Physician-Focused Payment Model Technical Advisory Committee
LOI: Environmental Scan and Relevant Literature

New York City Department of Health and Mental Hygiene (NYC DOHMH)
Letter Dated: 2/17/2017
Letter Received: 2/21/2017

Project INSPIRE is a Center for Medicare & Medicaid Innovation (CMMI) healthcare innovation awardee, that is a collaboration between the NYC DOHMH; Weill Cornell Medical College; two managed care organizations, HealthFirst and Visiting Nurse Service of New York (VNSNY) CHOICE; and two clinical partners, Mount Sinai Medical Center and Montefiore Medical Center. Project INSPIRE is a service delivery model of care coordination for the treatment of hepatitis C virus (HCV) in New York City. This model emphasizes case conferencing and tele-mentoring consultation services, in conjunction with clinical care and treatment, to achieve sustained virological responses (SVR or HCU cure). This model incentivizes providers to screen and treat those at greatest risk of infection. Currently, there is no payment model supporting care coordination (CC) for hepatitis C viral (HCV) infection management. CC provides an integrated system of medical and behavioral healthcare, including comprehensive psychosocial assessment and treatment readiness counseling, medication adherence support, health promotion, and health coaching to promote patient self-sufficiency.

NYC DOHMH is proposing a multi-provider, bundled episode-of-care as the basic structure of payment for the currently unreimbursed service of CC by unlicensed providers. Physicians may bill directly for CC and provide the services, or subcontract those services to community partners via a payment arrangement consistent with the episode of care. The episode of care consists of three phases: (1) clinical evaluation, preparation for treatment, and initiation of CC services; (2) treatment phase, where CC services are key to support medication adherence; and (3) post-treatment phase, which ends with demonstration of cure via a laboratory test.

Expected participants include beneficiaries that have a detectable HCA RNA viral load. Patient services will take place at institutions that have the necessary infrastructure to deliver ongoing CC successfully and to a wide mix of patients, including those living in urban and rural areas.

Key Search Terms

Behavioral health care; bundled episode of care payment model; care coordination; CC; chronic hepatitis C virus; CMMI; cost; HCV; hepatitis C; Hepatitis C New York City Report; HCIA Round Two Report; Project INSPIRE; Medicare; Mount Sinai Project INSPIRE; Multi-provider; payment; sustained virologic response; SVR

Research Task	Section	Contents
Environmental Scan	Section 1	Key documents, timely reports, grey literature, and other materials gathered from internet searches (5).
Relevant Literature	Section 2	Relevant literature materials (4).
Related Literature	Section 3	Related literature materials (1).
References	Section 4	References to relevant and related literature.

Section 1. Environmental Scan

Environmental Scan		
Key words: Multi-provider; bundled episode of care payment model; chronic hepatitis C virus; HCV, Project INSPIRE; CMMI; sustained virologic response; SVR; care coordination; CC; behavioral health care		
Organization	**Title**	**Date**
Centers for Medicare & Medicaid Services Innovation (CMMI or the Innovation Center)	Health Care Innovation Awards Round Two: New York (State Profiles)	Accessed 3/7/2017 Last Updated: 03/7/2017
Purpose/Abstract		
Background: The Fund for Public Health in New York and the New York City (NYC) Department of Health and Mental Hygiene (DOHMH) are testing a model called Project INSPIRE NYC (Innovate & Network to Stop HCV & Prevent Complications via Integrating Care, Responding to Needs and Engaging Patients &Providers). This model will identify persons with Hepatitis C viral (HCV) infection utilizing the NYC DOHMH HCV surveillance database, electronic medical and laboratory records from participating facilities, and referrals from neighborhood organizations that perform HCV testing. ***Summary:*** Eligible persons will undergo an interdisciplinary, comprehensive medical and behavioral health assessment, for substance use and social support and benefits needs. Patients' behavioral health will be assessed using the Psychosocial Readiness Evaluation and Preparation for Hepatitis C Treatment (PREP-C), to identify areas of psychosocial functioning that require attention before and after beginning HCV treatment. HCV and related co-morbidities will be managed within an integrated, patient-centered clinical and behavioral health environment. Primary care and/or HIV providers will be supported by addiction medicine specialists, psychiatrists and hepatologists, who will be available for telemedicine-based consultation. Providers will be trained and mentored in HCV care and treatment by the institutions' hepatologists. Web-based teaching modules and weekly case management video conferences with hepatologists and providers from all participating clinics will be used. Patient management will be supported and facilitated by care coordination, defined as health system navigation and patient support to keep medical appointments, health promotion, medication adherence assistance, and coaching for improvement of self-sufficiency skills. Comprehensive care coordination programs and integrated care have been shown to improve health outcomes and reduce hospitalization and emergency department visits.		
Additional Notes/Comments		
Hep Free NYC is comprised of the NYC Hep B Coalition and NYC Hep C Task Force. Resource page for Project INSPIRE: https://hepfree.nyc/projectinspire/		

Environmental Scan

Key words: Project INSPIRE; HCIA Round Two Report

Organization	Title	Date
Centers for Medicare & Medicaid Services (CMS)	Evaluation of the Round Two Health Care Innovation Awards (HCIA R2) First Annual Report	8/1/2017

Purpose/Abstract

Background: This report is the first annual report evaluating Round Two of the Health Care Innovation Awards (HCIA). The report begins highlighting variations in awardee and program characteristics, including differences in the awardees' service delivery and payment models. It continues synthesizing the implementation experience of the 39 awardees, identifying the barriers and facilitators they encountered during the first year of program implementation and, when possible, highlighting strategies for effectively overcoming the first-year implementation challenges. Finally, the report summarizes the results from impact evaluability assessments.

Summary: The report presents the findings for each of the 39 awardee programs individually in Appendix B. Please find an evaluation of the New York City Department of Health and Mental Hygiene's (DOHMH) Project INSPIRE in appendix B.14 of the report. In appendix B.14, the report presents a general description of Project INSPIRE, findings from qualitative analyses, implementation effectiveness, implementation challenges and the strategies developed to address those challenges, awardee level decision making towards program-related changes, and the extent to which the awardee has begun to plan/implement payment reforms.

Additional Notes/Comments

Environmental Scan

Key words: Hepatitis C; cost

Organization	Title	Date
Health Affairs Blog	The Cost of a Cure: Revisiting Medicare Part D and Hepatitis C Drugs	11/3/2016

Purpose/Abstract

Background: Two years ago, soon after the Food & Drug Administration (FDA) approved the first breakthrough treatment for hepatitis C, the authors wrote about the potential cost of a cure to Medicare Part D and its beneficiaries. For that piece, authors used the best available data to estimate the number of people on Medicare who might seek treatment and the impact on Medicare spending.
Summary: In this article, the earlier analysis is revised using new data released by CMS, and considers both the ongoing impact of hepatitis C drugs for Part D and the broader implications for Medicare of new high-priced drugs entering the market. According to this data, 57,400 Medicare beneficiaries received prescriptions for one of the three available hepatitis C drugs in 2014 — which is less than 20 percent of the Medicare population with hepatitis C, and about one third of the population who are aware that they have hepatitis C. (Another 600 filled prescriptions at the end of 2013, but most are probably counted in 2014 when receiving their next month's supply). Total spending on these three drugs in 2014 (including the amounts at the end of 2013) was about $4.7 billion, or 4 percent of Medicare Part D spending.

