

May 18, 2017

Physician-Focused Payment Model Technical Advisory Committee
c/o U.S. DHHS Asst. Secretary for Planning and Evaluation
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Proposal for a Physician-Focused Payment Model: 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

Dear Committee Members,

On behalf of Project INSPIRE and the New York City (NYC) Department of Health and Mental Hygiene (DOHMH), please accept our submission for a Physician-Focused Alternative Payment Model (APM) for PTAC review.

Project INSPIRE is a Center for Medicare & Medicaid Innovation (CMMI) awardee that is a collaboration between the NYC DOHMH, Weill Cornell Medical College, two managed care organizations, HealthFirst and VNSNY CHOICE and two clinical partners, Mount Sinai Medical Center and Montefiore Medical Center. These partners have developed an innovative model of care coordination for treatment of the HCV for high-needs patients with multi-morbidity in New York City.

We believe that implementation of this proposal will result in improved quality of care, reduced mortality and will produce significant cost savings to CMS as is intended by MACRA.

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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

Prepared and submitted by Bureau of Communicable Disease (BCD) at New York City Department of Health and Mental Hygiene (DOHMH)

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Table of Contents

	Page
1. Project INSPIRE Abstract	4
2. Background and Model Overview	5
3. Criterion 1: Scope of the Proposed APM	6
4. Criterion 2: Quality and Cost	8
5. Criterion 3: Payment Methodology	13
6. Criterion 4: Value over volume	19
7. Criterion 5: Flexibility	20
8. Criterion 6: Ability to be evaluated	21
9. Criterion 7: Integration and Care Coordination	21
10. Criterion 8: Patient Choice	22
11. Criterion 9: Patient Safety	22
12. Criterion 10: Health Information Technology	23
13. Appendix A.1: Expected Cost of Care Averted Calculation	25
14. Appendix A.2: Complex Chronic Care Management Codes	26
15. Appendix A.3: PFPM Proposal Endnotes	28

Project INSPIRE Abstract

Project INSPIRE is a demonstration project funded by a three-year Centers for Medicare & Medicaid Services (CMS) Health Care Innovation Award (HCIA) received by the Fund for Public Health in New York, the NYC Department of Health and Mental Hygiene and five community partners – Mount Sinai Medical Center, Montefiore Medical Center, Weill Cornell Medical College, VNSNY Choice and Healthfirst – to focus on treating HCV in NYC.

Project INSPIRE NYC (**I**nnovate and **N**etwork to **S**top HCV and **P**revent complications via **I**ntegrating care, **R**esponding to needs and **E**ngaging patients and providers) provides Medicare and Medicaid beneficiaries a comprehensive model of care that combines the use of care coordination, health promotion, medication adherence support and expert tele-mentoring consultation to support hepatitis C infection-centered primary care integrated with mental health, behavioral health and social services to achieve the Triple Aim¹:

1. *Better care*, by increasing the number of patients starting hepatitis C therapy, strengthening management of behavioral health problems, reducing hospitalizations and emergency department visits, and maintaining a high level of satisfaction among enrollees;
2. *Better health*, by increasing hepatitis C cure rates, reducing hepatitis C-related complications, and increasing screening for depression and alcohol abuse; and
3. *Lower costs*, by reducing expenses from preventable hospitalizations, emergency department visits, and complications of hepatitis C infection

The value proposition associated with implementation of a payment model supporting the INSPIRE care delivery model is far-reaching across many different health sector participants.

- For policymakers, the goal is to substantially impact liver-related population health metrics by reducing the prevalence of end-stage liver disease and liver cancer due to chronic hepatitis C by increasing cure rates among infected patients. Policymakers may also be interested in value-based efforts that achieve population health milestones, such as the now realizable goal of hepatitis C elimination in the United States.
- Patient participation will likely improve the quality of care in the diagnosis, treatment and cure for hepatitis C and co-morbid conditions by providing coordination of care, care navigation, medication adherence support and better access to care through personal attention, reminders, and referrals for support services.
- For payers, the opportunity to reduce both short- and long-term healthcare costs by preventing ineffective health care utilization and the onset of end-stage liver disease and liver cancer is potentially significant.
- For hospitals, the model presents the proposition of expanding hepatitis C health services to the primary care setting through training and knowledge dissemination, and consultations with specialists allowing providers to treat more patients, which is ultimately necessary in order to achieve policymakers' population health goals.

Background and Model Overview

Almost four million Americans have chronic hepatitis C infection (HCV)^{2,3} and, without treatment, approximately 1.8 million and 400,000 persons may develop cirrhosis and hepatocellular carcinoma, respectively. Recent data show that, in over just five years, the number of new hepatitis C infections reported to the Centers for Disease Control & Prevention (CDC) has nearly tripled, reaching a 15-year high.⁴ In New York City (NYC), where an estimated 146,500 residents have HCV⁵, only 17% of these persons are estimated to have received HCV treatment.⁶ In 2015, the NYC Department of Health and Mental Hygiene implemented Project INSPIRE, an HCV care coordination model to promote patient medication adherence and self-efficacy to improve HCV treatment initiation and cure rates, and ultimately reduce healthcare utilization and costs associated with this patient population.

The Project is based on these assumptions: (1) a large proportion of persons in the U.S. infected with HCV in the 1970s and 1980s have developed advanced liver disease and will continue to develop severe complications of chronic HCV infection in the coming years, costing \$694M - \$1.66B per year in direct medical costs,⁷ and (2) a revolutionary change in HCV treatment now produces very high cure rates (>90%) for most patients.

Many individuals infected with HCV come from neighborhoods with underlying health disparities, including high levels of unemployment, poor health care access and poverty.⁸ Approximately 15–30% of persons with chronic HCV infection develop cirrhosis within 30 years. Of those with cirrhosis, decompensated, end-stage liver disease occurs in roughly 30% within 10 years, and liver cancer (or hepatocellular carcinoma) is diagnosed in another 1–3% per year.⁹ Liver cancer is one of the fastest growing cancers in the US, and 50% of cases are related to HCV infection. Chronic HCV is the leading cause of hepatic failure and accounts for approximately 40% of liver transplants in the US.^{10,11}

Approximately 75% of persons with chronic HCV infection were born from 1945-1964. This aging population is more likely to have additional chronic illnesses that can complicate or be complicated by HCV infection. An estimated 40% of persons living with HCV have co-morbidities, including behavioral health problems, substance use, and chronic diseases such as HIV infection, diabetes, and kidney disease.¹² Persons with a history of injection drug use, many of whom commonly have numerous co-morbidities, are at the greatest risk for HCV infection. The CDC recently recommended one-time HCV testing of all persons born from 1945-1965, as between 25 and 75% of them are unaware of their infection or the risks of advanced liver disease. Advances in HCV antiviral treatments have been fast-paced and a new class of antiviral agents was approved by the Food and Drug Administration (FDA) in 2013. New treatment regimens are easier to tolerate and achieve sustained virologic response (SVR)—cure—at a rate as high as or greater than 90%.^{13,14}

HCV screening is cost-effective as long as it is combined with early treatment.^{15,16} Nearly 57% of liver-related HCV deaths can be prevented if 75% more persons with HCV are identified and treated with medications that result in 75% cure rates. For NYC specifically, it is unlikely that the 40-50 hepatologists currently practicing could manage and treat all new patients with chronic HCV infection. This assumption is likely to hold across the U.S.¹⁷ In 2012-2013, DOHMH demonstrated in its Check Hep C NYC program that clinicians in primary care clinics, trained via telemedicine, can effectively manage and treat HCV infection.¹⁸ Researchers using

the Extension for Community Healthcare Outcomes (ECHO) model have found similar results.^{19,20}

Patients with chronic illness and co-morbidities have better outcomes if treated in an integrated medical care system, where they can receive all or most services in one location.²¹ Integrated medical and behavioral health service models, which have demonstrated utility in environments where HCV prevalence is substantial, are rare. With the recent expansion of Medicare monthly chronic care management codes, key supportive services (such as health promotion and medication adherence support that are critical for patients to achieve self-sufficiency and treatment completion) are now reimbursable to providers and can foster creation and adoption of a payment model to support integrated care leading to a cure for HCV.

