at such a rapid pace. A new drug [unintelligible], FDA approved yesterday. It's really hard for anyone who's not specifically specialized in hepatitis C at this time to be current, to be able to adequately educate and navigate patients, you know, in an optimal way through the care system.

DR. BERENSON: So let me just understand. The prior authorization, then, I assume, is for the -- for the dispensing of a very costly hepatitis C medication. Is that what we're talking about?

DR. WEISS: Correct. And that process can take weeks to, at times, months.

DR. BERENSON: And what are the typical hang-ups? Why is it so difficult to get that prior authorization?

DR. WEISS: [Laughter]

DR. BERENSON: Well, I mean, I'm curious. Is it clinical, or is it, I mean, just in general? I mean, if you've got a patient who's got documented hepatitis C, some level of fibrosis, is it that you're looking for a specific severity? I mean, I'm just guessing.

DR. WEISS: Sure.

DR. BERENSON: You tell me why, what the challenges are in just getting a prior authorization.

DR. WEISS: So the most common response to submitting a full package for a prior authorization is a denial letter. That's the most common response.

DR. BERENSON: And the denial letter is coming from whom?

DR. WEISS: The insurer.

DR. BERENSON: From the insurer.

MS. BRESNAHAN: The Medicare company, and then the care coordinators resubmit, get any additional information requested, and then they -- I talked to a care coordinator at Montefiore this morning who -- they've had two denials, and now they're appealing it to the state. And they will likely get authorization, but sometimes the states have to intervene.

DR. LITWIN: It's all part of the process because of the expense, and so you have to be on top of understanding. You know, the issues that denials are based on, kind of the stage of disease or certain comorbidities that you need to have, if

you don't have advanced-stage disease, such as even diabetes or severe fatigue, also if there's issues with addiction. And many plans have moved to be more lenient, but some still require urine toxicologies and other types of things, data, or periods of abstinence, and so providing guidelines which refute the evidence for that, that, in fact, people that are actively using can be eligible and do well with treatment, so being able to make these cases and 99 percent of the time are successful. But it's a lot of work.

DR. BERENSON: So there's some basic information here. We wear, generally, Medicare hats, and so now we understood that these are often duals, at least the Medicare demo would affect duals. And in many places, the duals are not part of managed care. They are sort of separately managed by the -- by the state, but are you basically saying that the duals in New York are in managed care, and that the managed care companies then will develop their own criteria for approving drugs?

DR. LITWIN: That's correct, but there's also some around fee-for-service. In New York,

there's been a lot of improvement, but, you know, even then, you know, in the early days, you'd have to do the same type of process, which is, you know -- so it's a little bit of both.

DR. BERENSON: So part of our issue is that we're trying to develop payment models that have broad applicability. Is there an inordinate amount of time in the care coordination role in New York City related to New York-specific issues of getting approval that are not generally applicable, or is this -- I mean, how would you respond to that concern that this is a New York problem?

DR. LITWIN: No, not at all. I think, if anything, we're spending quite a bit of time, but New York is probably ahead of most of the other states because of advocacy. And so there's more time required in other states around this issue and more advocacy and more -- I think a bigger role for care coordinators across the country, and that's been well documented in papers and so forth without all the types of barriers, you know, related to addictive disorders, HIV, and even the provider type, you know, whether primary care providers and so forth are treated -- can, you know, treat. But

these are things that can be overcome through careful documentation, citing, you know, guidelines, the AASLD (American Association for the Study of Liver Diseases), IDSA (Infectious Diseases Society of America) guidelines, and, you know, patients are able to gain access to medications across the country. But it takes a lot of work.

So in answer to your question, it is generalizable.

DR. BERENSON: Okay.

DR. BAILET: Bob?

DR. BERENSON: Yeah. Go ahead, Jeff.

DR. BAILET: Well, I wanted to maybe change, you know, if you're finished or to chase this one down. I had sort of a related but new sort of category I'd like to explore, and I know Grace and I had some opinions about this as well, if you're --

DR. BERENSON: Go for it. Yeah, go.

DR. BAILET: So it was unclear in your proposal what happens -- you know, I guess let's back up. So what are the percentages, if you have that information, on the folks who complete treatment? So of the ones that are identified as

having the virus, what percent actually complete their treatment? I'll just ask questions, and you guys can kind of read your answers appropriately. What happens to people who opt out, meaning they start treatment and then for some reason opt out or they decline treatment altogether? So what kinds of interventions or connections are made for those particular patients for their own medical health but also to avoid further spread?

