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Health Care Reform and Hepatitis C: A Convergence of Risk and Opportunity

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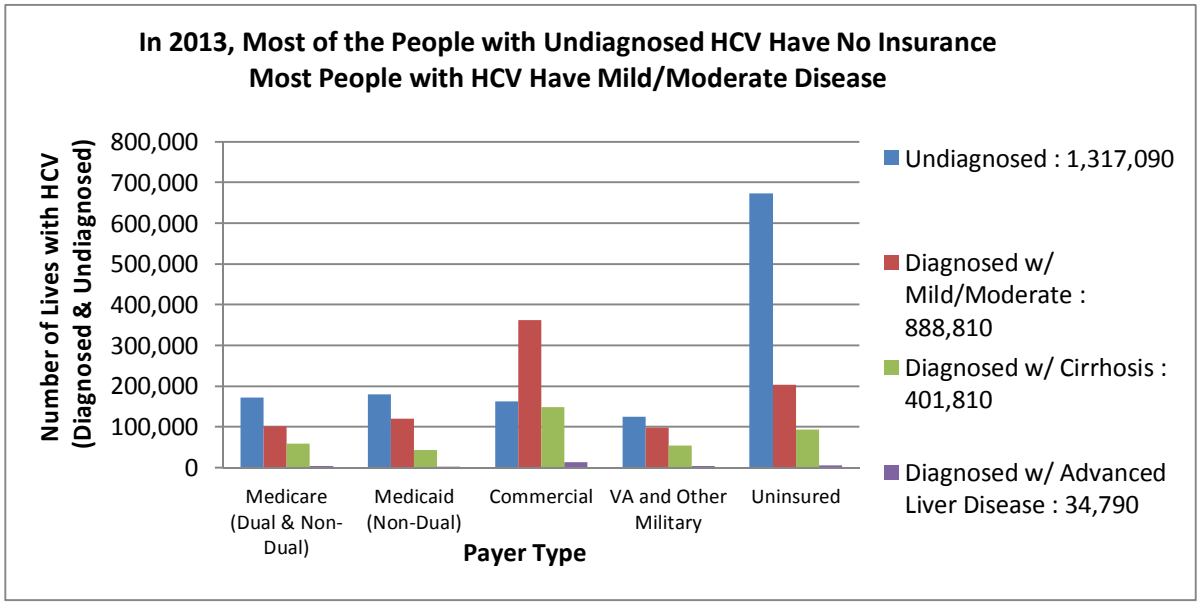
EXECUTIVE SUMMARY

The purpose of this paper is to provide insights to public and private payers and to public health and public policy interests about the hepatitis C epidemic. Changes from the Affordable Care Act (ACA) are dominating the healthcare landscape as this paper is being written in late 2013. As explained below, ACA is very important for people infected with hepatitis C virus (HCV). In addition, 2013 has seen increasing federal public health efforts aimed at diagnosing people with HCV. The leading edge of baby boomers—the generation with most HCV-infected people has begun to age into Medicare. Furthermore, several new HCV treatments are under development and expected to become available over the next several years. This is a time of convergence for people with HCV, with both risks and opportunities for the affected people and organizations.

HCV infection is an epidemic both worldwide and specifically in the United States. Approximately 3.2 million Americans are chronically infected with HCV. About half the infected population is undiagnosed, and these are concentrated among the uninsured. Only 220,000-360,000 individuals have been treated with anti-viral therapy.[1] Because of testing for HCV presence by blood banks and other changes, new infections of HCV have become less common, with an estimated 17,000 in 2010.[2] Today, the epidemic is concentrated in the baby-boomer generation, and the bulk of the infected population will age into Medicare eligibility over the next 10 years. Unfortunately, HCV is a progressive disease, and a portion of infected individuals will develop fibrosis, cirrhosis, advanced liver disease or hepatocellular cancer (listed in approximate order of increasing severity) each year. Figure 1 shows the current disease state of the HCV population by payer type.

Figure 1: 2013 HCV Population by Disease State and Payer



Source: Authors' analysis of NHANES, MarketScan 2010, Medicare 5% Sample, and Medicaid Contributor data. Does not include prison population.

The prevalence of HCV infection in the corrections (prison) population has been estimated at 23-39%.[3] There are no requirements for screening the prison population, and estimates for this population are based on relatively small studies in a few states. The high reported prevalence suggests a need for more research, but given the limited data, this report does not examine the prison population.

The undiagnosed represent a reservoir of "hidden" HCV infection that will likely become more evident with increased screening of undiagnosed individuals in the baby boomer age group. In addition, the uninsured, with their high numbers of HCV-infected people also represent a hidden population that payers and some other stakeholders have not yet encountered.

For Americans with HCV, this decade will see the convergence of significant changes:

- Before most infected people age into Medicare, the Affordable Care Act (ACA) will create new coverage that uninsured individuals and others can access. A large portion of diagnosed and undiagnosed infected individuals are uninsured.
- Both the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Preventive Services Task Force (USPSTF) recommend screening for HCV in those born between 1945 and 1964 [4, 5] in addition to continuing the recommendation for screening individuals at high risk for HCV. This is intended to reduce the number of undiagnosed individuals and create effective pathways into care.

These changes mean hundreds of thousands of uninsured people with HCV will get new coverage, hundreds of thousands of people will be newly diagnosed with HCV, and new therapies will potentially be available to the 3.2 million infected Americans. While this is happening, hundreds of thousands of people with HCV will age into Medicare coverage.

This paper presents how these changes may affect various elements of the U.S. healthcare system. We created a population forecast model that captures the expected changes over the next several years for the HCV-infected population. The major drivers of the model are:

- The ACA's expansion of coverage opportunities through Exchanges and Medicaid expansion;
- The aging of the HCV-infected population;
- The increased attention to screening for chronic HCV infection as a result of CDC and USPSTF recommendations; and
- The likely increase in treatment with increase in diagnosis.

The nature of the insurance choices available on and off Exchanges, combined with the demographic characteristics of people with HCV, lead us to several forecasts about how people with HCV may obtain coverage. For example, we expect that Silver plans will attract a significant portion of the uninsured as well as uninsured people with HCV. This and additional dynamics are described in the body of the report.

The intent of treatment with medications is to produce sustained virologic response (SVR), which can be considered eliminating HCV from the body or curing the infection. Achieving SVR is associated with decreased morbidity and mortality.[6] Reasonable scenarios for changes in the clinical and insurance landscape suggest that in five years, fewer people in

the United States will be living with HCV. Fewer people with HCV means a smaller reservoir for spreading the infection to others; such contagion has been a public health concern. Figure 2 summarizes the potential reductions under the scenarios presented in this report.

Figure 2: Impact of Treatment Scenarios on Number of People with Sustained Viral Response (Tabulated from 2013 to 2017 and to 2020)

Scenario	Estimated 2013 # Lives with HCV	Projected # with SVR by 2017	# with SVR by 2017 as a % of 2013 lives with HCV	Projected # with SVR by 2020	# with SVR by 2020 as a % of 2013 lives with HCV
Status Quo	2,642,520	217,800	8.2%	371,200	14.0%
Low Impact		387,090	14.6%	634,950	24.0%
Medium Impact		477,020	18.1%	766,930	29.0%
High Impact		638,580	24.2%	984,510	37.3%

Source: Authors' analysis of NHANES, MarketScan 2010, Medicare 5% Sample, and Medicaid Contributor data. Low Impact Scenario – 20% increase in screening, 50% increase in treatment rate, and 90% treatment efficacy; Medium Impact Scenario – 50% increase in screening, 100% increase in treatment rate, and 90% treatment efficacy; High Impact Scenario – 100% increase in screening, 200% increase in treatment rate, and 90% treatment efficacy. Does Not Include Prison Population

This report was funded by Janssen Therapeutics, which has interests in infectious diseases. This report should not be interpreted as an endorsement of any particular treatment or legislation by Milliman. Two of the authors, Bruce Pyenson and Kosuke Iwasaki, are Members of the American Academy of Actuaries and meet its qualification standards for issuing this report. The report reflects the authors' findings and opinions. Because extracts of this report taken in isolation may be incomplete or misleading, we ask that this report be distributed only in its entirety.