Criterion 1: Scope of Physician-Focused Payment Model (PFPM)

Q 1.1: What types of physician or other eligible professionals' practices would be able to participate in this payment model? How many physician or other eligible professionals' practices or numbers of physicians or other eligible professionals have expressed interest and willingness to participate in the model if it is approved? The Project INSPIRE payment model targets employed physicians at hospital-based outpatient clinics. However, the INSPIRE payment model can support inclusion (via a tele-mentoring component) of a wide mix of physicians, including infectious disease specialists, gastroenterologists and primary care providers (PCPs). Two-thirds of INSPIRE providers (24/35) are internal medicine physicians. The [Agency for Healthcare Research and Quality](#) estimated over 71,000 practicing primary care physicians specializing in general internal medicine in 2010.

Q 1.2: How many physicians or other eligible professionals and patients could participate if the model were expanded to scale? The Medicare population that is estimated to be infected with hepatitis C could participate in this model. A Milliman study of MarketScan 2013 data revealed a prevalence rate of HCV in aged beneficiaries of 0.3% (3% for dual eligible).²² The Kaiser Family Foundation estimated [55.5 million beneficiaries in 2015](#), with a historical rate of approximately [21% being dual eligible](#). This indicates a minimum Medicare population of 481,185 (0.9% of all 2015 beneficiaries) who could benefit from the proposed payment model.²³ Importantly, the proportion of dual-eligible Medicare beneficiaries has increased 60% from 2000 to 2013, whereas the comparative increase for only aged beneficiaries has increased by 20%. Thus, in the coming years, it may be expected that a subset of the Medicare FFS population with higher prevalence of HCV will become a more prominent component of Medicare's total costs.²⁴ Physician participation is identified in Q 1.1 and 1.6.

Q 1.3: How would the payment model work for physicians or other eligible professionals who are employed and for those that are independent, and what changes in compensation might be necessary for employed physicians or other eligible professionals, if applicable? As will be discussed in the response to Q 3.1, the initial bundled payment and any subsequent bonus payments (for a risk-adjusted facility-based SVR score meeting a benchmark) would be made to the facilities treating patients. All employed physicians treating patients with HCV at a facility would be required to participate. Employed physicians may structure their own individual bonus "triggers" as a result of the facility-based SVR score or as a proportion of the total annual facility

bonus received. However, the INSPIRE payment model does not specifically address those terms.

Q 1.4: Has the model been implemented by other payers, and if so, what was the experience?

The model has not yet been implemented. We may conduct a retrospective simulation analysis of reimbursements received among the INSPIRE clinical partners and review those results with INSPIRE's Medicaid managed care partners to gain further understanding of the model's acceptability among payers and providers.

Q 1.5: Are the costs or financial risks associated with the payment model feasible for small practices? Our proposal targets hospital-based outpatient clinics. In 2014, 53% of physicians identified themselves as employed by a hospital, up from 44% in 2012.²⁵ Physician practices may sub-contract with hospital outpatient clinics that have set-up the infrastructure to deliver care. In these cases, the physician would sub-contract a portion of the episode of care payment (see Q 3.1 for details on this target price) to the outpatient clinic.

Q 1.6: What is the size of the population anticipated to benefit from the model in its initial stages and if the model were expanded to scale? The data (from Q 1.3) indicate a minimum Medicare population of 481,185 (0.9% of all 2015 beneficiaries) who could potentially benefit from the proposed payment model. The INSPIRE payment model targets hospital-based outpatient clinics. These institutions offer services that are not otherwise available in the community to vulnerable patient populations. According to data reported by the American Hospital Association, hospital outpatient clinics serve a higher percentage of dual-eligible patients than physician offices (28% versus 19%), a higher percentage of disabled patients (23% versus 15%) and non-white patients (20% versus 14%).²⁶

According to [2013 CMS Statistics](#) (page 4), 24.2 million individuals received reimbursable fee-for-service outpatient hospital services under Medicare during 2011. This statistic represents approximately half of the total Medicare beneficiaries in that year (49%). Thus, by targeting hospital outpatient clinics, we are maximizing the reach of Medicare beneficiaries and also including a mix of underrepresented patients that will make future risk adjustments to our payment model clinically meaningful. The model could be expanded in a tiered approach: a first-stage expansion might include providers in federally qualified health centers, community health centers and rural health clinics (POS Professional Claim #50, #53, #72) and a second-stage expansion would add physician practice offices (POS Professional Claim #11). However, sub-contracting arrangements could be implemented before these formal extensions. It is possible that these arrangements could provide an additional income stream to large hospitals that establish, sustain and even expand robust care coordination programs.

Q 1.7: How are patients expected to benefit and how would they be protected against unintended consequences? For example, what protections would be in place to protect against the denial of needed care, overutilization, or less than optimal patient outcomes? Patients will benefit with support through HCV treatment (which includes overcoming economic and social difficulties associated with initiation and adherence) and cure as well as better learn to navigate the health

care system so as to avoid continued reliance on the emergency department (ED). Low-income patients have reported preferring this point of care over ambulatory services,^{27,28} even though this care is often more expensive²⁹ and of lower quality. For example, a recent study reported only 24% of patients with a confirmed HCV RNA+ test in an ED made follow-up appointment for treatment.³⁰ Thus the personal interactions involved within the INSPIRE care delivery model will encourage a conversion of thinking from what is considered routine care in the ED among disenfranchised populations.

Q 1.8: What are the expected spillover effects on Medicaid, CHIP, TRICARE/VA, or private health spending, or on those beneficiaries/enrollees, if any? There are likely to be spillover effects on Medicaid programs, as approximately 349,650 dual-eligible beneficiaries will be treated (see footnote #16 in Q 1.2). Furthermore, payment structures for value-based initiatives, including the model proposed here, may be expanded as a result of Medicare’s lead in implementing the INSPIRE payment model (see Q 3.2).

Criterion 2: Quality and Cost (High Priority Criterion)

Q 2.1: How is care delivery expected to improve in order to achieve savings or improve quality? Care delivery as a result of the INSPIRE intervention can be described to (1) reduce ineffective current health care utilization (e.g., ED visits) and (2) increase rates of SVR that will mitigate the long-term financial impact of untreated infection. SVR12, defined as undetectable serum HCV ribonucleic acid (RNA) levels 12 weeks after completing treatment, is used as a measure of treatment success. We present the impact of the INSPIRE intervention on the rate of ED visits before and after initial enrollment in Table 1.

Table 1. Impact of INSPIRE care delivery intervention on ED visit rate

INSPIRE Enrollment month	# Enrollees	Pre-enrollment observation period	Pre-enrollment ED rate per 1000	Post-enrollment observation period	Post-enrollment ED rate per 1000
July 2015	128	July 2014- June 2015	438	July 2015- June 2016	359

This ED metric describes the rate of ED visits among INSPIRE Medicaid enrollees in June 2015. It gives the rate of ED visits among INSPIRE participants from their enrollment month through the final month of observation available for analysis (June 2016). Thus it includes one year of observation after enrollment. Also included is a one-year pre-enrollment ED rate assessment among the same INSPIRE enrollees as comparison of the effect of the INSPIRE intervention on short-term health care utilization. We assessed the ED utilization among 128 INSPIRE enrollees in July 2015, six months after the project began initial enrollment. We calculated the ED rate, or the number of visits per 1000 persons, for both the year immediately prior to the identified enrollment month (July 2015) as well as the year immediately after. These are noted as the observation periods in the table. The results show an 18% decline in the ED rate for the patients enrolled in July 2015.