Additional Notes/Comments

Environmental Scan

Key words: Hepatitis C New York City Report

Organization	Title	Date
New York City Department of Health and Mental Hygiene	Hepatitis B and C: Annual Report of Activities, 2015	10/4/2016

Purpose/Abstract

Background: On October 4, 2016, the New York City Health Department released a report detailing the City's hepatitis B and C surveillance, research, and programs.

Summary: This report presents an overview of the New York City Health Department's 2015 surveillance and research data on hepatitis B and C, as well as the Health Department's programmatic activities to address these epidemics. Surveillance data revealed that, between 2014 and 2015, reports of chronic hepatitis C decreased 4.7 percent. From 2005 to 2015, the rate of newly reported hepatitis C experienced an overall decline. However, from 1999 to 2014, the number of-hepatitis-C-related deaths increased 38 percent. The report briefly touches on Project INSPIRE (page 27) showing that in 2015 the program enrolled 1,370 patients, for which 1,012 were eligible treatment candidates. Of those eligible, 600 initiated treatment, with 565 following treatment to completion. After completing treatment, 404 patients had a sustained virologic response (SVR/cure).

Additional Notes/Comments

Environmental Scan

Key words: Mount Sinai Project INSPIRE

Organization	Title	Date
Hep Free NYC	Project INSPIRE NYC: Hep C Taskforce Meeting	5/20/2015

Purpose/Abstract

Background: The New York City Hep C Task Force (Task Force), founded in 2004, is a citywide network of service providers and advocates working to prevent, manage, and treat hepatitis C. The Task Force's mission is to build community capacity for the effective prevention, screening, management, and treatment of Hepatitis C by promoting collaboration among key stakeholders and effecting change through participation in policy advancement, initiating innovative projects, and facilitation of enhanced knowledge sharing.

Summary: This presentation, at a Hep C Task Force Meeting, provides a brief overview of Project INSPIRE, including the project's major activities, key components, care coordination, and four general statistic graphics.

Additional Notes/Comments

Section 2. Relevant Literature

Relevant Literature		
Key words: Hepatitis C; care coordination		
Organization	**Title**	**Date**
Clinical Infectious Diseases	From Care to Cure: Demonstrating a Model of Clinical Patient Navigation for Hepatitis C Care and Treatment in High-Need Patients	12/10/2016
Purpose/Abstract		
Background: The NYC Department of Health implemented a patient navigation program, titled Check Hep C, to address patient and provider barriers to HCV care and potentially lifesaving treatment. Services were delivered at two clinical care sites and two sites that linked patients to off-site care. Working with a multidisciplinary care team, patient navigators provided risk assessment, health education, treatment readiness and medication adherence counseling, and medication coordination***.*** ***Methods:*** An examination of the program participant data between March 2014 and January 2015 revealed that 388 participants enrolled in Check Hep C, 129 (33 percent) initiated treatment, and 119 (91 percent of initiators) had sustained virologic response (SVR). ***Findings:*** Participants receiving on-site clinical care had higher odds of initiating treatment than those linked to off-site care. Check Hep C successfully supported high-need participants through HCV care and treatment, and SVR rates demonstrate the real-world ability of achieving high cure rates using patient navigation care models.		
Additional Notes/Comments		
https://www.ncbi.nlm.nih.gov/pubmed/27940945		

Relevant Literature

Key words: Hep C Medicare payment

Organization	Title	Date
The American Journal of Managed Care (AJMC)	Coverage for Hepatitis C Drugs in Medicare Part D	5/1/2016

Purpose/Abstract

Objective: The recent arrival of new hepatitis C virus (HCV) drugs has brought fiscal pressures onto Medicare Part D; spending on HCV drugs in Part D jumped from $283 million in 2013 to $4.5 billion in 2014. The authors examined the current benefit designs for HCV drugs in Part D plans and analyzed patients' financial burden for those drugs.
Study Design: A cross-sectional analysis of CMS' July 2015 Part D Plan Formulary File and the Wolters Kluwer Health Medi-Span Electronic Drug File v.2.
Methods: Researchers analyzed the type and amount of cost sharing for HCV drugs and the extent to which plans apply utilization management tools. Researchers then estimated total out-of-pocket spending for beneficiaries to complete a course of treatment.
Results: All Part D plans covered at least one recently introduced HCV drug, as of July 2015. Nearly all plans charged relatively high coinsurance and required prior authorization for new HCV drugs. For enrollees with no subsidy, the mean out-of-pocket spending needed to complete a course of treatment is substantial, ranging from $6,297 to $10,889. For enrollees with a low-income subsidy, out-of-pocket spending varies between $10.80 and $1,191.
Conclusions: Under the current Part D benefits, HCV drug users with no subsidy face sizable financial burdens, even with catastrophic coverage and the recent in-gap discount for brand name drugs. As baby boomers, the group most likely to have HCV-join Medicare, efforts should be made to ensure patient access to these needed drugs.

Additional Notes/Comments

https://www.ncbi.nlm.nih.gov/pubmed/27266952

Relevant Literature

Key words: Hepatitis C; Medicare

Organization	Title	Date
Alimentary Pharmacology and Therapeutics	Presence of hepatitis C (HCV) infection in Baby Boomers with Medicare is independently associated with mortality and resource utilisation	5/1/2016

Purpose/Abstract

Background: Hepatitis C virus is common among Baby Boomers (BB). As this cohort ages, they will increasingly become Medicare eligible.
Aim: To evaluate resource utilization and mortality of BB Medicare recipients with HCV.
Methods: The authors used in-patient and out-patient Medicare databases (2005-2010). HCV was identified using ICD-9 codes. Outcomes included resource utilization [payment/case and in-patient length of stay (LOS)] and short-term mortality.
Results: Of 1,153,862 BB Medicare recipients (2005-2010), 3.2% (N = 37 365) had HCV. During this period, in-patient Medicare-BB (39,793-55,235) and their claims (78,924-106,232) increased. Furthermore, their overall mortality increased from 8.94% to 10.25% (P < 0.0001). In multivariate analysis, HCV [OR = 1.23 (1.16-1.29)], older age [OR = 1.98 (1.82-2.14)], male gender [OR = 1.25 (1.22-1.29)], ESRD [OR = 1.31 (1.26-1.36)], Charlson score [OR = 1.41 (1.40-1.42)] and LOS [OR = 1.02 (1.02-1.02)] predicted mortality. LOS decreased from 12.98 to 11.74 days (P < 0.0001), whereas total payments increased from $22,157 to $23,185 (P < .0001). During the study, the number of outpatient Medicare BB patients (123,097-192,110) and claims (863,978-1,340,260) also increased. Furthermore, overall mortality increased from 3.15% to 3.31% (P = 0.0131). Again, HCV [OR = 1.23 (1.16-1.30)], older age [OR = 2.03 (1.89-2.17)], ESRD [OR = 3.40 (3.28-3.51)], disabled status [OR = 1.49 (1.40-1.58)] and Charlson score [OR = 1.39 (1.38-1.40)] predicted mortality. Annual total outpatient payments increased from $3,781 to $4,001 (P < 0.0001). HCV [36.04% [34.28-37.82%)], 45-49 age [4.21% (3.14-5.28%)], ESRD [966.31% (954.86-977.88%)], disabled status [43.22% (41.67-44.80%)], Charlson score [46.78% (46.31-47.26%)] and study year [2.72% (2.58-2.85%)] independently predicted increases in payments.
Conclusion: In BB Medicare recipients, diagnosis of HCV is independently associated with higher mortality and resource utilization.