BACKGROUND: THE CHANGING HCV LANDSCAPE

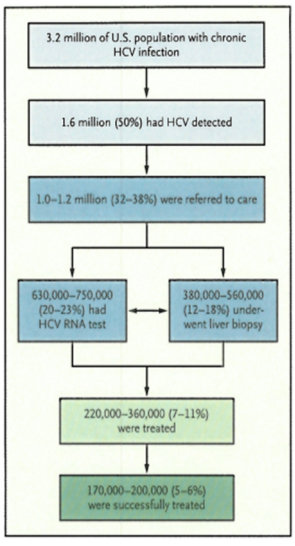
For people with HCV, this decade is seeing dramatic changes in screening recommendations, treatment options and the financing of care. And, of course, the majority of infected individuals are among the baby boomers who are aging into Medicare.

Population and Disease Profile

Chronic hepatitis C virus (HCV) infection is an epidemic both worldwide and within the United States. HCV is transmitted by direct exposure to infected blood. Exposure to infected blood, primarily through injection drug use, is the most common risk factor for HCV infection. Sexual transmission of HCV can also occur. Chronic HCV infection became an epidemic because of blood transfusions, hemodialysis, and injections of legal and illegal drugs. About 3.2 million Americans have HCV, but new cases are relatively few, estimated to be 17,000 in 2010. [2] The rate of new infections has declined due in part to improved blood supply screening. Medical surveillance has detected worrisome outbreaks due to improper sterilization or other breakdowns in proper medical technique;[2] this contagion risk could increase as people with HCV age and obtain more medical services.

Most people who are acutely infected with HCV appear asymptomatic, but some may have fatigue, nausea, generalized aching, or abdominal pain. Most patients who are infected (74-86%) develop chronic infection. HCV targets the liver, where it may lead to inflammation, scarring (fibrosis), and, eventually, cirrhosis (end stage liver disease) and liver failure. Individuals with chronic infection often have no overt symptoms of HCV, because of the liver's ability to continue to function despite HCV infection. Many HCV infections are discovered only when routine liver function tests are found to be abnormal. Cirrhosis develops in about 15 to 20% of patients with chronic HCV infection. Additionally, patients with HCV-related liver disease have an increased risk of developing hepatocellular carcinoma (primary cancer of the liver). The chance of progression of liver disease is related to the genetic strain of HCV, and the timing of progression from initial infection to advanced liver disease varies greatly among individuals.[7]

A 2013 overview of HCV in the United States estimates that approximately 3.2 million individuals (95% confidence interval: 2.7-3.9 million) are living with chronic HCV infection, and that about 1.6 million of the infected (50% of the total) have had screening and have evidence of HCV infection. Approximately 1-1.2 million (32-38% of the total) have been referred for care, of whom 630,000-750,000 have had HCV RNA testing for the presence of active disease and 380,000-560,000 have had a liver biopsy. Approximately 220,000-360,000 individuals have been treated with antivirals--170,000-200,000 of them successfully.[1]

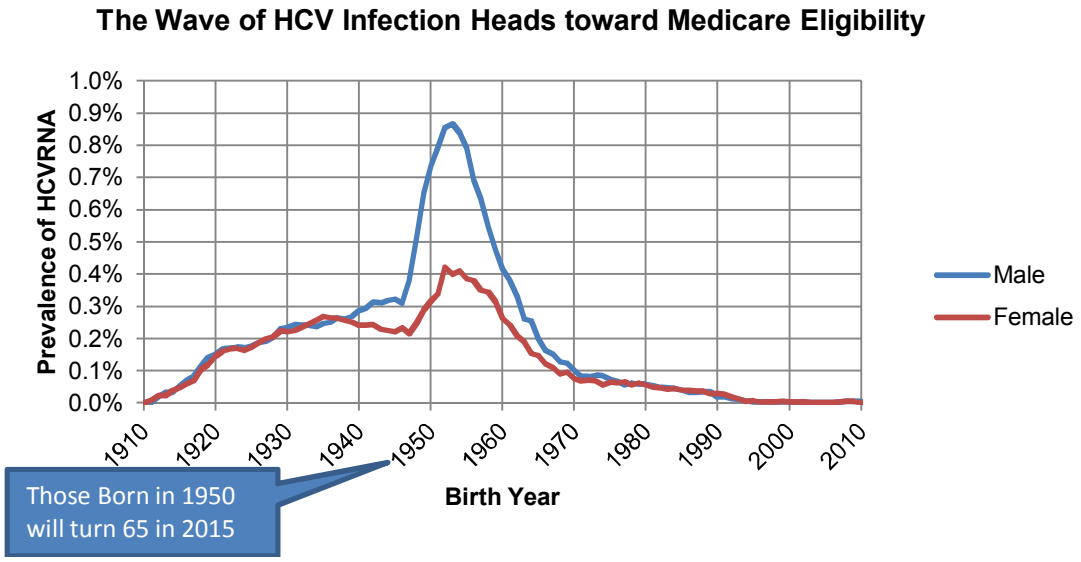


HCV-Infected People in the U.S. and Estimated Rates of Detection, Referral to Care and Treatment, S. Holmberg. Hepatitis C in the United States, *New England Journal of Medicine*, May 2013

One of the challenges of HCV treatment is that treatment response is partially determined by the genetic make-up of the virus. Genotyping is performed prior to treatment and currently is used to decide on the treatment regimen, duration, and the chance of a positive response. In the U.S., approximately 73% of chronic HCV patients are infected with genotype 1; 14% with genotype 2; and 8% with genotype 3. Genotypes 4, 5, and 6 are uncommon in the U.S. population.[8] Infection with genotype 1 has had the most unfavorable prognosis.[7] The intent of treatment with medications is to produce sustained virologic response (SVR).[6]

Most Americans with HCV are baby boomers, when examining age—with peak prevalence among those born in the1950s. The oldest baby boomers have aged into Medicare coverage when they turned 65, and hundreds of thousands of infected baby boomers will, over the coming decade, enter Medicare. Figure 3 displays HCV prevalence by birth year.

Figure 3: HCV Prevalence by Birth Year



Authors' analysis of NHANES. CDC, National Health and Nutrition Examination Survey (NHANES) 2005-2006, 2007-2008, and 2009-2010

The number of deaths and the age-adjusted mortality from HCV infection rose significantly between 1999 and 2007. The age-adjusted mortality rate is 4.16 deaths/100,000 population per year and nearly three-fourths of the HCV-related deaths occurred in individuals in the 45-64 year age group.[9] In the Chronic Hepatitis Cohort Study (CHeCS), 75% of the enrolled patients with chronic hepatitis C were born during 1945-1964.[10]

The population of those who will have insurance coverage for treatment is expanding. At the same time, the "baby boomer" population, representing the largest HCV population, is aging into Medicare. Our models show that, under reasonable assumptions, the number of HCV-infected individuals will decrease from 2014 to 2017, through treatment and mortality. Although the infection rate is rising in the 18-24 year old age group, the total number of HCV infected patients will decrease.

New Screening Recommendations

In 2010, the Institute of Medicine (IOM) published a report on hepatitis and liver cancer in which it highlighted the health concerns regarding viral hepatitis and documented the barriers to achieving improvements in the incidence of viral hepatitis. The report recommended evaluation and improvement of core and active surveillance for HCV infections and highlighted the conflicting guidelines for surveillance among Federal agencies that existed at the time.[11]