Providing integrated medical and behavioral care with comprehensive care coordination has been shown to reduce missed appointments and medication non-adherence as well as inefficient health care utilization, notably excessive use of inpatient care. For example, the Commonwealth Fund (2013) reported that care management programs reduced hospital admissions, re-admissions and ED visits by more than 20%.³¹ Our preliminary statistical analysis of the year one INSPIRE intervention has demonstrated similar effects for Medicare enrollees. For example, we have found a 1% increase in Part B payments in 2014 produced a 0.61% (95% CI: 0.59, 0.61) (p<0.001) increase in payments in 2015 for 22,827 non-INSPIRE FFS beneficiaries. For INSPIRE enrollees, however, the intervention demonstrated a 0.46% (95% CI: 0.33, 0.58) (p<0.001) increase in payments in 2015. Thus for year one of the three-year project, on average, 137 Medicare FFS INSPIRE enrollees experienced a significant 15% reduction in Part B payments.³²

Table 2 shows the current and projected cost reductions associated with treatment and cure. We have three tracks at the bottom of the table depicting total cost of care: one is for those receiving treatment and INSPIRE services, a second for receiving treatment in the absence of care coordination, and the final for those receiving neither treatment nor the INSPIRE intervention. The “No therapy” column refers to per beneficiary per year (PPPY) cost to Medicare. Cost of services were acquired by Milliman, Inc. (2013).³³ These costs were added to derive the total annual cost for untreated HCV in 2010, or \$32,256.

For individuals receiving treatment, the inpatient and outpatient costs were reduced by 20%, in line with the published literature mentioned above. The costs of the HCV medications and the INSPIRE intervention were included in the treatment year costs. Pharmacy costs included the [\\$45,000 discounted cost per 12-week regimen for the Veteran’s Administration \(VA\)](#).³⁴ In addition, \$760 was included as a maximum cost of the delivery of care coordination services accompanying treatment of HCV, as implemented in the INSPIRE care delivery model (see Q 3.1 for detailed derivation of the target price).

To derive costs after the treatment year for those patients achieving SVR, we used cost ratio estimates also derived from the literature.³⁵ We projected the reductions in categorical (inpatient, outpatient and pharmacy) costs associated with SVR. These projections were then inflation-adjusted for subsequent years. The Medicare Hospital Inpatient Prospective Payment System (IPPS) Hospital Market Basket (base year 2010) and the Medicare Economic Index (base year 2010) were used to adjust future costs for inflation.³⁶ These indices were used to estimate inpatient and outpatient costs, respectively, five years out in 2010 dollars, a methodology used previously.³⁷ For pharmacy costs, we used the prescription drug consumer price index (CPI) to inflate costs for all prescription drugs dispensed by pharmacies, including those imported.³⁸ A similar inflation-adjusted methodology, using the no therapy baseline categorical costs, was used for patients receiving treatment without care coordination and those not receiving treatment.

Over six years (including the treatment year), the total cost to Medicare for an untreated HCV patient is \$200,089. With treatment using the VA price with care coordination (total cost \$169,639), per-patient savings of \$30,450 accrue to Medicare five years after treatment. With treatment in the absence of care coordination, savings were only \$2,634 per patient. Applying these cost projections to the total Medicare population with HCV (481,185, derived in Q 1.2) suggests a maximum range of potential savings for Medicare from \$14.6 billion within a decade

of INSPIRE payment model implementation. The return on investment (ROI) from use of care coordination was 39 when using this VA price.³⁹ Comparatively, no use of care coordination produced savings of \$1.3B with an ROI of only 2.5.

These returns may also be conservative. Medicare-aged beneficiaries with HCV experienced about a 35% increase in total payments from 2005 to 2010.⁴⁰ AARP Public Policy Institute previously identified that the Medicare share of total personal health care expenditures of fee-for-service beneficiaries was approximately 58%.⁴¹ These findings suggest the projected per-patient annual cost to Medicare five years after the treatment year is under-estimated by 12% (\$38,700 versus \$34,700).

Q 2.2: What are the nature and magnitude of barriers and risks to the model's success and how will they be overcome? One barrier is the reluctance among providers to participate in the payment model because of SVR variability. In particular, lower rates of SVR12 in patients with advanced liver disease or non-genotype 1 infection were reported in a recent real-world, retrospective study of HCV patients treated within the Veteran's Health with direct acting antivirals (DAAs).⁴² Furthermore, the possibility of drug interactions is not trivial for an aging population, which may trigger provider reluctance to treat.^{43,44} Through intensive patient interaction and engagement, the INSPIRE care coordination model is intended to provide a means to address both barriers.

Q 2.3: What metrics will be used to assess performance under the model including the impact of the model on total cost of care, and will any of the metrics include patient-reported outcome measures or measures of beneficiary experience of care? The metric used to assess performance will be a risk-adjusted facility-based SVR score. No patient-reported outcomes measures will be included in performance assessment. The outcome measure that supports this payment model is Hepatitis C Virus (HCV) - Sustained Virological Response (SVR), which has been previously considered and published by CMS/HHS under the [2015 Measures Under Consideration \(MUC\) by the Measures Application Partnership \(MAP\) at the National Quality Forum \(NQF\)](#) (MUC ID: MUC15-229, see MAP report 2015-2016). However, as of 2017, this outcome has not undergone MUC/pre-rulemaking or final rulemaking.

Once a candidate measure has been through proposed rulemaking and final rule, and CMS has defined an "Effective Date," then that measure record's status in the CMS public inventory will change from "Considered" to "Finalized" and then to "Implemented." A finalized status means that in a Final Rule, CMS has adopted or agreed to deploy and use the measure, and the measure usually stays in such status through a lag time or trial/phase-in period of data collection, until the measure is used to affect actual funding.

It is our collaborative's understanding that CMS does not mandate that NQF endorsement be a requirement for a measure to be finalized and put into use in the field by a CMS program. In order to implement the proposed INSPIRE payment model (see Q 3.1), it is necessary for CMS to consider and adopt this measure, even in the absence of formal NQF endorsement. It is critical to calculate SVR scores and annual bonus payments.

Table 2. Costs associated with care coordination participation and achieving SVR

	TREATMENT YEAR		POST-TREATMENT YEAR					Total Cost with Treatment
	No Therapy (2010)	Treated During Year	1 Year After Therapy w/ SVR	2 Years After Therapy w/ SVR	3 Years After Therapy w/ SVR	4 Years After Therapy w/ SVR	5 Years After Therapy w/ SVR	
Inpatient [*]	\$17,052	\$13,642	\$9,529	\$8,996	\$6,942	\$7,142	\$13,724	\$59,975
Outpatient [†]	\$12,636	\$10,109	\$8,719	\$7,983	\$8,186	\$10,021	\$9,322	\$54,340
Pharmacy [§]	\$2,568	\$47,568	\$2,302	\$1,335	\$372	\$1,857	\$1,130	\$54,564
Care Coordination		\$760						\$760
Total – Treated w/ Care Coordination	–	\$72,079	\$20,550	\$18,314	\$15,500	\$19,020	\$24,176	\$169,639
Total – Treated w/o Care Coordination		\$77,256	\$25,112	\$22,558	\$19,281	\$23,311	\$29,937	\$197,455
Total – Untreated	\$32,256	–	\$33,040	\$32,645	\$32,063	\$35,385	\$34,700	\$200,089

* Future cost adjusted using the 2010 (base year) Medicare Hospital Inpatient PPS market basket, † Future costs adjusted using the 2010 (base year) Medicare Economic Index, § Future costs adjusted using the prescription drug-specific CPI.