And then the last part of the question is for long-term downstream sequela from being hepatitis C-positive, such as liver cancer, as you've noted, these folks do have cirrhosis, and there are other associated sequela from cirrhosis. And how do you guys support those patients? How are they tracked? Sort of just give us the picture of not only when they're in your program but the pre and sort of post, what happens to these folks. That’d be helpful.

DR. WINTERS: Maybe we could start -- maybe the Health Department can start with a little bit of an overview, and then maybe the clinical sites can talk a little bit about the long-term management? So, we do have 2,775 patients

enrolled, and of those, the majority, 2,508, completed an assessment, and 2,440 had a medical evaluation completed. Not all of those were considered treatment-eligible candidates based on a variety of issues that may have been higher-priority medical or behavioral health issues. And of those, they are still followed by the clinical sites, but they may not be started on treatment.

And then as of May, we know that 1,800 initiated treatment, 1,496 completed treatment, and 1,123 have been cured. And we expect those numbers to go up significantly by the time we complete the project.

And in terms of long-term follow-up, as Alain mentioned, we did have at least half of our enrollees at the higher level of fibrosis, and of course, those patients will require ongoing clinical monitoring.

So I don't know if -- Alain or Shuchin or Jeff, if you guys want to talk about how that is managed.

DR. LITWIN: Sure. This is Alain Litwin.

So we do have registries for the patients with advanced fibrosis, either Stage III or IV, who

need ultrasounds every six months, and so they need to be followed for life, even if they're cured. And, again, 95 percent of our patients, you know, are cured, so the rates are great. But it's more than just a viral eradication, and so that's something that has to be part of the ongoing role of the care coordinators, so the patients understand that it's more than just clearing their virus. And that's reinforced during the seventh health promotion module post treatment, that, you know, congratulations -- in most cases, congratulations, you did well, you know, however, you know, we still need to continue to monitor you regularly.

And part of, again, we believe the success of the program is intensifying the engagement of a pretty marginalized group of people within primary care, where this follow-up can happen, because a lot of the patients can be followed up with ultrasounds if they just have Stage III or IV in primary care settings and then, if identified, to have either a precancerous lesion or cancer because of the linkages made through the program can be expeditiously referred to the team, specialty team

or for whatever types, whether it's surgical or radiological interventions, IR, interventional radiology, or transplant.

I don't want to digress too much, but one of the other big things that was developed in the program was a recognition that a lot of our end-stage renal disease patients weren't actually adequately being evaluated for transplant, and the hep C became almost -- became a means to really get people evaluated for transplant because there is actually a medication where you can treat people with end-stage renal disease, something called elbasvir and grazoprevir. But we want to make sure that they've been evaluated for transplant first because it actually -- [unintelligible] be a benefit if you still have hepatitis C, and so it's just another added, you know, kind of benefit of this program.

But there's a lot that's done for these patients with advanced disease.

Shuchin or Jeff?

DR. WEISS: Yeah. This is Jeff.

You know, I think this is where you're really going to find a lot of national differences

that are distinct from New York. So we're very fortunate and are able to treat patients, pretty much regardless of their stage of liver disease. So if a patient remains engaged with us, they will get treated. The patients that we lose are, you know, patients that sort of disappear. We can't find them. They might reappear six months later. But if a patient is engaged, they will get treated.

That's not the case in many states throughout the country. There are many states in which patients who have early-stage liver disease cannot right now be treated, and that's really, I think, a key role for care coordinators, is to retain those patients and keep those patients engaged in primary care and liver care to make sure that, you know, they don't get lost.

And, you know, also, as I think, Jeff, you pointed out, those patients are obviously at risk for transmitting hepatitis C. So it's certainly crucial that those patients are also engaged in, you know, harm-reduction programs if they're injecting drugs. So that's really an area that we have not had to focus on, is keeping that group of patients who are not medically or insurance-

eligible for treatment engaged in care to ensure both that they're not transmitting hep C and that they eventually will get treated, hopefully with, you know, changes in state guidelines. But that only increases the need and role for hepatitis C-specific care coordinators.

DR. LITWIN: I totally agree with you, Jeff.

And then one other advantage of keeping this within the primary care community is that people have their timeline. It might take six months, a year, two years, but if you have these programs in place when patients are ready -- and we see this all the time -- they can then re-engage. You know, 50 percent or more are ready to engage right away, but there are competing priorities. And so by engaging them within their medical home, we don't lose them, you know, because they might be re-engaged, you know, a year later or beyond.