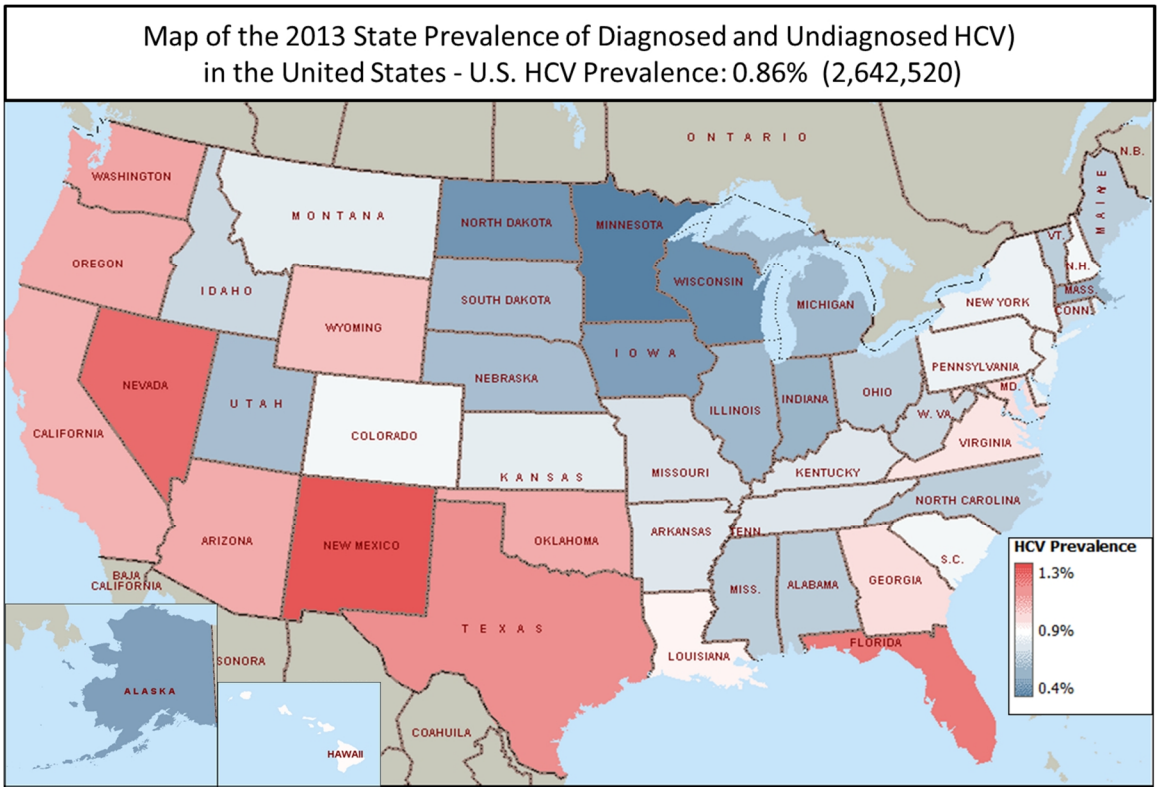
In 2013, the USPSTF updated its policy on HCV testing to be consistent with that of the CDC. Both organizations now recommend one-time screening for HCV infection in the general population born from 1946 to 1964.[4, 5] Previously, only those with high-risk behaviors or a history of exposure to transfusion of unscreened blood were recommended for screening. The USPSTF recommendation for screening has additional implications. Under the provisions of the Affordable Care Act (ACA), HCV screening is a covered service that must be provided at no cost to an insured individual. This should increase the number of individuals who are aware that they are infected with HCV.

In response, the U.S. Department of Health and Human Services (HHS) developed a comprehensive strategic action plan that included expansion of screening, with improved linkage to care that would identify individuals appropriate for treatment and provide them with that treatment.[12] In June 2013, HHS asked for public input as it began efforts to renew the 2011 Action Plan for the Prevention, Care, and Treatment of Viral Hepatitis to include actions that could be undertaken in 2014-2016.[13] Expansion of screening recommendations to include everyone born between 1945 and 1964 should increase the number of individuals who know that they may need treatment.[4, 5] In the near future, the population born between 1945 and 1964 will become eligible for Medicare, which will be presented with a relatively large number of potential patients who are appropriate for HCV treatment. Additionally, the expansion of Medicaid and the creation of health insurance Exchanges under the terms of ACA will mean that the HCV population will be more likely to have health insurance.

Varying Prevalence by Region

As shown in Figure 4, HCV prevalence varies widely from state to state, ranging from 1.3% in New Mexico to 0.4% in Minnesota. States with higher-than-average prevalence also include Florida, Texas, California, Oregon, Washington, and Virginia. Among the states with lower prevalence of HCV infection are Illinois, Indiana, Wisconsin, Iowa, and Ohio. Clearly, the variability in prevalence means payers and other interested parties will face different challenges depending on their locale and the communities most affected.

Figure 4: The Varying Regional Prevalence of HCV



Source: Authors' analysis of NHANES, MarketScan 2010, Medicare 5% Sample, and Medicaid Contributor data. Prison population is not included.

HCV, the Uninsured, and Income

The Affordable Care Act (ACA) expands health insurance coverage by expanding Medicaid and by creating health Exchanges. A health Exchange is a marketplace for individuals to purchase health insurance, and certain low income individuals will be eligible for premium and cost sharing subsidies.

Because so many people with HCV are uninsured, the ACA reforms have the potential to affect the course of treatment and care for the HCV-infected population. About one-third of people with HCV in 2013 are uninsured. Expanding coverage to the uninsured through Exchanges, employers or Medicaid is a prime goal for the ACA, so hundreds of thousands of infected individuals may have new access to treatment. The elimination of medical underwriting and application of pre-existing conditions means that people with HCV cannot be turned down for insurance because of their health status—on or off the Exchange. In addition, limits on out-of-pocket expenditures will make expensive therapy more affordable to individuals with benefits who might otherwise face high cost-sharing. Figure 5 shows the prevalence and number of infected individuals by health insurance type.

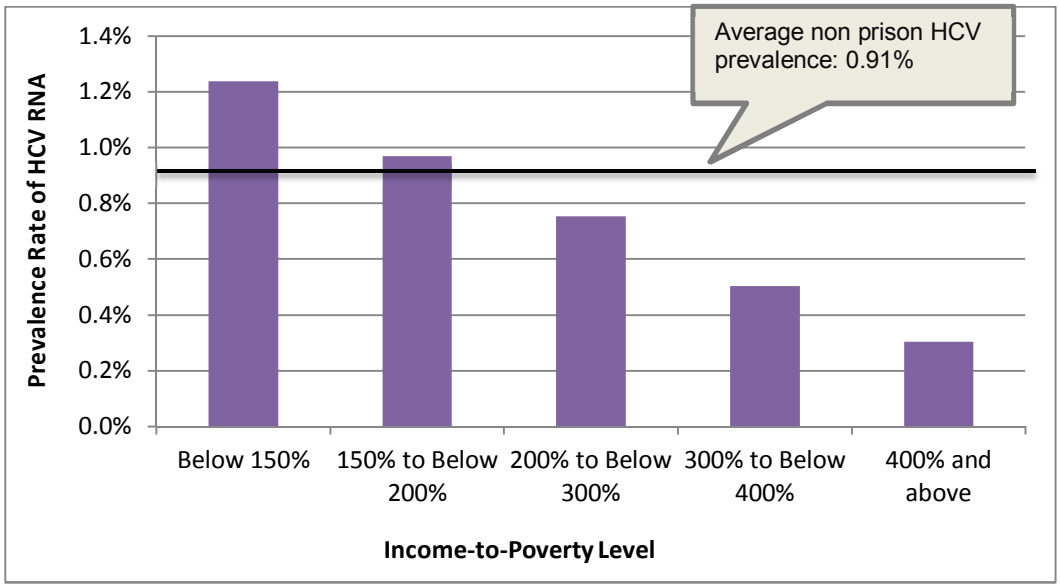
Figure 5: HCV Prevalence in 2013 by Health Insurance Type

Health Insurance Type	Total U.S. Population (Thousands)	Estimated Prevalence of HCV-RNA+	Estimated Number of HCV-RNA+ (Thousands)
Uninsured	48,600	2.08%	1,012
Veteran Affairs	5,600	5.40%	302
Commercial	164,200	0.47%	779
Dual Medicare and Medicaid	6,900	2.91%	201
Medicare (non dual)	37,600	0.31%	117
Medicaid	43,300	0.87%	377
Other Military	2,200	0.47%	10
Prison	1,500	30.0%	450
Total	**310,000**	**1.05%**	**3,249**
Total without Prison	**308,500**	**0.91%**	**2,799**

Sources: Authors' analysis of NHANES. Variable:LBXHCR - Hepatitis C RNA (HCV-RNA) in NHANES. Chien N, Dundoo G, Horani M et al. Seroprevalence of viral hepatitis in an older nursing home population. J Am Geriatr Soc. 1999;47:1110-3. Dominitz JA, Boyko EJ, Koepsell TD et al. Elevated prevalence of hepatitis c infection in users of the United States veterans medical centers. Hepatology. 2005;41:88-96. Chak E, Talal A, Sherman K et al. Hepatitis C virus infection in USA: an estimate of true prevalence. Liver International. 2011;10:1090-1101.