Q 2.4: What approach will be used to develop any innovative metrics proposed for inclusion in the model, such as specialty-specific measures or patient-reported outcome measures, and how will this approach leverage existing measures, standards, value sets, etc.? SVR is a specialty-specific existing measure demonstrating quality of care in HCV. This payment model does not seek to develop or support the development of new metrics, but rather their new use. The benefit of the INSPIRE care delivery model is that the specialty-specific measure (i.e., SVR) can now be reported by not only specialists, but also primary care providers after their participation in tele-mentoring training, which is supported by the payment model (see Q 3.1). Furthermore, our focus on the quality outcome of SVR aligns with the priority and value patients place on HCV treatment.⁴⁵

Q 2.5: What approach will be used to incorporate data from multiple sources to support total cost of care, resource utilization, or clinical quality metrics? Within the INSPIRE model, physicians and other specialists note in the EHR clinical observations of patient health status. Providers relay this information to care coordinators, who then may help document milestones in treatment of HCV (e.g., initiating into care coordination, attaining SVR, etc.) on claims forms using CPT/HCPCS, diagnosis and treatment codes. At their discretion, CMS will be able to independently audit total cost of care and resource utilization between the dates of enrollment into care coordination and achieving SVR by patient and/or by facility. It may also be possible to audit these outcomes among HCV patients treated in other facilities and for whom care coordination is not initiated as a result of other competing healthcare priorities or other reasons, including a facilities' decision not to participate in this APM.

Q 2.6: What approach to electronic reporting of and timely feedback on performance measures will be used? How will the approach take into account capturing and sharing data from the EHRs of all clinicians who provide relevant care for the attributed patient population, aggregation and calculation of measures, and provision of timely feedback to support performance improvement? CMS will be able to calculate a risk-adjusted SVR score for each facility participating in the payment model if and only if Hepatitis C Virus (HCV) - Sustained Virological Response (SVR) quality indicator is adopted (MUC ID: MUC15-229, see Q 2.3). As indicated in the MAP 2015-2016 report, this adoption will allow CMS to calculate the percentage of patients aged 18 years and older with a diagnosis of HCV who have completed a full course of antiviral treatment with undetectable HCV RNA 12 weeks after cessation of treatment (SVR12). Facilities may also be able to internally calculate their own SVR progress throughout the year (by assessing EHRs of patients being treated by primary care physicians, specialists, or both) to ensure modifications can be made to ensure meeting an annual threshold necessary to acquire the bonus.

Q 2.7: What level of monitoring or auditing will be required? As further discussed in Q 3.4, a facility's SVR score will be calculated, risk-adjusted and compared to a representative benchmark of all payment model participants. Facilities achieving a score at or above the benchmark ('high-performing facilities') will receive an annual bonus payment. This payment

corresponds to a proportion (i.e., the shared savings rate) of the per-patient expected savings generated summed across all patients with confirmed SVR. Those facilities below the benchmark ('low-performing facilities') must engage in payback, corresponding to a proportion of the per-patient expected savings missed summed across all patients with undocumented SVR. The payback or bonus will be adjusted for age and disease state of the patients enrolled into care coordination and will also reflect the corresponding shared savings rates established by CMS (see Q 9.2).

Q 2.8: Are there any prior or planned statistical analyses to estimate the impact of the model on spending and quality of care? Additional analyses to come from the INSPIRE collaborative include describing the impact in terms of our quality outcome (i.e., SVR) and total cost of care:

- A matched cohort analysis of hepatitis surveillance data will assess the receipt of INSPIRE care coordination services on odds of achieving SVR using DAAs
- A matched cohort study analyzing the impact of care coordination on total cost of care for Medicare and Medicaid fee-for-service beneficiaries before, during and after the INSPIRE intervention, and
- A mixed-methods provider acceptability study encompassing regression, simulation and survey analysis

The second analysis is patient-focused, whereas the third analysis is provider-focused. The latter study will model the outcomes associated with INSPIRE APM adoption in hospital outpatient settings and will characterize provider acceptability towards participation given these outcomes. More specifically, this component will describe and calculate clinic-based SVR scores for the Project INSPIRE facilities (regression, see Q 3.5 for details), will incorporate these scores into an APM evaluation exercise that determines the spectrum of potential bonuses and paybacks as a consequence of APM participation (simulation) and finally will assess physician acceptability of these results (survey). Ongoing results will be available starting September 2017, after which implementation projects using the payment model should be possible.

Criterion 3 of 10. Payment Methodology (High Priority Criterion)

Q 3.1: How would entities be paid under the proposed model, including the amount of new payments (e.g., per beneficiary per month, shared savings payments, etc.), and what is the methodology for calculating such payments? The INSPIRE APM aligns to a value-based payment methodology. The model includes an outpatient bundled payment with the opportunity for shared savings. Under the model, providers are incentivized to deliver highly-coordinated, cost-efficient care to treat HCV. There are three phases that contribute to the value-based bundled payment: pre-treatment assessment involving care coordination comprises phase I; the treatment period constitutes phase II; and report of SVR12 concludes the final phase. The initiation into care coordination through report of SVR12 defines the episode of care. Although screening of HCV is a requirement for diagnosing HCV and ultimately initiating care coordination, screening is not included in phase I of the episode of care. Costs associated with each phase have been identified in association with project collaborators and are identified in Table 3 (*manuscript in preparation*).

Each clinical partner consisted of multiple sites: partner #1 had eight outpatient clinics; partner #2 had four outpatient clinics involved in INSPIRE. For both clinical partners, the

average duration of the episode of care is ten months. Table 3 presents the average bundled payment amount for partner #1 as \$801 and for partner #2 as \$684, with the plurality of services delivered in phase I. Based on the overall distribution of 2,774 enrollees (concluding in February 2017), the weighted bundled payment amount for care coordination is \$760 per episode of care.

This amount (\$760) is the suggested target price for delivery of care coordination. Note that the target price may be adjusted in future years by excluding the portion of the payment associated with Phase III. This cost is associated with training and mentoring of primary care providers in the treatment of chronic HCV. As more providers are trained over the initial years of payment model implementation, this target price may be modified to reflect a lower need for tele-mentoring activities. Furthermore, CMS may choose for this episode payment to be geographically adjusted in a manner similar to payments made according to the Physician Fee Schedule.

Table 3. INSPIRE care coordination cost of care by phase (2015 US\$)

	Clinical Partner 1				Clinical partner 2			
	Phase I*	Phase II**	Phase III***	Total	Phase I*	Phase II**	Phase III***	Total
Total cost per participant per month	110	46	122	278	92	42	121	255
Total cost per participant per treatment phase period with overhead [†]	396	221	184	801	283	216	185	684

*Enrollment to treatment initiation; **Treatment initiation to treatment completion; ***Treatment completion to SVR record; payment covers tele-mentoring costs. This is total per participant cost reaching SVR per month with overhead.

The lowest overall cost among the eight sites associated with partner #1 was \$642 (\$118 savings per episode relative to target price); the highest was \$958 (\$198 additional cost per episode). The lowest overall cost among the four clinics associated with partner #2 was \$600 (\$160 savings); the highest was \$736 (\$24 savings). Thus, there is variability in the costs of care delivery. Providers may be able to retain savings for efficiently delivered care coordination services, or may have to absorb the extra costs for prolonged delivery of services in excess of what the target price accommodates.

The target price will support the following in-person and non-face-to-face care coordination services as described by the INSPIRE service care delivery model:

- 1) Physician time spent conferencing with care coordinators
- 2) Physician time spent on formal case conferencing with other physicians
- 3) Physician specialist time spent conducting tele-mentoring sessions and physician non-specialist time spent attending tele-mentoring sessions
- 4) In-person and non-face-to-face care coordination services including:
 - a) Medication coordination (including prior authorizations)

- b) Referrals for psychosocial issues or other comorbid conditions
- c) Accompanying patients to appointments by care coordinators or peers
- d) Direct counseling services (excluding counseling separately billed for by provider), including health promotion, alcohol counseling and treatment readiness assessment and counseling or medication adherence measurement and counseling

The payment model will not cover (1) labs, procedures and imaging, (2) medications, or (3) mental health and psychiatric services or (4) treatment of hepatocellular carcinoma (HCC)/transplant cases.