DR. BAILET: Great.

Grace, did you have any other questions around this?

DR. TERRELL: No. I don't have any other questions. Thank you.

DR. BERENSON: So I was going to bring up one final topic. Jeff, do you have anything else you want to bring up? Because I want to go to the shared savings approach.

DR. BAILET: No. Go ahead, Bob.

DR. BERENSON: So a basic question, I guess, we have is if you are adequately paid for care coordination, whether through a new payment model or through some modifications of what Medicare will pay for -- you know, exactly how they define care coordination, why do you need shared savings based on lifetime savings to the program? I mean, that sets a pretty audacious precedent on what to base shared savings. Why -- if you got paid for care coordination, isn't that sufficient is my question.

DR. FLUEGGE: This is Kyle.

Well, that's what we started with when we originally developed the proposal, but then upon reading the guidelines in the RFP (Request for Proposal), it stated that we needed to include aspects of the parent model that puts physicians and providers at more than nominal risk of achieving the quality outcome. And so that --

that's sort of the genesis behind why we created and included the shared savings component because that puts providers at significant risk for not achieving a high SVR (sustained virologic response) rate. But it's not -- it's not imperative that it's included in order to make the model work.

DR. BERENSON: I see. Okay. So let no good deed go unpunished.

Explain for me -- and then I'll turn it over to Grace. I think it's there in your response, but I'd like you to just state it. What is the financial risk that the clinicians are bearing?

DR. FLUEGGE: So the institution is the APM (Alternative Payment Model) Entity, and all physicians treating HCV (hepatitis C virus) would be a part of that entity. And they would be at risk for paying back a portion of the potential shared savings for patients that do not achieve SVR, who were treated and do not achieve SVR, and so --

DR. BERENSON: But they're only at risk for the additional revenues that they receive?

DR. FLUEGGE: That they -- they're at risk

for the revenues that they -- they're at risk for the patients that don't achieve SVR and have to pay that money back, so the savings that the institution could have generated they have to pay that back to CMS and Medicare.

DR. BERENSON: I understand, but they're no worse off than they were to begin with. It's just they're paying back some of the additional care coordination money that they --

DR. FLUEGGE: Right. Exactly yes -- essentially yes.

DR. BERENSON: Okay. I just -- go ahead, Grace.

DR. TERRELL: No, that answered my question. It was about the difference between shared savings and shared risk, and so I think that explains where they're coming from.

Thank you.

DR. BERENSON: But, it's important for us to understand. This was developed because of the requirements to be an advanced APM.

DR. FLUEGGE: Yes. That's right. Exactly.

DR. BERENSON: But to be an APM or to get

a care coordination fee somehow through the standard mechanism of a fee schedule or something would also be a way to help you do what you're trying to do?

DR. FLUEGGE: That is an alternative, yes.

DR. BERENSON: Okay, okay.

And okay. Well, that's helpful. That's very helpful.

Any -- we were coming on to the hour. I think we've had a very good discussion. Grace or Jeff, do we have just a couple of minutes? Do you have any additional things you want to clarify?

DR. TERRELL: I'm good. Thank you.

DR. BAILET: As am I. Thank you.

DR. BERENSON: This has been a very useful hour, and again, you can't get it all from the paper. And we now have a much better appreciation of what you've been doing, why you've approached us with this payment model, et cetera. So, it's possible we'll be back to you to ask a few additional questions but not necessarily. We will now take some time to sort of discuss amongst ourselves and prepare for a public meeting later in the year. So thank you very much.

MS. BRESNAHAN: That's great.

DR. BERENSON: Any final questions from you about process?

MS. BRESNAHAN: No. There's terrific information on your website about the process, and the PTAC staff have been really, really helpful when we've sent inquiries. So, yeah, we really thank you for taking the time. So nice to meet you all.

DR. BERENSON: Yeah. I know you're doing -- you're doing God's work up there. I do come back to visit New York sometimes, but keep up the good work, and thank you very much for pulling you all together for this -- for this meeting. You're all busy, so we appreciate it.

MS. BRESNAHAN: Thank you.

DR. WINTERS: Thank you very much.

MS. BRESNAHAN: And thank you, Montefiore, Sinai, and Healthfirst, for joining us. We really appreciate it.

DR. WINTERS: Yes.

DR. BERENSON: Okay.

[Whereupon, at 12:57 p.m., the conference call concluded.]