Many people with HCV are lower-income and may qualify for Medicaid or for premium subsidies or cost-sharing subsidies if they obtain insurance through Exchanges. Such individuals may know that they are infected but in the past may not have received treatment because they lacked health insurance or the ability to pay for treatment. Figure 6 shows the distribution of HCV-infected people by their income.

Figure 6: The Prevalence of HCV is higher among Lower-Income Individuals



Authors' analysis of NHANES 2005-2006, 2007-2008, and 2009-2010. Excludes Prison Population

As shown in Figure 6, lower income individuals are more likely to have HCV. Many states are expanding Medicaid eligibility under ACA provisions. Under Exchange rules, lower income individuals may receive premium subsidies (for income under 400% of Federal Poverty Level—FPL) or may receive cost sharing subsidies (for income under 250% FPL). However, as Figure 7 shows, a high portion of undiagnosed HCV people are low-income. Because they are undiagnosed, they are unaware of their disease and, therefore, do not realize that they could benefit from treatment.

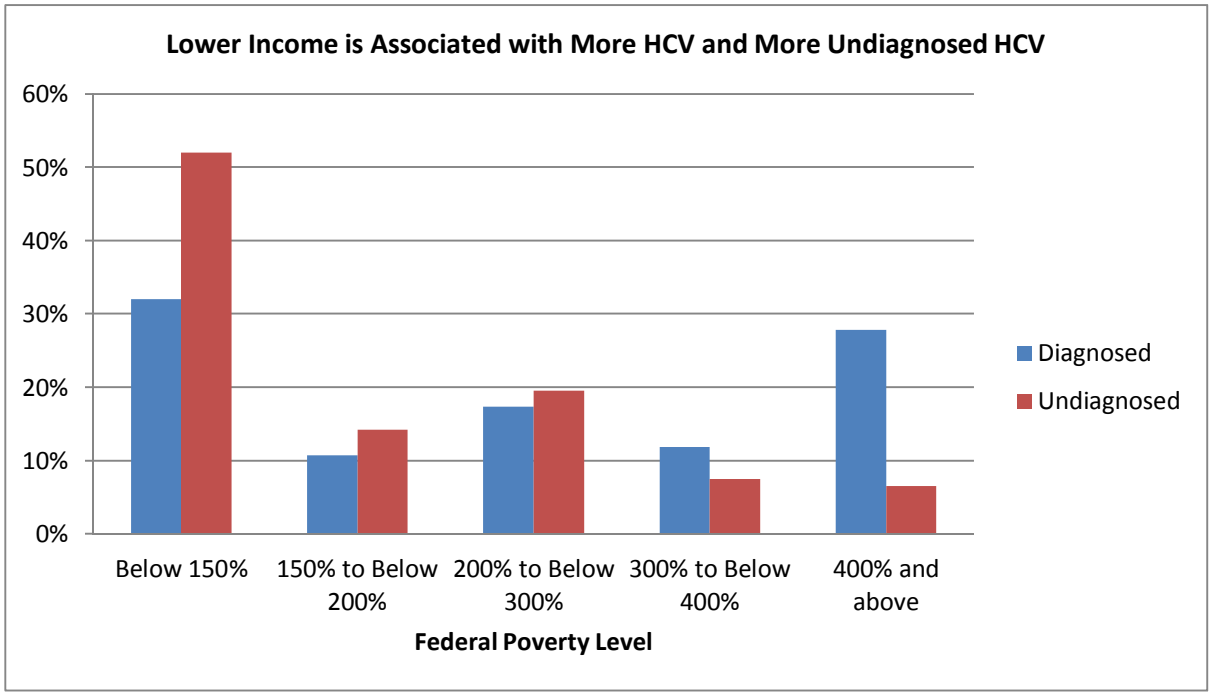
While the Exchanges and Medicaid expansion are scheduled to start in January 2014, forecasts of enrollment growth show that even after 4 years of operation, tens of millions of individuals are likely to remain uninsured. However, Exchange forecasts predict that individuals with medical conditions and older individuals are more likely to obtain insurance[14]—and both the medical condition and age factors tend to apply to people with HCV.

The authors' models of Exchange and Medicaid enrollment assume that individuals who are aware of having poorer health status or are older tend to be more likely to enroll than individuals having better health status or are younger. [14] The expansion of testing for HCV will likely help more individuals understand they are infected, and aware individuals are more likely to obtain coverage. This dynamic creates a chicken-egg dilemma, as an undiagnosed individual is more likely to be tested, diagnosed and treated if he or she already has coverage, but is more likely to obtain coverage if he or she has been diagnosed and is aware of their status.

Figure 7 shows the distribution of HCV-infected population by income, based on NHANES data. More than 30% of the diagnosed cases of HCV infection occur in the population whose

income is below 150% of the Federal Poverty Level (FPL), which for 2013 is $11,490 for an individual and $23,550 for a household of four. Additionally, more than 50% of the undiagnosed HCV population is below 150% FPL. Again, this is currently a reservoir of "hidden" HCV infection that will likely become more evident under scenarios of increased screening of asymptomatic individuals because of improved insurance coverage under ACA.

Figure 7: Portion of Diagnosed and Undiagnosed HCV Patients by Percent Federal Poverty Level



Authors' analysis of NHANES 2005-2006, 2007-2008, and 2009-2010.
Excludes Prison Population.
Diagnosed bars add to 100%; undiagnosed bars add to 100%

HCV Economic Landscape

The authors identified five studies that calculated costs based on national spending estimates from public data sources, but the studies' costs were not easily comparable because of different analysis years and data sources.

An earlier report by co-authors of this report provided 20-year cost projections for the HCV-infected population, based on treatment protocols and insurance eligibility in place at the time. It found that the total annual direct medical costs for the HCV-infected population would rise from $30 billion to $85 billion (in 2008 dollars), and that the cost to the Medicare program would increase five-fold.[15]

Other analyses have looked at costs from the payer perspective. An analysis of a large claims database from 30 managed care organizations for the years 2003-2006 found that the

total cost for a patient with chronic HCV infection in the year following the diagnosis was approximately $21,000, compared with approximately $5,500 for a control. HCV disease-related costs accounted for nearly one-third of all costs in patients with chronic HCV infection.[16] An analysis of healthcare costs from 2002-2010 from a large private insurer's database found that, overall, 56% of the total health cost for patients with chronic HCV infection were disease-related. Additionally, higher costs for chronic HCV infection were associated with higher severity of liver disease. [17] In a follow-on study, the authors compared medical costs for patients with chronic HCV who received treatment with costs for those who did not: they found that receiving treatment for chronic HCV infection was associated with lower costs. The model accounted for comorbid medical conditions, as well as demographic and geographic variables.[18]

CONVERGENCE OF POLICY ISSUES

This section presents the authors' views of major policy issues related to HCV—and how they converge. We also identify issues where there is likely to be disagreement. The major structural changes to healthcare unfolding in this decade bring uncertainty to payers, government, providers of care, and patients. The uncertainty includes how well the Exchanges will work and the extent to which the number of uninsured will decrease. Other changes have included new insurance rules preventing medical underwriting or varying rates by sex, coverage requirements (Essential Health Benefits), and penalties for employers and individuals who do not provide or obtain insurance. These changes are occurring during a time of weak economy, consolidation of medical providers into Accountable Care Organizations, the continued transition of Medicaid into managed care, and shifts in benefits to higher cost sharing. All of this is happening as the decades-old HCV epidemic is at a major transition point, with new efforts to diagnose the hundreds of thousands of hidden cases.

Affected organizations and interests, including patient advocates and payers of different types, are unlikely to view these changes in the same way. We identify what we believe are important considerations for various stakeholders.

Public Health

- Increased treatment may reduce the pool of infected individuals, which reduces the potential spread to uninfected individuals. Multiple steps toward that end include identifying infected individuals through screening, promoting coverage for uninsured individuals, and promoting treatment initiation and treatment adherence.
- The increasing prominence of HCV may raise the significance of efforts to reduce new infections among high risk groups, such as injection drug users
- Public health interests will face the challenge of balancing resource allocation among primary prevention efforts (such as vaccination or discouraging teenagers from smoking), and HCV screening, which is secondary prevention. The authors believe HCV screening will fit well with other secondary prevention efforts such as colorectal cancer screening or smoking cessation. HCV screening is secondary prevention because it does not prevent infection, but, rather, may help promote treatment.