The full bundled payment is made at the initiation of care coordination. Providers shall use the complex chronic care management (CCM) code (CPT 99487) with a primary diagnosis of HCV (ICD-10 diagnosis codes B18.2, B19.20 or B19.21) and/or a level II CPT code indicating HCV viremia (the previously NQF endorsed quality measure #0393, see Q 4.1) to indicate initiation into care coordination, upon which the full bundled payment is made to the facility for each patient. Retrospective reconciliation may be made at the discretion of the facility for patients not deemed eligible for treatment (see Q 3.4). The CPT code identified above limits payment model implementation to patients with a minimum of two chronic diseases (see Appendix A.2 for the complete list). For a Medicare (aged and dual-eligible) population, this is likely to cover a majority of the HCV patient pool. Furthermore, comorbidities associated with HCV are highly prevalent⁴⁶ and indeed why care coordination is necessary to ensure rates of treatment eligibility and outcomes are high.

Table 4a. Payment model inputs to calculate future savings generated by achieving SVR

	Mild/Moderate Fibrosis (F1-F3)	Cirrhosis (F4)	Adv. Liver Disease (i.e., liver cancer / transplant)*
Total annual Medicare costs ⁴⁷ (US\$ 2010)	\$23,916	\$21,708	\$61,680
Annual transition rate to next state	10.7% ⁴⁸	5.3% ^{49,50}	3.5% ⁵¹ (post-transplant w/ HCV)
Expected annual cost (EAC) avoided w/ SVR	\$2,323	\$3,270	\$614

*Post-liver transplant lifetime costs (2010 US\$) among HCV-positive patients were \$210,552 (see footnote #47), for annual cost of \$17,546. By comparison, present value of lifetime earnings per death (in \$US) in 2010 associated with cancer of the liver and intrahepatic bile duct was \$289,147.⁵² The former figure is used to calculate the expected cost avoided with SVR. The 5-year probability of survival after HCC diagnosis was converted to an annual rate (R) of transition (3.5%) using the formula $R = \frac{-\ln(1-p)}{t}$, where $p = 0.16$ and $t = 5$.

The payment model bonus proposed is based on a shared savings structure, wherein providers share with Medicare in the projected future savings generated by attaining SVR for the patients treated. Because the payment model is primarily applicable to facilities, it is necessary that all employed physicians within a facility join the APM proposed here in order to make the shared savings methodology workable.

Table 4a describes the inputs necessary to calculate shared savings. In order to calculate estimated savings, it is necessary to know the disease stage (METAVIR system of histological activity) and the age of the patient treated. Using this information, we acquire from the literature

estimates of (1) the transition rates between the METAVIR stages, (2) the Medicare-specific costs associated with them and (3) the life years (LYs) gained from an SVR cure. The final state (not shown in Table 4a) was identified as post-transplant w/ HCV infection, a state whose lifetime cost was \$210,552: life expectancy of 12 years in this state produced an annual cost of \$17,546 associated with continued HCV infection (see footnote #47). This cost multiplied by the transition rate to the post-transplant state (3.5%) was \$614, as identified in the table.

Patients with advanced liver disease (ALD) were assumed to have a life expectancy of two years.⁵³ For patients with decompensated cirrhosis (i.e. Child–Pugh class B and C disease), HCC, and model for end-stage liver disease (MELD) score ≥ 25 , a preemptive post-transplant HCV treatment strategy was found to be the most cost-effective,⁵⁴ although such strategies have not yet been widely implemented in the DAA era. Using older therapies, a modeling study showed those post-liver transplant patients infected with genotype 1 gained 1.44 LYs, whereas patients with genotypes 2 or 3 gained 4.53 LYs.⁵⁵ Using a weighted average based on the U.S. genotype distribution of HCV,⁵⁶ we calculated two LYs gained overall. As with the other disease stages, we assumed that LYs gained declined (in the same proportions as that identified for the F4 cirrhotic stage of disease) as a function of patient age.

Table 4b. Sample payment model table of bonus or payback calculations per SVR

LYs gained with SVR ⁵⁷	Mild/Moderate (F1-F3)			Cirrhosis (F4)			Adv. Liver Disease (i.e., Liver cancer / require transplant)*		
	n_a	J	ETC_{FV}	n_a	J	ETC_{FV}	n_a	J	ETC_{FV}
age ≤ 40	31.6	6.3	\$29,878	17.8	10.2	\$48,308	2	2	\$119.65
age $41 \leq 45$	28.7	4.6	\$18,143	16.9	8.4	\$38,157	2	1.6	\$95.49
age $46 \leq 50$	25.6	3.2	\$11,704	15.9	6.6	\$29,200	2	1.3	\$77.36
age $51 \leq 55$	22.3	2.1	\$7,115	14.6	5.1	\$21,529	2	1.0	\$59.23
age $56 \leq 60$	19.0	1.3	\$4,098	13.2	3.8	\$15,214	2	0.7	\$41.46
age $61 \leq 65$	15.7	0.8	\$2,352	11.5	2.6	\$10,225	2	0.5	\$29.62
age $66 \leq 70$	12.5	0.4	\$1,104	9.7	1.7	\$6,445	2	0.3	\$17.77
age $71 \leq 75$	9.5	0.2	\$520	7.8	1.1	\$3,791	2	0.2	\$11.85
age $76 \leq 80$	7	0.1	\$247	5.9	0.6	\$2,116	2	0.1	\$5.92

Notes: n_a is the number of years of life expected (n) in the absence of SVR for patient in age group a ($a = 1, 2, \dots, 9$), j represents each additional LY gained ($j = 1, 2, 3, \dots, J$) where J is the total LYs gained. ETC_{FV} is the expected total cost of care avoided in the LYs gained with SVR.

An expected total cost avoided with SVR is calculated as the following:

$$\text{Expected total cost avoided (ETC)} = \text{Expected annual cost avoided (EAC)} \times \text{LYs gained,}$$

where $\text{EAC} = \text{Annual transition rate} \times \text{annual Medicare cost of next disease state}$

Total savings per patient were computed using an algorithm and demonstrated with an example, as described in Appendix A.1. The total projected savings are identified in Table 4b. Briefly, the EAC was inflated for each LY gained with SVR (beyond the years of life already expected) and

then summed over all LYs gained. This total was then discounted back to the present using a rate of 10%.

This payment model design is intended to award the greatest potential bonuses to providers curing patients in a fibrotic or cirrhotic state, especially those in the younger age categories. For example, almost \$30,000 for a 40-year-old patient with early fibrosis, and even higher for the same individual with cirrhosis, but only a tiny fraction of that total (<1%) for a patient, even a younger one, who has already advanced to end stage liver disease. Such a focus is indeed possible given the high accuracy rate associated with identification of cirrhotic patients using claims data.⁵⁸ Existing research shows that younger age is the most important independent predictor of Medicare spending, as younger patients with liver disease who qualify for Medicare can only be enrolled due to their disability.⁵⁹

The INSPIRE bundled payment plus shared savings model creates a dual incentive for delivering cost-efficient care that achieves quality outcomes. Providers who achieve these milestones will (1) retain a portion of the per-patient bundled payment by delivering care coordination services at a cost below the target price of \$760 and (2) acquire additional savings from achieving SVR to offset program setup costs and enhance physician compensation structures.

Q 3.2: Will the proposed model include other payers in addition to Medicare, and if so, is a different payment methodology needed for those payers? Researchers with the National Bureau of Economic Research have recently reported that improvements in Medicare's payment models may act as public goods by exerting substantial influence over the rates that private insurers pay.⁶⁰ We expect that such federal payment model implementation recommendations may also influence state Medicaid programs to expand their own value-based care initiatives. For example, in New York State (NYS), the Medicaid program is currently embarking on a journey to transition 90% of its Medicaid dollars to value-based payments (VBP) by 2020. This proposal could inform how NYS Medicaid might include HCV treatment in its VBP bundles.

Q 3.3: How will the model enable entities to sustain the expected changes in care delivery over time? The model's tele-mentoring component allows primary care providers to be trained to treat HCV. Therefore, new providers can be continually recruited and trained to further expand the scope of delivery using the INSPIRE model. Furthermore, facilities may retain generated savings by re-investing in, and potentially expanding, their care coordination infrastructure.