Additional Notes/Comments

https://www.ncbi.nlm.nih.gov/pubmed/26991652

Relevant Literature

Key words: Hepatitis C; care coordination

Organization	Title	Date
Public Health Reports	Barriers to Treatment among New York City Residents with Chronic Hepatitis C Virus Infection, 2014	5/1/2016

Purpose/Abstract

Objective: New, highly effective hepatitis C virus (HCV) medications recently changed the landscape of HCV treatment. Access to treatment, however, is limited. The New York City Department of Health and Mental Hygiene conducted an enhanced surveillance project to better understand the reasons patients are not treated for HCV.

Methods: In June 2014, researchers randomly selected 300 adults who were reported through routine surveillance as having a positive HCV ribonucleic acid test result and who had seen a medical provider since June 2012. Researchers collected information on demographics, treatment, and barriers to treatment from these 300 patients and their providers by telephone, fax, mail, and medical record review.

Results: Of 179 providers, 74 (41%) cited co-occurring conditions and 50 (28%) cited patients not keeping follow-up or referral appointments with specialists as common barriers to treatment. Forty providers (22%) reported that they do not prescribe HCV medications and instead refer patients to specialists for treatment. Of 89 patients citing barriers to treatment, 30 (34%) cited co-occurring conditions, 26 (29%) cited concerns about side effects, 21 (24%) indicated not feeling sick, 15 (17%) cited waiting for a better treatment regimen, and 12 (13%) cited medication costs or insurance issues. Only 11 providers and 10 patients denied any barriers to treatment.

Conclusion: Increasing the number of New York City residents with HCV infection who are treated and cured will require programs to increase provider capacity, change provider behavior in treating patients with substance use and medical conditions, improve patient awareness of new medications, provide patient navigation and care coordination support through treatment, and initiate advocacy and policy work.

Additional Notes/Comments

https://www.ncbi.nlm.nih.gov/pubmed/27252563

Section 3. Related Literature

Related Literature		
Key words: Sustained virological response; payment		
Organization	**Title**	**Date**
Journal of Viral Hepatitis	The cost of treatment failure: resource use and costs incurred by hepatitis C virus genotype 1-infected patients who do or do not achieve sustained virological response to therapy	8/1/2013

Purpose/Abstract

Background: Chronic hepatitis C virus (HCV) infection places a considerable economic burden on health services. Cost-effectiveness analyses of antiviral treatment for patients with chronic HCV infection are dependent on assumptions about cost reductions following sustained virological response (SVR) to therapy.
Objective: This study quantified the medium-term difference in health resource usage and costs depending on treatment outcome.
Methods: Retrospective chart review of patients with HCV genotype 1 infection who had received at least 2 months pegylated interferon and ribavirin therapy, with known treatment outcome, was conducted. Disease status was categorized as chronic hepatitis, cirrhosis, or decompensated liver disease. Health resource use was documented for each patient in each disease state. Unit costs were from the NHS 'Payment by Results' database and the British National Formulary.
Findings: One hundred and ninety three patients (108 SVR, 85 non-SVR) with mean follow-up of 3.5 (SVR) and 4.9 (non-SVR) years were enrolled. No SVR patient progressed to a more severe liver disease state. Annual transition rates for non-SVR patients were 7.4% (chronic hepatitis to cirrhosis) and 4.9% (cirrhosis to decompensated liver disease). By extrapolation of modelled data over a 5-year post-treatment period, failure of patients with chronic hepatitis to achieve SVR was associated with a 13-fold increase (roughly £2300) in costs, whilst for patients who were retreated, the increase was 56-fold, equating to more than £10 000.
Conclusions: Achievement of an SVR has significant effects on health service usage and costs. This work provides real-life data for future cost-effectiveness analyses related to the treatment for chronic HCV infection.

Additional Notes/Comments

http://onlinelibrary.wiley.com/doi/10.1111/jvh.12132/abstract

Section 4. References

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PHYSICIAN-FOCUSED PAYMENT MODEL TECHNICAL ADVISORY COMMITTEE (PTAC)

PRELIMINARY REVIEW TEAM (PRT)

CONFERENCE CALL

Call with a Clinical Expert/
David Goldberg, MD, Medical Director for Living Donor Liver Transplantation, University of Pennsylvania

Wednesday, July 12, 2017
Noon

PRESENT:

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

MARY ELLEN STAHLMAN, PTAC Staff Director, Office of the Assistant Secretary for Planning and Evaluation (ASPE)
SARAH SELENICH, MPP, ASPE

JANET PAGAN-SUTTON, PhD, Social & Scientific Systems, Inc. (SSS)

DAN WALDO, Vice President and Economist, Actuarial Research Corporation (ARC)

DAVID GOLDBERG, MD, Medical Director for Living Donor Liver Transplantation, University of Pennsylvania

P R O C E E D I N G S

[12:04 p.m.]

MS. SELENICH: Thank you, Dr. Goldberg, for joining us. As you know, the Preliminary Review Team (PRT) of the PTAC (Physician-Focused Payment Model Technical Advisory Committee), which is three members of the larger 11-person Committee, they sort of take the first stab at doing an in-depth dive on the proposal, and then they report back out to the full Committee. And so they were interested, as you know, in speaking with you to get your insights on this proposal that's come to us related to HCV (hepatitis C virus).

And then just as a matter of housekeeping, I think, Bob, you weren't on the call, but for the reporter, please make sure that when you ask a question or when you respond that you all are stating your names, just so she's got that in the transcript.

And, again, the first portion of the call, when you're talking to Dr. Goldberg, will be transcribed, and then the subsequent portion of the call, after Dr. Goldberg drops off, will not be. And that's when we'll be going through the analysis

and further discussion of the proposal.

So, with that, Bob, I can turn it over to you.

DR. BERENSON: Okay. So we haven't done introductions yet.

MS. SELENICH: Yeah.

DR. BERENSON: Everybody should know who's on the call. Right?

MS. SELENICH: Yeah.