Patient Advocates

- The tasks for patient advocates include shaping policy, increasing awareness, increasing screening, encouraging appropriate coverage for the uninsured, and facilitating treatment.
- The complexity and rapid changes of healthcare reform will create new challenges for uninsured patients who must decide on choosing plans and coverage options. Open enrollment periods create deadlines for guiding patients.
- The high concentrations of HCV infected people in difficult to reach subpopulations, such as the uninsured and prison populations will likely require innovative approaches for screening, referral and treatment.

Payers

- Payers' risk will vary dramatically depending on their locale and insured population. An early task for most payers will be to quantify the payer's exposure to HCV and to update that estimate regularly.
- Review of formulary policy for newer and older HCV treatments could be required several times in the next few years as new therapies emerge.
- Payers will want to incorporate evidence-based criteria for treatment appropriateness, patient support, and how to handle non-responders.
- Payers will want to consider systems that can track treatment outcomes.
- Undiagnosed HCV infected patients are likely to be lower cost patients, as they probably do not interact much with the healthcare system, and efforts to improve diagnosis will bring more people into contact with the healthcare system. This will likely increase cost but may improve the quality of care.
- Insurers operating on or off Exchanges will face adverse selection as individuals who perceive they need treatment, such as some individuals with HCV, are more likely to buy insurance, which increases the cost of the pool. Because some HCV treatments are relatively short duration and can generally be planned in advance, individuals could choose to buy insurance for their treatment, and not participate in the insurance pool before and after treatment. The same adverse selection could occur with individuals with other short-term medical needs such as pregnancy, elective surgery and the like.
- New requirements for HCV testing will increase the use of these laboratory tests and increase costs.
- Payers will want to evaluate referral criteria, as some treatments might be managed by primary care physicians rather than by specialists.
- Essential health benefits rules allow payers to use medical management, limited formularies, step-therapies, limited networks, and specialty tiers to manage costs.

Providers

- Providers will be encouraged to assimilate and adopt the new HCV screening guidelines and understand contemporary therapies.
- Guidelines on clinical criteria for treatment (e.g., appropriate fibrosis level for treatment rather than watch-and-wait) may evolve over time, and providers will be encouraged to follow the latest recommendations.
- Increased screening and treatment could be limited by provider capacity in some locales.
- Some treatments could be managed by primary care physicians rather than by specialists.

Medicare (including Medicare Advantage—MA--and Part D Plans--PDPs)

- Infected baby boomers who delayed treatment until they obtain Medicare may bring higher comorbidities and more advanced disease. The dramatic increase in diagnosed, HCV infected people may lead CMS to reconsider its risk adjustment factors for HCV-related diagnosis codes.
- The trend of enrolling dual Medicare-Medicaid eligibles into MA plans may bring these higher-need, higher cost populations into coordinated care programs.

- New requirements for HCV testing will increase the use of these laboratory tests and increase costs.
- Stand-alone prescription drug plans (PDPs) will likely consider HCV therapies delivered through the pharmacy benefit as specialty drugs, subject to limited formularies, step-therapies, limited pharmacy networks, and specialty tiers to manage costs. Most treated patients will enter the catastrophic coverage corridor where 80% of drug costs are assumed by the federal government. One-third of PDP members receive low-income subsidies and are insulated from high cost sharing requirements, including those associated with specialty tiers.
- MA plans may adopt the same techniques as PDPs, but will also attempt to manage care through limited provider networks including Accountable Care Organizations.

State Medicaid Departments

- State Medicaid programs will face pressure to increase premium rates to Medicaid MCOs if treatment costs threaten their solvency.
- Medicaid departments may want to establish quality and access metrics to ensure that MCOs appropriately serve infected members.
- Efforts to promote enrollment through Medicaid expansion may encourage both current eligibles and new eligibles to enroll in Medicaid, but these enrollees have different financial consequences to the states due to the higher federal subsidy for the expansion population.

Pharmaceutical Companies and Managers

- All common pharmaceutical treatments for HCV are brands, and brand manufacturers will want favorable coverage including low cost-sharing for their particular brands
- Specialty Pharmacy Benefit Managers (SPBMs) are likely to consider HCV drugs in their portfolio because of their high cost. As with other therapeutic classes, they will need to convince payers that SPBMs can do a better job of controlling treatment cost, promoting compliance, and appropriateness than the payers themselves.

The authors forecast the following net results of the “great convergence”:

- Increased screening and diagnosis of HCV-infected individuals,
- Increased numbers of HCV-infected individuals in Medicare as baby boomers age,
- Uninsured HCV-infected individuals obtaining coverage through Exchanges or Medicaid expansion,
- More people treated, and
- A reduced number of people living with HCV.

Although the HCV population is aging and will decline because of mortality, the number of HCV-infected people will be substantially lower if more people are successfully treated.

KEY FINDINGS

This section reports the results of the authors' forecasts of the changing HCV landscape through 2017. The scenarios test different screening, treatment and SVR rates, which are imposed on the population shifts due to ACA, aging, and disease progression. For details of the model, please see the Methodology section of this paper.

Scenarios for Increased Screening, Treatment and Sustained Virologic Response

To understand how the HCV landscape might change over the next few years, we developed a model using scenarios for HCV screening and treatment rates, and for treatment efficacy. We used published rates for current screening and treatment patterns, and also developed low, medium, and high impact scenarios for possible changes in these patterns, described in Figure 8.

Figure 8: Scenarios for Increased Screening, Treatment and SVR

Scenario	Increase in Annual Screening Relative to Status Quo	Increase in Annual Treatment Rate Relative to Status Quo	Sustained Virologic Response for Treated Patients
Status-Quo	n/a	n/a	52%
Low	20%	50%	90%
Medium	50%	100%	90%
High	100%	200%	90%

Figure 9 shows the key model assumptions of the diagnosis rates, treatment rates and SVR rates for the various scenarios.

Figure 9: Key Model Assumptions by Scenario

Annual Rate Assumption	Scenario			
	Base	Low	Medium	High
Diagnosis Rate of Undiagnosed HCV				
Commercial	14.6%	17.5%	21.9%	29.2%
Medicare Non-Dual	6.0%	7.2%	9.0%	12.0%
Medicaid Non-Dual	6.0%	7.2%	9.0%	12.0%
Dual-Eligible	6.0%	7.2%	9.0%	12.0%
VA	6.0%	7.2%	9.0%	12.0%
Uninsured	2.3%	2.7%	3.4%	4.6%
Treatment Rate of Diagnosed HCV	7.6%	11.3%	15.1%	22.7%
Rate of Sustained Virologic Response (SVR) for Treated HCV	52%	90%	90%	90%
SVR Rate of Diagnosed HCV (=Treatment Rate x SVR Rate of Treated HCV)	3.9%	10.2%	13.6%	20.4%

Changes in the HCV Population

Figure 10 shows the impact of different screening and treatment scenarios. Under any scenario, we would expect a decrease in the total U.S. HCV population. The decrease in the HCV population reflects SVR, mortality from HCV, and the low rate of new infections. Notably, under any of the scenarios other than the status quo, there is further decrease in the number of HCV-infected individuals. As screening and treatment rates rise, the HCV population will decrease. In the high impact scenario, the decrease in the number of HCV-infected individuals is more than twice what it is under the status quo.