Q 3.4: How are the targets for success defined, and what are the penalties for failure? Success is defined as institutions moving beneficiaries through the entire episode of care to achieve SVR. To achieve an annual bonus, a facility's SVR score would be calculated and then adjusted for patient clinical and demographic characteristics known or suspected to be associated with achieving SVR. This risk-adjusted SVR score would be compared to a benchmark such as the average SVR for all the facilities participating in the program. A facility would earn an annual bonus if, compared to the benchmark, its risk-adjusted SVR classifies it as a high-performing facility.

There may be instances in which the bundled payment of \$760 is received for an episode of care in which the patient doesn't actually start treatment. In these cases, the provider/facility has two potential options: (1) returning to Medicare annually the portion of the \$760 associated with phase II & III for each untreated patient (the weighted average would be a return of about \$400 for each patient not starting treatment). In this case, these patients would be excluded from the denominator for purposes of facility SVR score each year; or (2) the provider/facility could not return anything and continue to include patients who don't start treatment in their SVR calculation, increasing the risk of an annual payback, which may or may not be higher than the \$400 per patient figure. As a decision input for payment model implementation, the facility would be required to make a decision a priori on which track to choose. Option #1 may encourage providers to engage complicated patients initially, but does not subject them to substantial losses if HCV treatment was not medically justified at the time. In the end, these complicated patients will at least get some form of care coordination to help manage their other conditions, which may have some impact on short-term utilization, even in the absence of HCV treatment.

Q 3.5: What methodology will be used for risk adjustment (if relevant)? Three components will be included to estimate a facility-specific SVR rate or score, as described in the literature.⁶¹ First, because we consider the patient-specific binary SVR outcome, a Bernoulli random variable hierarchical model operating at the patient level will be used. Patients with HCV are nested within hospitals so that their outcomes may be correlated, owing to receiving care from clinical staff in the same facility. Second, a case-mix, risk adjustment model will be developed to appropriately capture patient-level influences on SVR likelihood. Third, we will plan to stabilize the rates for clinics in which the number of patients achieving SVR is small. To do so, we will use a Bayesian formulation that posits a prior distribution for facility-specific, random effects and a data model that incorporates these effects along with the patient-level influencers identified in the case-mix model. This Bayesian approach produces the posterior distribution of the facility-specific random effects and includes this distribution to produce the risk-standardized SVR rates. This method has been used by the Centers for Medicare & Medicaid Services (CMS) in the Hospital Compare program. This analysis constitutes one of three projects to be completed by September 2017 (see Q 2.8).

Q 3.6: How does the payment methodology differ from current Medicare payment methodologies? Why cannot it be tested under current payment methodologies/CMMI models? What degree of financial risk will the entity and its physicians bear as a consequence of this proposed model (i.e., will physicians be at financial risk for their portion of care within the framework of the model, and how will this be determined)? The proposed payment methodology follows the Medicare Prospective Payment System (PPS) in that a provider receives a flat dollar amount for the episode of care and is responsible for providing whatever services are needed by the patient to achieve SVR. This differs from the Oncology Care Model, in which a per-beneficiary Monthly Enhanced Oncology Services (MEOS) payment for the duration of the episode is used. Another difference is that this methodology applies to outpatients, through Medicare Part B. Part B payments for evaluation and treatment visits are determined by the

Medicare Physician Fee Schedule (PFS). Appendix A.2 describes the reimbursements expected under the PFS. Note that for the expected duration of the episode of care using the INSPIRE care delivery model, use of monthly PFS payments is not sufficient to support the episode. Hence, we recommend a single payment for the episode of care in any initial implementation of the INSPIRE payment model.

Q 3.7: Where relevant, how will the model address:

- *Establishing the accuracy and consistency of identification/coding of diagnoses/conditions?*
- *Clinical appropriateness of the payment unit (e.g., procedure or other treatment for which payment would be made)?*
- *Accurately assigning claims for payment to particular episodes of care?*

The proposed payment model is based on the use of several diagnosis and CPT/HCPCS codes:

- ❖ ICD-10 diagnosis code K74.0 for hepatic fibrosis
- ❖ ICD-10 diagnosis code K74.6 for other and unspecified cirrhosis of liver
- ❖ ICD-10 diagnosis code C22.0 for liver cell carcinoma
- ❖ ICD-10 diagnosis codes B18.2, B19.20, B19.21 for chronic HCV
- ❖ Complex CCM CPT code 99487 (see Appendix A.2 for details)

A primary diagnosis of HCV must accompany an initial complex chronic care management code (99487) to initiate the episode of care target price payment of \$760. In addition, disease stage should be categorized by one of the first three diagnosis codes when the episode of care begins. These codes differentiate the disease categories identified in Tables 4a and 4b. Patient age should also be recorded as routine. These inputs will enable the annual bonus or payback calculation to be made based on the facilities' risk-adjusted SVR score, as compared to a rate set by CMS.

Q 3.8: Barriers that make a new payment methodology necessary:

- *Are there any barriers in the current payment system that prevent or discourage the change in care delivery?*
- *Are you aware of any barriers that exist in state or federal laws or regulations (such as current coverage limitations in Medicare or state-specific scope of practice limitations)?*

A new payment model is necessary for the treatment of HCV because it is now a highly curable condition. One existing barrier is the lack of direct support for non-clinical providers to deliver care (under clinical guidance), which is a hallmark component of the INSPIRE model. The proposed episode of care payment removes the need for clinician-directed PMPM payment distribution to these providers. Finally, a major barrier includes coverage limitations for expensive HCV medications. Within Medicare, Part D enrollees using new HCV drugs face significant financial burdens, even with catastrophic coverage.⁶² The support given through INSPIRE care coordination will be essential to helping patients acquire and maintain adherence to very expensive HCV medications despite these barriers.

Criterion 4 of 10. Value over Volume

Q 4.1: What financial incentives will be provided to encourage physicians and other eligible professionals to deliver high-value health care?

- *How will these incentives influence physician or other eligible professionals' behavior? Please be clear about how you expect changing incentives to be manifested throughout the delivery system.*

The shared savings portion of the payment model promotes a bonus to facilities for achieving HCV cure, which may influence compensation structure for physicians. This bonus is an indirect advertisement for increased screenings by providers to recruit participants into the model. Thus it potentially alters physician behavior with respect to screening, which then influences the number of participants eligible to receive care under this payment model. This is an important contribution, given the slower than expected uptake of HCV screenings among Baby Boomers.⁶³ Furthermore, the NQF endorsed quality measure #0393 (hepatitis C: confirmation of HCV viremia) and #0397 (hepatitis C: antiviral treatment prescribed) on July 31, 2008 but removed said endorsements on November 9, 2016 and January 8, 2013, respectively. The INSPIRE payment model is designed to promote and reward physician behaviors that pursue SVR confirmation, which necessitates increased screenings and treatment initiation.

Criterion 5 of 10. Flexibility

Q 5.1: Can the proposed model be adapted to accommodate the breadth and depth of differences in clinical settings and patient subgroups? Our payment model will support services at hospital-based outpatient clinics targeting primary care, infectious diseases including HIV, hepatology, and drug treatment.

Q 5.2: How can the proposed model be adapted to account for changing technology, including new drug therapies or devices? The model is not sensitive to changes in drug therapies for HCV because the outcome is a metric based on SVR. The same outcome would have applied to HCV treatments in the far less effective interferon treatment era as well. However, with better treatments now available, physicians may be able to leverage this technology into an enhanced compensation structure that simultaneously promotes value-based care.

Q 5.3: To what extent will practitioners have to adapt to operational burdens and reporting requirements that result from the proposed payment model? The model currently exists for implementation in facility settings. Employed physicians will not have additional operational burdens for participation other than appropriately documenting the beginning and end of an episode of care.