DR. BERENSON: So I will start, and then I guess what we'll do is have the three PRT members, then the ASPE (Assistant Secretary for Planning and Evaluation) staff, and then others who are on the call, and then we'll just ask Dr. Goldberg to just say a couple of things about his current work with hepatitis C.

So I'm Robert Berenson. I'm a member of the PTAC. I was a practicing general internist. In recent years, I've been a policy fellow at the Urban Institute.

And let's move to another PTAC member, whoever wants to speak up.

DR. BAILET: Grace, go ahead.

DR. TERRELL: I'm Grace Terrell. I am a

practicing internist at an organization called Cornerstone Health Care that's part of Wake Forest University. I was the CEO (chief executive officer) of that group for 17 years. I am -- but spend most of my time now at Envision Genomics, which is a precision medicine company working on rare and undiagnosed diseases, where I'm the CEO.

DR. BAILET: And I'm Jeff Bailet. I'm currently the executive vice president of Health Care Quality and Affordability at Blue Shield of California. I am a former otolaryngologist trained at UCLA (University of California at Los Angeles) and had the pleasure of supporting Dr. Busuttil, his liver transplant team while I was there, and look forward to this discussion this morning.

DR. BERENSON: And I should add that Jeff is also the Chairman of the PTAC, so you are speaking to important people here.

Let's go to ASPE.

MS. SELENICH: So I'm Sarah Selenich, and I -- ASPE is the Assistant Secretary for Planning and Evaluation. We're in the Office of the Secretary at the Department of Health and Human Services, and I am one of the folks that staffs

PTAC and the proposal manager on the staff side for this particular Preliminary Review Team and proposal.

MS. STAHLMAN: And this is Mary Ellen Stahlman, and I direct the staff that supports PTAC, the staff that's here at ASPE.

DR. BERENSON: SSS?

MS. SELENICH: I don't know that I heard anyone from SSS.

DR. BERENSON: Okay.

MS. SELENICH: Dan -- Dan is on the line.

MR. WALDO: Yeah. Hi. My name is Dan Waldo. I work for Actuarial Research Corporation, which is a subcontractor to SSS in the support of ASPE and the support of the PTAC.

DR. BERENSON: Anybody else, other than Dr. Goldberg?

[No response.]

DR. BERENSON: I thought there were nine people on. When I came on, they told me I was joining nine people.

MS. SELENICH: Yeah. The -- so the reporter is on the line, and she also has an additional line open --

DR. BERENSON: Got it.

MS. SELENICH: -- as well for the transcription.

DR. BERENSON: Okay. And, Dr. Goldberg, we have your CV (curriculum vitae). Should we know anything more about you other than -- I mean, say just a few words so we can --

DR. GOLDBERG: Right. So my name is David Goldberg. I'm a transplant hepatologist at the University of Pennsylvania. I've been here on faculty for four years and five years before that as a GI (Gastrointestinal) and Liver Fellow. I do a mix of clinical and health services, epidemiology research, using large administrative databases, but also some clinical trials in hepatitis C, and obviously as a hepatologist have a large patient cohort with hepatitis C and have been at least involved in this since fellowship long enough to have seen the evolution of hepatitis C care over the past nine years.

DR. BERENSON: Okay. And I guess before we get started in asking you some questions, are you -- are you knowledgeable as much as you need to be as far as you're concerned about what the PTAC

is and what our mission in life is, what we're doing, why we're talking to you?

DR. GOLDBERG: Yes. So, actually, I had a call with Janet earlier today --

DR. BERENSON: Okay.

DR. GOLDBERG: -- Janet Pagan-Sutton, and I had actually spoken with Joanne Levy at Penn, at the Wharton, at the Leonard Davis Health Institute, who explained PTAC to me, and so I think I have a general sense of what it is and what my -- how I can help out potentially.

DR. BERENSON: And have you had a copy of the proposal that we're reviewing? Have you had a chance to look at that?

DR. GOLDBERG: Yeah. I've gone through it a couple times and taken notes and actually a couple things also that I had, sort of questions I had raised or concerns and whatnot as well, so --

DR. BERENSON: Okay, great.

And I should say that we have had a relationship with the University of Pennsylvania clinical staff but haven't been really using it very much up till now. So we very much thought we should start doing that. We scheduled this call a

number of weeks ago, so it would get on everybody's calendar, not knowing to what degree we wanted to actually delve down into clinical aspects of care. So it's not clear how long we'll actually go. If we don't go too long, you shouldn't take it personally. It's because -- it would be because some of the aspects of care are really not -- of the payment model may not be related specifically to clinical issues, although there are some that I personally want to pursue.

So -- so that's just by way of introduction, and we would certainly want to get some observations from you about the model since you've spent the time in reviewing their proposal.

So, Sarah, is there any more I need to do by way of preliminaries, or are we ready to just jump into -- to talking about the proposal itself?

MS. SELENICH: I think you're ready to jump in, and just, again, a reminder to make sure that you state your name as you kind of ask questions or provide a response, just for the reporter.

DR. BERENSON: All right. Well, then I'll get started a little bit. I'll get started. I

think what we'll do is have members of the PRT or other staff ask questions. To the extent that you have a chance to then make your comments in response to our questions, that will be the way to do it. If after our questions run out, you still have some other observations you would like to make, Dr. Goldberg, we'll provide you an opportunity to do that.

DR. GOLDBERG: Okay.

DR. BERENSON: So one of my initial questions is -- relates to the sort of clinical complexity of managing treatment for hepatitis C. I was a general internist. Grace is a general internist. I'm aware of the ECHO (Extension for Community Healthcare Outcomes) program, which provides mentoring by telemedicine to primary care physicians by clinical specialists, experts in hepatitis C. There's some reference in this proposal to not having enough hepatologists and gastroenterologists to primarily care for the drug management of hepatitis C, so a reliance on primary care. Could you just give us a little sort of perspective on the competence of -- of primary care physicians and being the primary managers of drug

treatment for hepatitis C, and are there any particular issues that -- that need attention?

Most of this proposal is around care coordination, with just some suggestions of specialists' expertise being called upon. What would you tell us about that issue of primary care physicians being the primary managers of hepatitis C treatment?

DR. GOLDBERG: So, you know, as I read the grant, I thought, you know, through this, and I think it -- it makes a lot of sense. So, you know, for those who practiced 10, 15 years ago when we were using interferon-based therapy, I don't think this would have been a feasible proposal because of the toxicities of the drugs, the medication interactions, and things like that.

The new therapies that we have now, you know, when we treat a patient, the side effects are really few and far between. So the sort of management of someone once they're on therapy usually does not require much sort of direct physician attention, but there still is a sort of lot of work that goes into the preparation and to the actual treatment.

And to sort of give you what our -- you know, what we have at our system is that, thankfully, our health system has a 340(b) designation. So, you know, when patients get medications through our pharmacy, there's a discount when the hospital buys it and whatnot. So we have had an arrangement with our own pharmacy where they help with the prior authorizations, but they also provide our clinic with a Pharm.D. (Doctor of Pharmacy) to deal specifically with hepatitis C medications. And that deals with getting the prior authorization, reviewing the patient's, you know, drug-drug interactions, reviewing medication administration with the patient, calling them to follow up that they're compliant. So those are all things that, you know, we do, in essence, unfunded.