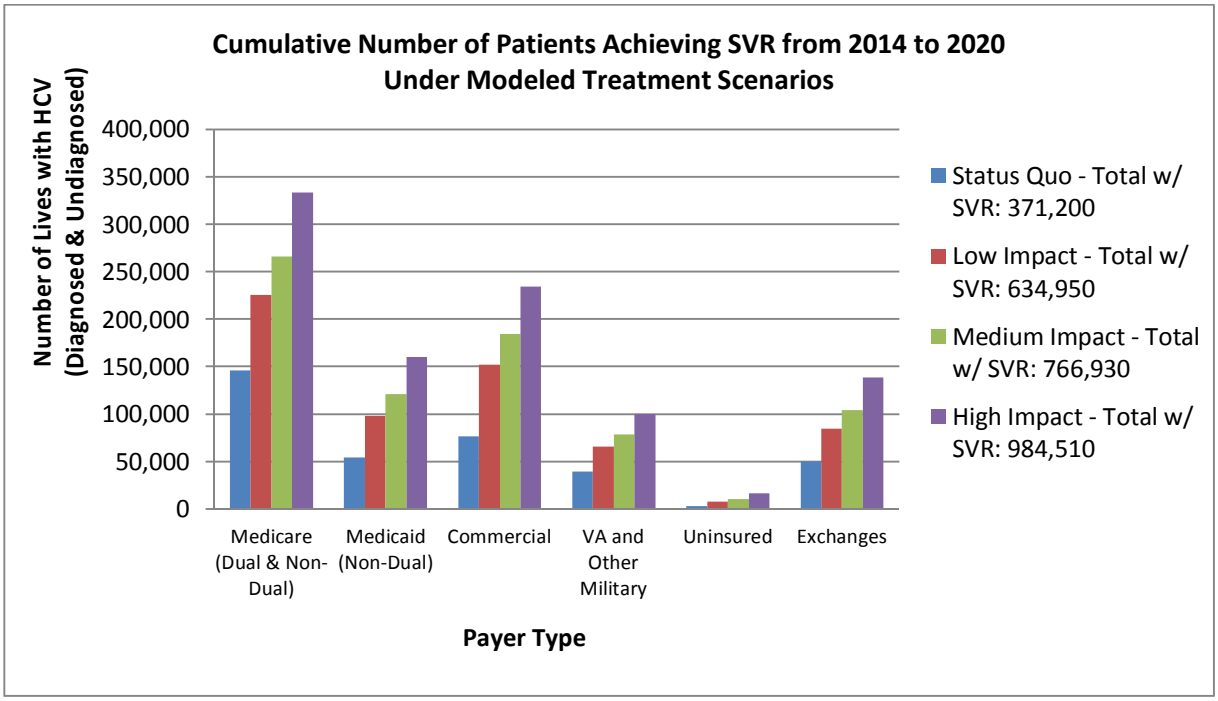
Figure 10: Impact on HCV+ RNA Lives under Screening and Treatment Scenarios

Screening and Treatment Improvement Scenarios	2013 # HCV infected lives	2017 # HCV infected lives	Change in total HCV infected lives 2013 to 2017	2020 # HCV infected lives	Change in total HCV infected lives 2013 to 2020
Status Quo	2,642,520	2,266,840	-14.2%	1,970,890	-25.4%
Low Impact		2,097,740	-20.6%	1,708,160	-35.4%
Medium Impact		2,007,800	-24.0%	1,576,720	-40.3%
High Impact		1,846,320	-30.1%	1,359,810	-48.5%

Source: Authors' analysis of NHANES, MarketScan 2010, Medicare 5% Sample, and Medicaid Contributor data.
Low Impact Scenario – 20% increase in screening, 50% increase in treatment rate, and 90% treatment efficacy
Medium Impact Scenario – 50% increase in screening, 100% increase in treatment rate, and 90% treatment efficacy
High Impact Scenario – 100% increase in screening, 200% increase in treatment rate, and 90% treatment efficacy
Prison population is not included.

Figure 11 shows how the number of lives achieving SVR by payer varies by scenario. Lives are assigned to payer based on their status in the final year of the forecast.

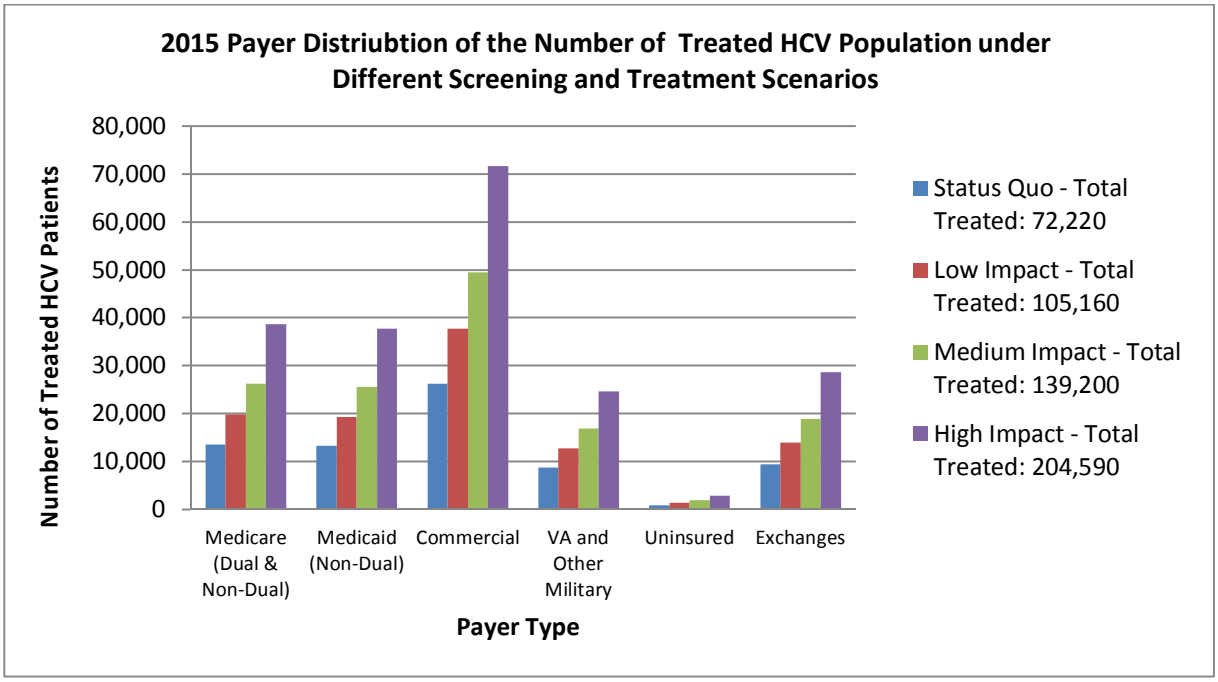
Figure 11: Number of Lives with SVR by Payer and Scenario, 2014 to 2020



Source: Authors' analysis of NHANES, MarketScan 2010, Medicare 5% Sample, and Medicaid Contributor data. Low Impact Scenario – 20% increase in screening, 50% increase in treatment rate, and 90% treatment efficacy; Medium Impact Scenario – 50% increase in screening, 100% increase in treatment rate, and 90% treatment efficacy; High Impact Scenario – 100% increase in screening, 200% increase in treatment rate, and 90% treatment efficacy. Does Not Include Prison Population

The model produces more patients with SVR for the more aggressive treatment scenarios. The numbers treated for each scenario for 2015 is shown in figure 12. Lives are assigned to payer based on their status in 2015.

Figure 12: How the Number Treated in 2014-2015 Varies by Scenario



Source: Authors' analysis of NHANES, MarketScan 2010, Medicare 5% Sample, and Medicaid Contributor data. Low Impact Scenario – 20% increase in screening, 50% increase in treatment rate, and 90% treatment efficacy; Medium Impact Scenario – 50% increase in screening, 100% increase in treatment rate, and 90% treatment efficacy; High Impact Scenario – 100% increase in screening, 200% increase in treatment rate, and 90% treatment efficacy. Does Not Include Prison Population