Q 5.4: How will model participants prepare and build the infrastructure to implement the proposed model? Clinical partner (i.e., hospital system) start-up costs ranged from approximately \$15,000 to \$17,000, including overhead (*manuscript in preparation*). There were eight clinics associated with partner 1 and four associated with partner 2. Each partner would need to enroll approximately 23 patients (about four patients per clinic site for partner 1 and eight patients per clinic site for partner 2) to receive the episode of care payment of \$760 per patient. Once this number is reached, the facility may receive a sufficient collective reimbursement to begin implementing care coordination services. On average, in the INSPIRE model, patients were in

contact with the care coordination team at the clinics within four to six weeks of being initially diagnosed with HCV.

Criterion 6 of 10. Ability to be evaluated

Q 6.1: Is the impact of the PFPM on metrics that are included as part of the proposed model able to be evaluated? If so please describe how. The metric is SVR. Currently this metric is not able to be evaluated as a component of the INSPIRE payment model because CMS has not officially adopted this previously proposed and published NQF measure (see Q 2.3) that allows a facility-based SVR score to be calculated. If adopted, a facility-based SVR rate catalogue could be established and updated annually to better evaluate quality standards over time and inform any benchmark set by CMS.

Q 6.2: What are the evaluable goals at various levels (e.g., for a population, for a provider entity, for individual physicians, etc.)? The INSPIRE model calls for distribution of a bundled payment specific to a patient and his or her clinician(s) and care coordinator. However, the shared savings component (based on future costs avoided from advanced liver disease) is structured in a way to influence broader population-level outcomes (such as HCV elimination efforts building across the country) by rewarding high-performing facilities.

Q 6.3: Are there any evaluations of the proposed model under development, underway or that have been conducted and that have not been referenced in other sections? If yes, please identify them and state whether findings from those evaluations can be shared. Data collection is ongoing, with a more complete evaluation of the care model available by fall 2017. See Q 2.8 for complete list of concurrent and upcoming evaluation activities.

Criterion 7 of 10. Integration and Care Coordination

Q 7.1: What types of physicians, non-physicians, and other eligible professionals would likely be included in the implementation of this model in order to achieve desired outcomes? The model is designed to include primary care physicians, specialists, nurse practitioners and physician assistants across the specialties of infectious diseases, gastroenterology and hepatology as well as mental health specialists.

Q 7.2: How would the model lead to greater integration and care coordination among practitioners and across settings? A key role of the care coordinator will be to support the development of a care coordination plan. This plan will be developed based on the unique needs of each patient and with input from all members of the care management team including the primary care physician, the liver specialist (most often, a gastroenterologist or hepatologist) and other clinical specialists involved in the patient's care, including the social worker, psychologist and psychiatrist.

Q 7.3: To what extent would the proposed model result in changes in workforce requirements compared to more traditional arrangements? No changes in workforce requirements are expected with this payment model.

Q 7.4: How will the model address coordination with care team members that are not financially accountable (e.g., through program requirements around care processes or voluntary agreements to share in savings/losses)? All INSPIRE participants are financially accountable, with respect to either their employment (i.e., care coordinators) or compensation structure (i.e., physicians and specialists).

Criterion 8 of 10. Patient Choice

Q 8.1: How is patient choice preserved under the model by accommodating individual differences in patient characteristics (including social needs, etc.), conditions, and health-related preferences while furthering population health outcomes? The care coordinator in the INSPIRE model works with the patient to address needs that may preclude their ability to start treatment. However, the patient is under no obligation to receive care coordination services as part of their treatment plan. If the patient accepts these services, the care coordinator will help the patient find and use resources to improve the patient's health. The care coordinator will check the patient's eligibility for benefits and programs, help acquire medical insurance or health care resources, help find other supportive services (such as HCV support groups, and mental health, alcohol and harm reduction counseling), and otherwise assist patients throughout HCV treatment to make sure the care patients receive fits their needs and is complete.

Q 8.2: How would the payment model affect disparities among Medicare beneficiaries by race, ethnicity, gender, disability, and geography? The payment model encourages hospitals to create a robust care coordination infrastructure. The hospital can then subsequently leverage this network by contracting their own care coordination services out to smaller institutional providers or practices not able to develop such an infrastructure. Hospitals can also use their bonus payments to develop, test and provide alternative forms of care coordination delivery, including telehealth options (for patients) and/or recruit and train care coordinators that come from disenfranchised populations (e.g., disabled, rural and/or immigrant) to foster greater HCV treatment uptake among reluctant patient populations.

Q 8.3: How would the payment model expand the demographic, clinical, or geographic diversity of participation in alternative payment models beyond existing CMS models (e.g., would the proposed payment model address populations which are not currently addressed in current CMMI models)? The model expands the possibility of primary care physicians (PCPs) participating in preventive medicine. Research demonstrates that PCPs are likely to practice evidence-based medicine targeting preventive activities, such as those published by the U.S. Preventive Services Task Force (USPSTF).⁶⁴ The USPSTF currently recommends (with grade B) screening for HCV infection in persons at high risk for infection, including people who inject drugs or engage in high-risk sex practices, as well as offering one-time screening to adults born between 1945 and 1965.

Criterion 9 of 10 Patient Safety

Q 9.1: How would the proposed model ensure that patients are not harmed by efforts to achieve savings or to improve specific aspects of quality/outcomes? Patients will not be harmed through interactions with a care coordinator. If a patient feels uncomfortable with the interaction at any point, they are able to decide either to decline treatment or to receive treatment from different providers.

Q 9.2: What measures would be used to ensure the provision of necessary care and monitor for any potential stinting of care? Given the single payment for the episode of care, it is possible providers could stint on care for the highest-intensity patients, whose episode duration may be expected to exceed the length for which the target price was intended to compensate. However, the inclusion of the shared savings potential associated with facility-based (not individual physician-based) performance is positioned as a way to avert this unintended consequence. In this way, a clinician with an especially difficult-to-treat patient will still have an incentive to care for him or her through SVR documentation, even if subject to moderate losses on the bundled payment because successful treatment increases the probability of achieving a high facility SVR score, thereby enhancing the likelihood of securing a bonus. CMS may also dilute the likelihood of stinting by structuring the shared savings rates to vary by patient age or disease state, such that complicated patients who are successfully treated would generate a higher shared savings rate for the provider. For example, using estimates from Table 4b, the shared savings rate for a facility with a satisfactory overall SVR threshold that successfully treated a 70-year-old with cirrhosis may be 60% (bonus = \$3,867), whereas for a 50-year-old with mild fibrosis may be 20% (bonus = \$2,341), a difference of \$1,526. Although the total expected savings are higher for the younger patient, CMS may reward treating an older patient with potentially more comorbidities to avoid the impending consequences of advanced liver disease in that patient. Thus, INSPIRE payment model includes the flexibility to modify the shared savings rates to incentivize physician behavior in ways that mitigate any potential stinting of care.

Q 9.3: To what degree will the proposed model ensure the integrity of its intended benefits and what embedded monitoring and potential adjustments are under consideration, should unintended or other incongruent behaviors occur? Collection of SVR data through implementation of the payment model will allow future adjustments to the SVR thresholds determined as a part of ongoing analyses related to Project INSPIRE (see Q 2.8). As DAA uptake grows with payment model implementation, it will be necessary to monitor at a facility-level any potential long-term (but as of yet unknown) side effects of the medication. As this inquiry is further addressed and documented in the scientific literature, CMS may be able to correlate any negative outcomes with bonus payments as a way to ensure integrity of the benefits that the INSPIRE care model supports.

Criterion 10 of 10. Health Information Technology

Q 10.1: How would patients' privacy be protected if new providers or caregivers will have access to personal health information (PHI)? Care coordinators will receive PHI training that is available at the facilities who join in the INSPIRE APM. At a minimum, this generally includes receiving PHI training on an annual basis. Within the clinical partner sites of the INSPIRE

collaborative, care coordinators receive HIPAA and corporate compliance training and also complete CITI program training online. Furthermore, each coordinator is trained to use a password-protected Microsoft Access database and patient management spreadsheet to protect patient information at all times.