I'm not doing any of that. I also have a sort of medical assistant (MA) that is following up with the patients as well, sending them the labs and things like that. So I think there's a lot of care coordination that goes on that's sort of beyond the scope of the physician, and if I didn't have those sort of aspects, I would not be able to

treat the number of patients that I treat.

As a physician, if I see someone with hepatitis C -- and I think this is the one thing that I don't know if they address sufficiently is -- if I see someone with hepatitis C, they don't have cirrhosis, they have early- or intermediate-stage fibrosis, I literally will get the basic tests, figure out which genotype they are. There's six main genotypes, and depending on the formulary and the costs and all that, different drugs are used for different genotypes. I then will write the prescription, and then the Pharm.D. and the medical assistant really take most of the legwork in sort of coordinating with the patient, reviewing the meds with the medic -- the patient had to take them.

Maybe I'll see them while they're on therapy, but usually, I don't see them until even after they complete therapy. And it's, you know, a rarity that I get any messages about those patients in terms of side effects or anything like that, except for, you know, patients doing well, viral load undetectable. There are a few medication interactions that they have to deal with, but from

the physician standpoint, it's not necessarily that much that I have to deal with. So I think having a primary care doctor leading that is completely feasible because of the safety of the medications and the efficacy.

Now, the one thing that I don't -- I felt in reading this that was a little bit unclear is I'm not sure if someone who has cirrhosis necessarily -- how a primary care physician -- A, how comfortable they'd feel treating it and, B, you know, if that's the best way, because there's -- and, again, maybe this is where the telemonitoring or telehealth would fit in. But if someone has cirrhosis and they're well compensated and they had no complications, then it's not as complex. But if there's any complications, there are some increased risks of, you know, worsening symptoms during therapy, and then there also becomes the more nuanced discussion of is this someone a transplant candidate, is not; if so, is treatment right?

But for the run-of-the-mill patient with hepatitis C, I think it's completely conceivable for a primary care physician or even, you know, physician extender, an NP (nurse practitioner) or a

PA (physician assistant), to really be leading the care of the patient. And in our health system, a lot of the sort of run-of-the-mill hepatitis C never see a physician. They just see the PA or NP.

DR. BERENSON: Okay. That's very helpful, and it is true, I assume -- I mean, somewhere in this proposal, there was a breakdown of the number of patients who just had fibrosis and then moved on ultimately to serious cirrhosis. I assume, then, that that's the relatively small percentage that would be, in fact, that kind of a clinical dilemma where you -- say more, actually, about how treatment could actually worsen the patient, at least in the short term. What's that all about?

DR. GOLDBERG: So there had been some sort of early data that, you know, if people had cirrhosis and they have some liver test abnormalities, there is a rare risk but some -- not zero risk of hepatic decompensation. If it's a drug-induced liver injury, if it's a metabolism thing, it's unclear, but, you know, most of the studies, at least that have been published thus far, even of people with cirrhosis have been those with well-compensated disease.

Now, they're doing more and more studies with people that are sicker, but some of the drugs, depending on how -- what type of regimen it is, in someone whose liver not just has cirrhosis but cirrhosis and, you know, their bilirubin is elevated or their INR (international normalized ratio) is elevated, there may be some risk of worsening of liver function on therapy. It's a rare event but not a zero-risk event.

DR. BERENSON: And, at this point, there's no evidence-based guidance that patients are too sick to receive the drug treatment?

DR. GOLDBERG: Well, there are two -- there are -- it's twofold -- well, threefold. One, it depends on the regimen. So certain regimens that rely on something called a protease inhibitor, a medication like Zepatier, for example, that Merck makes can't be used in significant liver dysfunction because it's metabolized by the liver.

Secondly, if someone's MELD (Model for End-Stage Liver Disease) score, which is a sort of calculated value based on their creatinine, their INR, their bilirubin, and their sodium, is higher, there's not a lot of data about treating people

with a score that's, you know, above 15 to 20.

And the third thing, which I think is a very, very small number in the broad population that would be considered -- but if people are going to be considered for a liver transplant, for example, and their score is somewhat high, we actually, a lot of times, will defer treatment until after transplant, so they can get transplanted with a donor that actually already has hepatitis C. But, again, that's few and far between.

DR. BERENSON: Okay. Let me turn to my colleagues to start asking some questions. Grace, why don't you go next if you have some.

DR. TERRELL: My question is very specific. You said you had folks doing the care coordination for you in your practice. If this is -- this is about a payment fee-for-care coordination that they are asserting the current care coordination fees that are in the fee schedule are not effective for or ideal for, for some various reasons. So are you -- what sort of things is the actual care coordination used for from a, you know -- in your particular practice or ought to

be used for with respect to adherence or education or whatever? What's the exact -- you know, is there any sense you have of the amount of time per patient or the cost that takes? And is your clinic actually using any of the current care coordination fees?

DR. GOLDBERG: So I'll answer the latter question. I don't know if we're using those care coordination fees. I will have to plead ignorance on that. My suspicion is no, but I don't know for sure.

In terms of the time, you know, it might -- it really depends, obviously, on the patient. Now, part of the thing that I read about was that there, we're talking about care coordination beyond just a hepatitis C treatment, but the integrated mental -- the mental health and behavioral health, that is not something that we do in our clinic. So that's not something that's integrated into the care that we deliver.

I would say on average, you know, between, you know, the pharmacist calling the patient ahead of time to discuss it, giving them a phone education about the medication interactions, and

the -- you know, it's probably during the course of a 12-week therapy, probably three to four calls that they get about ensuring that they're up to date on their medication and they're compliant. It is several hours' worth of work that they're doing.

Now, I don't know the exact time that they're spending. It depends patient on -- patient to patient, but there are frequent calls that are made to remind people about taking the medications, about taking the labs, and I can tell you, if we didn't have that, if I was just a general GI doctor in practice, I don't know how I would be able to treat someone with hepatitis C.

I think in the general community, gastroenterologists that I speak with is -- and maybe they don't know about these care coordination billing codes -- are -- don't like to treat it because there's a lot of time and effort that goes potentially unbilled.

DR. TERRELL: So do you know of any data out there with respect to some of these enhanced services like behavioral medicine integration into a care coordination process that has any outcomes or impact on outcomes for these patients?

DR. GOLDBERG: Not that I'm specifically aware of, but I haven't sort of reviewed it in depth, that aspect of it.

DR. TERRELL: Thank you.

DR. GOLDBERG: And, again, it also depends obviously on the patient population you're treating, how prevalent, you know, underlying psychiatric or behavioral diseases are. I think being at the University of Pennsylvania, I potentially get a sort of somewhat biased view of what they may be dealing with in New York, having been -- I was a medical student at Mount Sinai and a resident at Columbia, and I think the patient cohorts that were being treated there at some points were different than what I may be seeing in my practice.