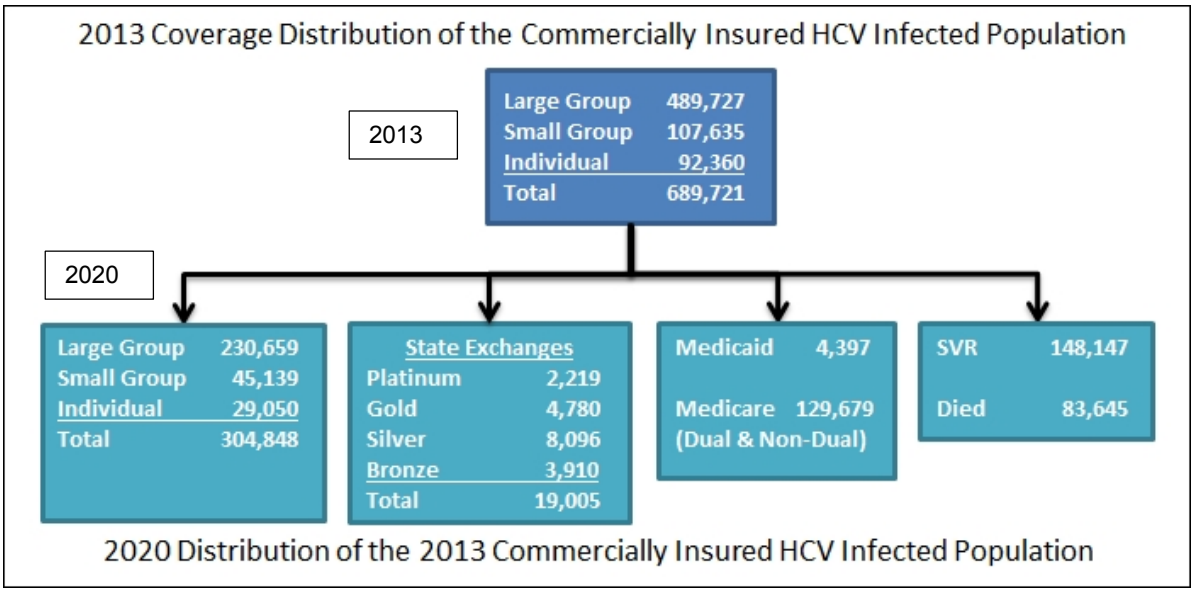
Migration of the HCV Population

ACA has many features, but for our purpose the most significant is expanding coverage of the uninsured. For the HCV-infected population, aging into Medicare is also an important element, and this is because baby boomers are reaching age 64, not directly because of ACA. Figures 13 and 14 show how the two 2013 HCV-infected populations—the commercially-insured and the uninsured—move by 2020.

Some of the more important dynamics in the HCV population migration are,

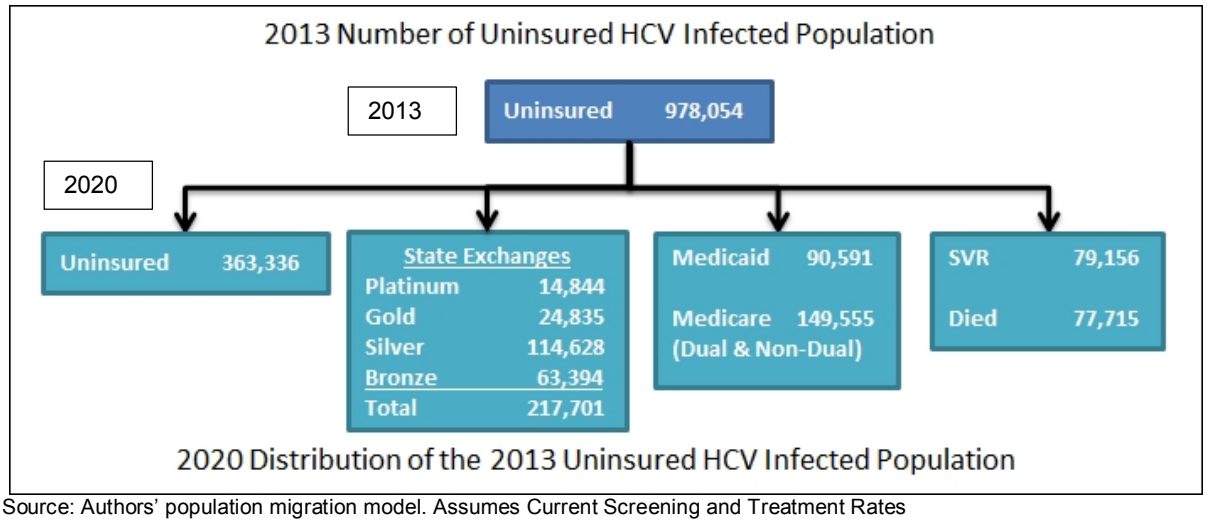
- Significant migration into Exchanges, especially the Silver plans, from commercial and uninsured populations. Silver plans are the only plans where low-income people can obtain cost sharing subsidies.
- Large growth in Medicaid through Medicaid expansion efforts and through efforts to enroll currently eligible individuals.
- Large growth in Medicare enrollment due to people reaching age 65.

Figure 13: 2020 Projection of the 2013 Commercially Insured HCV Infected Population



Source: Authors' population migration model. Assumes Current Screening and Treatment Rates

Figure 14: 2020 Projection of the 2013 Uninsured HCV Infected Population



Source: Authors' population migration model. Assumes Current Screening and Treatment Rates

Cost of the HCV Population

We summarized the costs to payers of treating HCV disease. Figure 15 shows the cost breakdown by types of services and by clinical stage of liver disease for the commercially-insured U.S. HCV population. Per member per month (PMPM) costs are highest for those with advanced liver disease, and approximately half of this is for inpatient care. Overall, the

per-member-per-month (PMPM) cost for commercially-insured patients with HCV is approximately 5.5 times the average commercial PMPM cost.

Figure 15: Cost of Medical Benefits (PMPM) by Disease Stage for the HCV Commercial Population

Cost of Services (PMPM) for the HCV Commercial Population by Disease Stage					
Benefit Type	Mild/Moderate	Cirrhosis	Advanced Liver Disease	All HCV	Total U.S. Commercial
Inpatient Facility	$360	$469	$2,735	$686	$79
Outpatient Facility	$362	$523	$1,193	$485	$96
Professional	$325	$434	$871	$406	$114
Prescription Drugs and Other	$355	$454	$724	$411	$75
Total	**$1,402**	**$1,880**	**$5,524**	**$1,987**	**$364**

Source: Authors' analysis of MarketScan 2010

Figure 16 details the cost breakdown by types of services and by clinical stage of liver disease for the Medicare population. Again, inpatient care drives the high cost of advanced liver disease. For Medicare, the PMPM cost for patients with HCV is approximately 5.8 times the average Medicare PMPM cost.

Figure 16: Cost of Medical Benefits (PMPM) by Disease Stage for the HCV Medicare Population

Cost of Services (PMPM) for the HCV Medicare Population by Disease Stage					
Benefit Type	Mild/Moderate	Cirrhosis	Advanced Liver Disease	All HCV	Total U.S. Medicare
Inpatient Facility	$913	$859	$3,184	$1,421	$400
Outpatient Facility	$455	$360	$690	$500	$147
Professional	$457	$428	$893	$553	$234
Prescription Drugs and Other	$168	$162	$374	$214	$106
Total	**$1,992**	**$1,809**	**$5,140**	**$2,687**	**$887**

Source: Authors' analysis of Medicare 5% Sample 2010, for parts A and B. Prescription drug costs paid through Part D are not included

Figure 17 (commercial) and figure 18 (Medicare) show the details of inpatient facility admissions for the HCV population. Compared with uninfected individuals, HCV patients have a higher proportion of medical, rehabilitation, psychiatric, and alcohol/drug abuse admissions. Both commercially-insured and Medicare-insured HCV patients have a much higher rate of skilled nursing facility admissions than for all commercial or members.