Q 10.2: How would the model facilitate or encourage transparency related to cost and quality of care to patients and other stakeholders? The model incentivizes providers to relay information to patients about their SVR status so patients have absolute certainty regarding their infection status. Furthermore, the model promotes facility-wide awareness of their own SVR score to encourage providers treating HCV patients to raise their efforts where needed with regard to SVR reporting to ensure the facility receives the annual bonus.

Q 10.3: Will interoperability of electronic health records be needed to guide better decision-making? Interoperability is minimally necessary for the INSPIRE care delivery model. Data exchange may be necessary to conduct tele-mentoring of PCPs. De-identified details of clinical cases are used to describe best treatment practices and facilitate training of HCV among non-specialists.

Q 10.4: Will any information technology innovations be used to support improved outcomes, improve the consumer experience, or enhance the efficiency of the care delivery process? The use of IT is a feature of the care delivery model; however, it is non-proprietary, readily available and inexpensive to acquire and use. Conference call technology, including WebEx Meetings and Zoom applications, have been used by INSPIRE providers. The costs of these technologies have also been incorporated into the infrastructure set-up costs (see Q 5.4 for details).

Q 10.5: How will any health IT requirements included in the model ensure that clinicians have the flexibility to choose from a variety of solutions to meet their needs and leverage existing technology assets where possible? In most cases, clinicians may work with their facilities' IT departments to acquire and use the technology that is already available. Where appropriate, clinicians may recommend IT upgrades that complement their training needs or expand training opportunities.

Appendix A.1

The following algorithm is used to calculate the expected total cost of care avoided with SVR. An example to demonstrate this calculation follows. The final values derived using this algorithm are presented in Table 4b.

1. Deriving the future value (FV) of the expected total cost (ETC) avoided with SVR by using the formula $ETC = \sum_j^J (EAC^M \times (1 + I)^{n_a + j})$, where EAC^M is the expected annual cost averted for Metavir category M ($M = 1, 2, \text{ or } 3$), I is the average inflation rate ([an average of 2% from 2007 to 2016](#)), $n_a + j$ represents the number of years into the future to calculate savings: n_a is the number of years of life expected (n) in the absence of SVR for patient in age group a ($a = 1, 2, \dots, 9$), j represents each additional LY gained ($j = 1, 2, 3, \dots, J$) where J is the total LYs gained
2. Discounting this future value back to the present using a discount rate of $d = 10\%$ with the formula $ETC \times \left[\frac{1 - \frac{1}{(1+d)^J}}{d} \right]$

For example, the future value of the EAC for the first LY gained for a 40-year old ($a = 1$) patient with mild/moderate disease ($M = 1$) achieving SVR would be calculated as $ETC_{FV,32.6}^{M=1} = \$2323 \times ((1+0.02)^{32.6}) = \4430 , where $n_a + j = 32.6$ and represents the $j = 1^{\text{st}}$ year of all $J = 6.3$ LYs gained beyond normal life expectancy for an untreated patient ($n_{a=1} = 31.6$ years). Repeating the process for all remaining LYs gained, would generate ETC of care of \$32,866. The discounted present value of these future savings would be \$29,878 for the 6.3 LYs gained for the hypothetical patient described above. The provider or facility would receive a tiered portion of this per-patient savings, as finalized by CMS. Extending our example, a potential 10% shared savings rate would generate a bonus payment of \$2988 for the facility treating this patient if the broader SVR threshold was met. If this facility also successfully treated nine additional patients with these same characteristics for facility SVR rate of 100%, the annual bonus using a 10% shared savings rate would be \$29,880 for the facility.

Appendix A.2

This appendix describes the HCPCS/CPT codes to be used for ongoing delivery of care coordination (up to nine months after initial visit). The codes described below⁶⁵ are presented to present a calculation of the reimbursement received under the Physician Fee Schedule (PFS) for an INSPIRE enrollee for a duration of ten months. These calculations are compared to the target price of \$760 per episode in the INSPIRE care delivery model.

CCM CPT 99490

Chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements:

- Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient
- Chronic conditions place the patient at significant risk of death, acute exacerbation/ decompensation, or functional decline
- Comprehensive care plan established, implemented, revised, or monitored

Complex CCM CPT 99487

Complex chronic care management services, with the following required elements:

- Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient

Examples of chronic conditions include, but are not limited to, the following:

- Alzheimer's disease and related dementia
- Arthritis
- Asthma
- Atrial fibrillation
- Autism spectrum disorders
- Cancer
- Cardiovascular disease
- Chronic obstructive pulmonary disease
- Depression
- Diabetes
- Hypertension
- Infectious diseases such as HIV/AIDS
- Chronic conditions place the patient at significant risk of death, acute exacerbation/ decompensation, or functional decline
- Establishment or substantial revision of a comprehensive care plan
- Moderate or high complexity medical decision making
- 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month

Complex CCM CPT 99489

Each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (listed separately in addition to code for primary procedure)

There are two tracks proposed for reimbursement calculation. Both tracks start with CPT code 99487 for overall evaluation of HCV treatment. Subsequent visits are recorded using CPT code 99490 for low-intensity patients and CPT code 99489 for higher-intensity patients (or a mixture of the two, where appropriate). Various scenarios of the use of these codes are demonstrated with use of the [Physician Fee Lookup Tool](#). Total reimbursements are calculated and compared to the target price of delivering care coordination from the INSPIRE intervention (\$760).

Table A.2 identifies the total facility (i.e., hospital) reimbursement received under each track. In both cases, the total is less than half the target price of the INSPIRE episode of care (\$292 for complex CCM services and \$347 for non-complex CCM services). Even if the complex CCM CPT code 99487 is used each month, the total reimbursement is \$527, still more than \$200 below the expected cost of the episode of care (\$760).

Table A.2: Sample of monthly reimbursements using 2017 PFS

	Care Management Need			
	Complex CCM Path		Non-complex CCM Path	
	HCPCS Code	PFS Rate	HCPCS Code	PFS Rate
Initial	99487	\$52.76	99487	\$52.76
Month x9	99489	\$26.56	99490	\$32.66
Total		\$291.80		\$346.70
Difference		-\$468		-\$413

PFS rate based on facility (i.e., hospital) reimbursement.

Difference refers to the difference in total reimbursements using the PFS and the target price identified in Q 3.1 (\$760).

Using these data, we conclude that exclusive use of monthly reimbursements with the PFS is not feasible in order to appropriately finance the episode of care as defined in the INSPIRE model. A one-time prospective payment of \$760 for the entire episode of care is more appropriate to ensure its optimal delivery.

Appendix A.3

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gives the total estimate of 349,650. By a similar calculation, 131,535 aged beneficiaries from 2015 were estimated to have HCV. The total eligible HCV Medicare population in 2015 is therefore $349,650 + 131,535 = 481,185$.

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NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Mary T. Bassett, MD, MPH
Commissioner

Demetre C. Daskalakis, MD, MPH
Acting Deputy Commissioner
Division of Disease Control
nyc.gov/health

May 18, 2017

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347-396-7728 tel
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Dear PTAC Committee Members:

As an authorized representative of the New York City Department of Health and Mental Hygiene, I am writing to express my support for the Project INSPIRE Payment Model Proposal that has been submitted for PTAC review. I have reviewed the proposal entitled “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” prepared by staff in the Viral Hepatitis Program in the Bureau of Communicable Disease in conjunction with all of the INSPIRE partners and I am in full support of this work.

I believe this proposal addresses a novel way to support people chronically infected with hepatitis C to work with care coordinators employed by physicians in hospital outpatient clinics to get treated and cured. I think that if recommended by PTAC and implemented by CMS that this payment model can support better health outcomes at lower costs to Medicare.

Sincerely,

A handwritten signature in black ink, appearing to read "Demetre C. Daskalakis".

Demetre C. Daskalakis, MD, MPH
Acting Deputy Commissioner