DR. BAILET: So this is -- this is Jeff.

And I sort of -- just listening to the conversation, I don't know about the other Committee members, but my initial sort of reaction was, you know, based on the fact that you don't hear a lot about these patients once they initiate therapy -- and I won't say autopilot, but there is -- there is -- doesn't seem to be a lot of complex,

challenging clinical issues that arise during treatment other than the usual suspects of compliance and potentially come questions about medications along the way.

I started to question whether, you know, what -- how much would be involved or do they need -- do they need additional supplemental support to cover those inter-treatment or intra-treatment challenges that may arise. But I also, then, as you continue to describe it -- it seems like your team -- your team does engage these patients on a regular basis during the 12 weeks of treatment, and I guess the question -- the question maybe we -- the Committee needs to digest is, are the coordination codes and the payment for those codes today sufficient to cover that work, so that's just one point.

And if I -- I guess I'd like to just ask. Did I misinterpret your comments about, you know, not hearing a lot about these patients during treatment?

DR. GOLDBERG: No. I don't think you did. I think from the sort of medical aspect of what I'm doing, I don't hear about them often, but there's a

lot of behind-the-scene stuff that's going on that we are able to do because of support from our health system and from sort of research dollars that my boss has put into this. But there's -- it's not as simple as like I prescribe the medication and nothing happened. It's just from the physician's standpoint, there's not necessarily that much.

DR. BAILET: Thank you.

And so my question then will focus on one of the back bones of this model is generating savings, avoiding complications. Particularly, they talked about ER (emergency room) visits, and what I was curious, Dr. Goldberg, is what is driving or what are driving these patients to the emergency room. Is there something specific about hepatitis C patients? I understand people with severe cirrhosis have all kinds of complications that end up and drive them to the ER, but that's the exception rather than the rule for the majority of the patients, I believe, that they're referring to. Do you have a sense of why these folks are ending up in the ER?

DR. GOLDBERG: So that is actually one of

the things I put in my notes, that Table 2 data about the decreased ER admissions within that first year -- I didn't actually -- couldn't think of a plausible explanation for that, actually. Sorry. Table 1. And I was actually thinking the same thing.

If someone with cirrhosis or really decompensated cirrhosis, I would 100 percent believe that if I treat them, get rid of the hepatitis C, we know that, you know, in the majority of people, it could prevent further decompensation or allow the liver to recover.

If someone with hepatitis C who doesn't, you know, have much scarring, which is the majority of people, I actually don't -- cannot think of a reason to explain Table 1. And now maybe those are people that are going to the ER for non-hepatitis C-related issues, perhaps behavioral health issues, but if I have someone with -- and that was one of the things that I was sort of questioning.

If I have a patient who has, you know -- it's a 60-year-old person getting a physical for the first time, gets diagnosed with hepatitis C, and they have stage 2 liver disease, there is

nothing related to their hepatitis C that would be bringing them to the emergency room.

So when I think about the cost savings of treating hepatitis C, if someone has really bad liver disease, there is the cost savings of sort of preventing the liver from getting sicker, but for someone with early-stage disease, it's really cost savings many, many, many years down the road. And one of the things in terms of the SVR (sustained virologic response) rate as the primary metric -- and, again, maybe this speaks to the risk adjustment model that will develop is might it lead to actually overtreatment of people and not cost savings. So someone with stage 2 disease with a limited life span from heart failure or cancer or something like that, to me, I don't treat, because there's no -- I don't see any medical benefit, and there's not going to be a cost-savings benefit if someone has a very limited life span.

Long answer to your question, but I'm unsure about the ER. It doesn't make sense to me, to be honest.

DR. BAILET: Well, and you -- in your answer, you touched on one of the concerns that the

Committee has globally about alternative payment models, which is do no harm. And it sounds like there -- I don't -- I didn't see it in the way they set this up -- that there should be some discrimination -- positive -- a positive hep C test in a vacuum does not automatically drive treatment.

DR. GOLDBERG: Right.

DR. BAILET: And I didn't see that in their -- maybe I missed it, but I didn't see some governance around selection on early -- patients who have just -- just maybe fibrosis. I didn't see any discrimination about treatment selection.

DR. GOLDBERG: So one thing there, I didn't see much. So there's the -- the early-stage treatment, there are debates about if everyone should be treated. Now, the new guidelines from the AASLD (American Association for the Study of Liver Diseases) and the IDSA, Infectious Diseases Society of America, that are going to be coming out are going to say treat everyone.

From people that had been part of that, there were some discussions about, well, that's going to lead to overtreatment of people, but part of the concern was that insurers were restricting

therapy too much.

Now, I think if someone is 40 -- you know, a 60-year-old with stage 1 disease and no other major medical comorbidities, an argument could be made, I think, about is treatment cost effective. You know, if money is unlimited, you treat them. But that's not the case.

My concern, though, was less of the over-treating the early stage, but over-treating people that are not going to derive a benefit, be it -- really, and they didn't cover that, like when is someone not a candidate?

DR. BERENSON: So just picking that up a little bit, this issue of comorbidity, at the University of Pennsylvania, if a patient, let's say, has well-established hypertension, congestive heart failure, is being seen either in cardiology clinic or in general internal medicine clinic or something, will they manage the hepatitis C treatment, or will there always be a referral into your program for that?

DR. GOLDBERG: There will always be a referral, but I think that's partly because the practice in Pennsylvania, it is a litigious

practice. But I think it's so uber-specialized, our general GI doctors at Penn won't treat hepatitis C.

DR. BERENSON: Wow.

DR. GOLDBERG: But that's, I think --

DR. BERENSON: Wow.

DR. GOLDBERG: But, now, that's, I think, a Penn thing and not the general community.

DR. BERENSON: Okay. Let me pick up one other thing. Did you get a copy of the Q's and A's that we sent to --

DR. GOLDBERG: Yes.

DR. BERENSON: So I was interested in your emphasis on the role of the pharm -- the pharm doc or the pharm specialist and their response to who the care coordinator is, the qualifications of the care coordinator was. The educational level preferred for care coordinators is a bachelor's degree with a focus on public health, biology, physics, psychology, and education. So I guess the question, does it look to you like in their model, the physician is a little more active on clinical issues, and therefore, the care coordinator doesn't need to be a Pharm.D. because they're not expecting

quite the same level of interaction and expertise that you are delegating at the University of Pennsylvania? I mean, is this -- on a quality basis, does this seem to you a reasonable approach?

DR. GOLDBERG: I think it -- I mean, I think especially when it comes to the issue of, you know, medication interaction, if there's not someone with that degree of training, it's going to have to be the physician who deals with that, which is not a simple thing, because there's, you know, a lot of different medications, a lot of different potential interactions and things that -- I'll be honest -- I overlook, and I don't know every one of them. So I think that might be a gap in the care coordination model, unless they feel like the onus is on the physician, you know.

DR. BERENSON: And you think that a general -- I mean a general internist or a family physician may be not -- well, yes -- would be able to manage those drug interactions and manage the drugs with reasonable mentorship?

DR. GOLDBERG: Potentially. But, again, you know, that takes time. So I guess you could argue as part of the payment model, they're being

covered for time, but I don't even know how often the hepatologists in regular practice are doing it versus some other Pharm.D. or something. But it's -- it's not an inconsequential amount of time. You know, certain of the statin drugs can't be used or you have to lower the dose. PPI (proton pump inhibitors) dosing has to be changed or whatnot.

I'm not sure if the average -- you know, potentially, the average primary care doc may feel comfortable with that, but, again, it is -- does take some degree of effort and understanding, you know, because you're going to have to then sit there and look through Lexicomp or whatever for the drug interaction or have a list and for every patient say, "Oh, they're getting Harvoni. This statin needs to be decreased. This PPI" -- you know, they can do it, but again, it's going to take time.

DR. BERENSON: What are the major reasons why somebody in your experience doesn't complete the full course of treatment?

DR. GOLDBERG: You know, with these new therapies, I can't recall a patient not completing the therapy. I've not had anyone ever stop, you

know, therapy due to side effects. I've not -- yeah. Even noncompliant patients have almost always completed therapy. Some people have forgotten doses, but I can't recall a patient that didn't complete therapy.

DR. BAILET: What about -- what about -- this is Jeff. What about the challenge in getting patients to accept and initiate therapy? Has that -- has that been a hard sell?

DR. GOLDBERG: Not at all, to be honest. I think most of the patients want to get rid of it. They say, "I want to get rid of this hepatitis C."

We've had patients who, you know, call us because like, "Oh, I saw the commercial on TV that you can now treat me easily. I want to get treated." It's actually been a very easy sell.

DR. BAILET: Thank you.

DR. TERRELL: Based on what I'm hearing is that your clinical experience is different than what was being described in the proposal, what is the sociodemographics of the population that you're taking care of at the University of Pennsylvania? Is it -- or do you have a high population of underinsured or those that have other, you know,

social challenges as part of your practice?

DR. GOLDBERG: Right. So we don't -- our -- we don't see patients without insurance. You have to have some form of insurance. So we're not seeing uninsured. We are seeing, you know, a sizeable population with, you know, Medicaid insurance.

DR. TERRELL: Okay.

DR. GOLDBERG: But, you know, within Philadelphia, it's very much sort of segregated. The West Philadelphia population will come to Penn. The North Philadelphia population goes to Temple. South -- you know, so, you know, very few non-English speakers, which is different than many of those hospitals in New York. Having been at Columbia and Mount Sinai, a lot of Spanish-speaking patients there. Never see it here. So language is a barrier, and it's almost nonexistent at our hospital.

There are people from -- that are, you know, low-socioeconomic status and what not from the West Philadelphia community. Many of them don't necessarily make it to our system. They may not get referred or whatnot. So I think it's a

little bit different than having practiced in New York.

DR. TERRELL: Thank you.

I guess my issue is, is there any care coordination benefit function that's population-specific that we need to think about with respect to outcomes, which really gets complex, you know, as you're trying to think about universal payment models?

DR. GOLDBERG: The ones -- and, again, maybe this is outside of the scope, and again, this is new to me. But nothing in the coordination models that I saw -- and maybe I missed it -- spoke about sort of, you know, as part of the care team is, you know, interpreters or things like that with the -- given the large population of non-English speakers that may have hepatitis C in these communities. And I don't know if that ever is part of the coordination model, but --

DR. BERENSON: Well, those hospitals really should have translation services for all their -- for all their patients, regardless of what conditions they're dealing with. That's of issue, but I'm not sure it's --

DR. GOLDBERG: Yeah.

DR. BERENSON: -- specific to hepatitis C.

DR. GOLDBERG: Right. Agree.

DR. BERENSON: Yeah.

REPORTER: Was that Dr. Berenson speaking?

DR. BERENSON: Yes. I'm sorry. That was Dr. Berenson. I figured you can tell my drawl, but yes, that was me.

REPORTER: I'm finding it difficult.

[Laughter.]

DR. BERENSON: I'll do better. I'll do better.

Were you surprised -- this is Dr. Berenson speaking. Given your New York experience that they -- apparently, they're citing a source that says that only 17 percent of their estimated 150,000 residents with HCV are under treatment or have received treatment? Is that -- does that sound plausible to you?

DR. GOLDBERG: A thousand percent. I mean, I think there's just some -- I thought I read a study that like in Colorado, only 10 percent, because many patients don't get tested. Even when

they get tested, they don't come to care, and then insurance doesn't cover it. So the 17 percent seemed completely plausible to me.

DR. BERENSON: Okay, okay.

So we've got a huge public health problem, and the question is whether this is the most effective way to address it -- or is an effective way to address it.

Other questions, Grace or Jeff?

DR. BAILET: Yeah. This is Jeff.

One question I had is the consideration for transplant and the mechanics behind that. That typically -- you know, that typically occurs when folks get sent for transplant evaluation, so there is some discernment in discrimination as these patients flow through the system, and it wasn't obvious, as I looked at their model, where or if that was occurring. Did that -- did you just -- is that just not an issue that people -- that's an automatic, people go through that process, and they didn't speak to it because it really -- it's common practice or -- I'd like your opinion on that.

DR. GOLDBERG: No. So that was actually one of the things that I wrote as not described.

It's how they were going to sort of manage the care coordination, not just of transplants, eligible patients, but just patients with cirrhosis. And that was actually one of the concerns I had, is that, you know, they don't describe where that flow is, and I don't think it's natural in any way, shape, or form, because if someone has early-stage hepatitis C, the only treatment is to treat the hepatitis C. You get rid of that, you really -- like if I see a patient with hepatitis C and they've not much scarring, I treat them. If they're cured, I never see them again.

But the people with cirrhosis, there's two questions. There's how bad is it and is transplant something that's considered, and we know that there's under-referral for transplant. But then once someone has cirrhosis, the care isn't just cirrhosis, it isn't just hep C, but it's screening for liver cancer, screening for esophageal varices. And I didn't see that in the model and described anywhere, and that was actually one of my concerns is, you know, what is the sort of trigger point for the telemonitoring or for referring, you know, because I would argue that anyone with cirrhosis,

you know, at the very least, there has to be some sort of discussion with a liver specialist by the primary care doctor, and how does the coordination of care for the cirrhosis fit in it, are they completely just disregarding the cirrhosis care as part of this, which I don't -- I don't think it's appropriate, because they're very much degraded. And it still might be 15, 20 percent of the patients that has cirrhosis, and that aspect of the care was sort of -- I think sort of concerningly, completely undescribed.

DR. BAILET: Yeah. Yeah.

And if this model takes hold, think about you're actually channeling these patients through this process in a concentrated -- concentrated manner, and that will become a bigger issue if this -- if this is -- if that side or that aspect of the more acute patients isn't addressed.

DR. GOLDBERG: Right. And, you know, so we've published and others that, you know, if you look at people with cirrhosis in general and not the cause, you know, the compliance with liver cancer screening guidelines is maybe 20 to 30 percent. And that's a big hole, and again, the

majority of those people in the greatest risk is in those with hepatitis C cirrhosis. So I think that's a glaring omission from this model.

Now -- and I think that how it should be addressed is, is it then going to be the primary care doctors who manage the hepatitis C in the cirrhosis complications, or is it -- just imply that they're going to get referred to a liver doctor, but if that's implied, that has to be described and sort of coordinated somehow, because the worst thing is that the focus is just treating hepatitis C. The primary care doctor treats it. Someone has cirrhosis, but there's not any coordination of care, and then two years later, they come in with an incurable liver cancer and they die.

DR. BAILET: That's a bad outcome.

DR. GOLDBERG: Right. And I think the people -- patients may think, "My hepatitis C is cured. I don't need to see a doctor anymore," and if they have cirrhosis, that's not the case, yet we see that not infrequently where people fall off the map as a result.

DR. BAILET: Thank you.

DR. BERENSON: Grace, do you have any more?

DR. TERRELL: Nope. I'm good.

DR. BERENSON: Jeff?

DR. BAILET: No. I found this to be extremely helpful. Thank you.

DR. BERENSON: Dr. Goldberg, do you have any other comments that we haven't addressed so far that you would like to share with us?

DR. GOLDBERG: Yeah. I just have sort of one -- I guess two issues, and I don't know if this is standard in these different PTAC models, but the issue of the risk adjustment that they talk about in their model has their risk adjusting at the level of the center or the facility is -- they don't describe what's going to go into the risk adjustment model that I saw, because in reading -- sorry -- you know -- sorry. They describe a risk -- a risk-adjusted facility score, but they don't necessarily describe what they're going to base that score on. And, you know, on question Q3.5 on page -- what page is this? -- page 18, they just say the components will be -- estimate a facility-specific SVR rate as described in the literature,

but the citation 61 that they're talking about is -- has nothing to do with hepatitis C. It's a methodologic paper from annual review statistics and its application, and they don't actually say what's going to be in their score. So that's one concern, is how good of a risk-adjusted model is it going to be.

But the second, as it pertains to that, is -- you know is SVR alone what you care about? Now, obviously, you care about curing the hepatitis C, but -- and maybe this is beyond the scope of what the PTAC does, but it's the sort of downstream complications that you really care about.

But I know they talk about the payment model and how you can opt out after step one of the -- phase one of the process, but might this lead -- you know, the perverse, I guess, incentives or the unintended consequence of this model be that, you know, they're cherry-picking those that are going to -- people -- you know, because we all know that we have risk-adjusted models and people behave differently, maybe not intended, but that they're sent -- the facilities may cherry-pick sort of the ideal patient, the patient with early-stage disease

are compliant, and not choose people that had negative risk factors that may not be in the model, you know, because they don't say what's in the model, and there may be clinical factors, but there may be sociologic factors that may make someone less likely to complete therapy that may cause people to opt out of that patient being treated after step one and then giving back the -- whatever it is, the $460 at that point, and on the flip side leading to inappropriate treatment.

So, you know, if the model, for example, has -- which they don't say has, you know, active, you know, injection drug use, as an example, if that's not in the model as a negative predictive factor, but their data that suggests that people with IV drug use may be less compliant and may not get SVR, if facilities then opt out of treating those people, those, you could argue, might be the ones that you want to most importantly target from a public health perspective, because it's almost treating as prevention, because they may then pass it to other people.

So that was a concern of mine, and again, I obviously defer to you as to what is done in

these models and how granular, but I wanted to see more about what was going to go into the model and how it may have potential unintended consequences.

DR. BERENSON: That's well taken. Thank you.

Anything else?

DR. GOLDBERG: The other thing, I guess -- and this, again, last question then -- is -- or two other things -- is that they mention that all employee physicians treating patients with hepatitis C at one of these facilities would be required to participate. I'm assuming that means anyone who's ever treated hepatitis C but what sort of opt-out there might be.

And as a sort of methodologic, when they talk about their cost estimates and potential cost savings -- again, I know Medicare payment models of medications. But they mention how they use the cost of medications based on the VA (Veterans Administration) prices, and I don't know how applicable that is in a Medicare/Medicaid framework, and if that may have made the numbers of cost savings look better because the VA is able to negotiate much better prices than others.

DR. BERENSON: Yeah. Yeah. We've had an ongoing issue with all -- almost all of the proposals, about proposals that seem to be specific to a particular provider versus generic models that could be more broadly applied. It seems like the Health and Hospital Corporation of New York has been able to achieve this VA discount, but that would not be available if this were -- to most other providers if this became a generic model rather than a fixed model for that particular organization. And so I think you've identified a bad issue which we keep facing.

DR. GOLDBERG: And I guess one last thing clinically in terms of the primary care provider, because we encounter this, not -- it's not rare. Patients who have prior treatment failures who now have resistance to certain therapies, I still in those cases have to talk to my boss, who has been doing this for 30 years, to decide on the optimal therapy, and those are not straightforward cases. And maybe those will be the ones that are built into the telehealth discussion, but there are more complex cases of people with multiple resistances at different points of the hepatitis C virus that

should -- you know, would be important to sort of have, you know, someone else as part of that care. And maybe that's what part of the care coordination is.

DR. BERENSON: Are you aware of the Project ECHO (Extension for Community Healthcare Outcomes) approach?

DR. GOLDBERG: Yes.

DR. BERENSON: Okay. And do you have any sort of general views about how well it works or --

DR. GOLDBERG: I think, you know, from my perspective, having read their papers, I spoke once to [unintelligible] -- I mean, I think it sounds like a great program. I think the one thing, that their focus has been really on the hepatitis C, and there's that other aspect of liver care that is less a part of it, which, again, that's my still concern here, is what about the 15 or 20 percent with cirrhosis? Where do they fit in?

DR. BERENSON: Yeah, yeah. Okay. No, that's all very good points.

So I will second Jeff's comment that he made earlier that this has been very helpful and should be a model for all of our work when we get

insights from clinical experts in these areas. You obviously know more than just clinical. You're actually delivering care.

So I don't think we'll need to call on you again, but I assume you're available if we see the need for that and --

DR. GOLDBERG: Absolutely.

DR. BERENSON: In the meantime, we very much want to thank you for the time you took in reading their proposals and thinking about it and then spending an hour on -- nearly an hour with us, so thank you very much.

DR. GOLDBERG: Oh, my --

DR. BERENSON: Does anybody else have anything that we need to say before we let Dr. Goldberg go?

DR. TERRELL: Thank you.

DR. BAILET: Thank you.

DR. GOLDBERG: Oh, thank you. It was my pleasure. I was happy to help.

DR. BERENSON: Thank you much.

[Whereupon, 12:55 p.m., the conference call concluded.]