Figure 17: Inpatient Admissions/1000 members/month by Disease Stage for HCV Commercial Population

Inpatient Facility Admissions (Per 1,000/Year) for the HCV Commercial Population by Disease Stage					
Benefit Type	Mild/Moderate	Cirrhosis	Advanced Liver Disease	All HCV	Total U.S. Commercial
Medical – General	113	162	815	210	22
Medical – Rehab.	2	2	11	3	0
Surgical	71	96	223	93	18
Psychiatric	16	15	19	16	3
Alcohol & Drug Abuse	20	21	26	21	1
Maternity	7	1	2	6	19
Skilled Nursing Facility	8	9	46	13	1
Total	**236**	**306**	**1,141**	**362**	**63**

Source: Authors' analysis of MarketScan 2010

Figure 18: Inpatient Admissions/1000 members/year by Disease Stage for HCV Medicare Population

Inpatient Facility Admissions (Per 1,000/Year) for the HCV Medicare Population by Disease Stage					
Benefit Type	Mild/Moderate	Cirrhosis	Advanced Liver Disease	All HCV	Total U.S. Medicare
Medical – General	478	531	1,750	771	218
Medical – Rehab.	12	14	36	18	10
Surgical	152	142	334	193	84
Psychiatric	134	107	98	123	14
Alcohol & Drug Abuse	51	70	52	53	2
Maternity	2	0	0	2	1
Skilled Nursing Facility	83	87	352	145	68
Total	**914**	**952**	**2,623**	**1,303**	**398**

Source: Authors' analysis of Medicare 5% Sample 2010

POLICY IMPLICATIONS

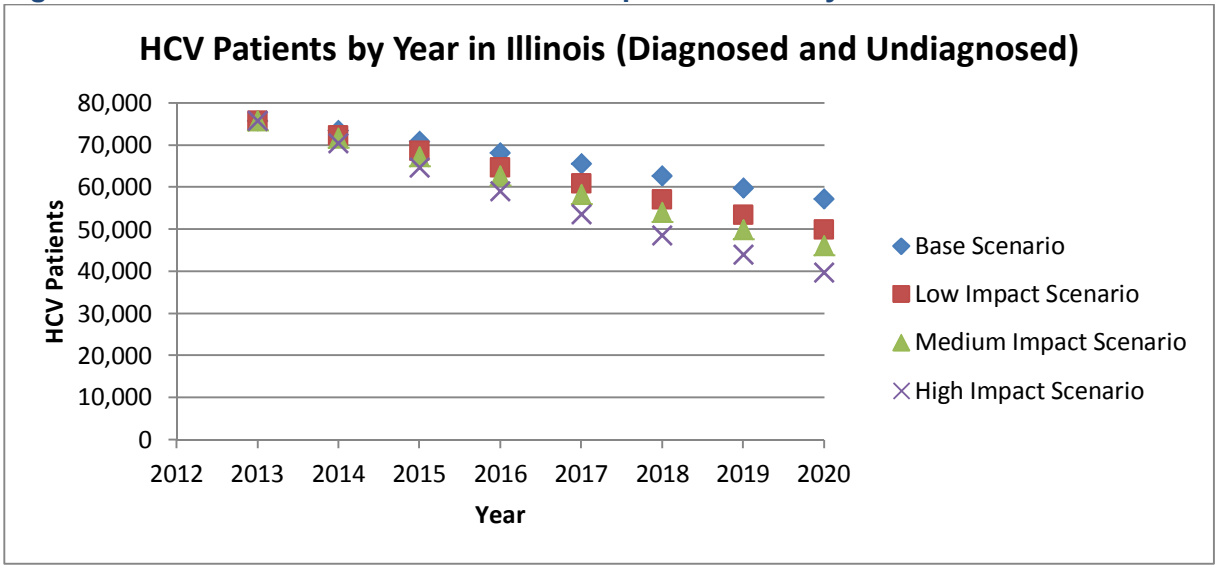
We used actuarial techniques to describe the current demographics, insurance status, and health care costs for the U.S. HCV population and then modeled potential changes over the next several years due to changes in screening rates, treatment, and the implementation of the ACA.

There is a "great convergence" of factors that will result in very significant changes to the HCV landscape. Recommendations for screening for HCV infection have broadened to include the entire population born from 1946 to 1964, not just the population with high-risk behaviors or a history of transfusion of unscreened blood. In addition, for insured individuals, this screening is a covered service that must be provided at no cost. This should increase the number of individuals who are aware that they are infected with HCV.

The population of those able to afford treatment by reason of having health insurance is expanding. Additionally, the "baby boomer" population, currently representing the largest HCV population, is aging into Medicare. Our models show a significant decrease in the number of HCV-infected individuals from 2014 to 2017 in the largest payer populations: commercial, Medicaid, and Medicare.

Figure 19 shows the decrease in the HCV population under different scenarios for the State of Illinois, which illustrates the impact on a single state. The high impact scenario, with more people treated, yields a lower population of HCV-infected people.

Figure 19: The Number of HCV-Infected People in Illinois by Year and Scenario



Authors' population migration model.

Currently and in the near future, the population born between 1945 and 1964 becomes eligible for Medicare, which will be presented with a large number of potential patients who are appropriate for HCV treatment. Additionally, the expansion of Medicaid and the creation

of health insurance Exchanges under the terms of ACA will mean that the HCV population will be more likely to have health insurance.

The net result of the "great convergence" (increased screening, baby boomers aging into Medicare, Medicaid and other insurance coverage expansion under ACA, and treatment for HCV) is that there will be a smaller population of HCV-infected Americans over the next few years.

LIMITATIONS

The forecasts depend on assumptions about future events, especially the behavior and choices of individuals in the new healthcare environment. Of course the enrollment in the Exchanges, Medicaid expansion and similar changes will not be known for some time, and the results could be very different from those in our forecast. We applied our understanding of HCV disease progression, but the rates we chose could overstate or understate actual progression. The extent to which screening will occur and produce newly diagnoses cases that will be treated are presented in scenarios, along with the rate of SVR. These are all subject to uncertainly. More certain are the aging of the HCV population, but the mortality rates we apply could also turn out to be too high or too low, and the same is true of our assumptions for people enrolling in Medicare. Because of these and similar uncertainties, our forecasts should be interpreted and applied cautiously.

Most of the figures including costs we present are national averages, and they may not be suitable for application to any particular subpopulation without adjustment. We recommend that appropriate actuarial and other expertise be used for such application.

APPENDIX A: DESCRIPTION OF KEY DATA SOURCES

Thompson Reuters MarketScan® Commercial Claims Databases, 2008-2010. This is an annual medical database that includes private sector health data from approximately 100 payers. The dataset contains more than 35 million commercially insured lives. It represents the medical experience of insured employees and their dependents for active employees, early retirees, COBRA continues and Medicare-eligible retirees with employer-provided Medicare Supplemental plans. The dataset consists of person-specific clinical utilization, expenditures, and enrollment across inpatient, outpatient, prescription drug, and carve-out services from a selection of large employers, health plans, and government and public organizations. The MarketScan databases link paid claims and encounter data to detailed patient information across sites and types of providers, and over time.

Medicare 5% Sample 2010 this limited data set contains all Medicare paid claims generated by a statistically-balanced sample of Medicare beneficiaries. Information includes county of residence, diagnosis codes, procedure codes, and DRG codes, along with site of service information as well as beneficiary age, eligibility status and an indicator for HMO enrollment.

U.S. Census Bureau, Current Population Survey. The Current Population Survey (CPS), sponsored jointly by the U.S. Census Bureau and the U.S. Bureau of Labor Statistics (BLS), is the primary source of labor force statistics for the population of the United States. The CPS is the source of numerous high-profile economic statistics, including the national unemployment rate, and provides data on a wide range of issues relating to employment and earnings. The CPS also collects extensive demographic data that complement and enhance our understanding of labor market conditions in the nation overall, among many different population groups, in the states and in sub state areas.

Centers for Disease Control and Prevention (CDC), National Health and Nutrition Examination Survey (NHANES) 2005-2006, 2007-2008, and 2009-2010. The National Health and Nutrition Examination Survey (NHANES) is a program of studies designed to assess the health and nutritional status of adults and children in the United States. The survey is unique in that it combines interviews and physical examinations. NHANES is a major program of the National Center for Health Statistics (NCHS). NCHS is part of the Centers for Disease Control and Prevention (CDC) and has the responsibility for producing vital and health statistics for the Nation.

APPENDIX B: ESTIMATING THE U.S. HCV POPULATION

Estimating the United States HCVRNA Population

Using the 2011 U.S. Census Bureau Current Population Survey (CPS) data, we distributed the U.S. population by health insurer (payer), age, sex, race, income-to-poverty ratio, and State. Payer status was designated according to 6 categories reported in CPS. The CPS does not include the prison population which we added as a separate population since HCV is highly prevalent in this population. The prison population is not included in our model and its estimates. We allocated the military coverage population reported in CPS (13.7 million) into 5.6 million in VA coverage (those enrolled in Veterans Health Administration and receiving their care in a Veteran's Integrated Service Network) [19] and into other military, commercial and Medicare. Table 1 provides the distribution of U.S. lives by payer.

The Prevalence rates for HCV RNA+ people by payer were estimated using the NHANES field LBXHCR (Hepatitis C: confirmed antibody, Hepatitis C RNA (HCV-RNA), and Hepatitis HCV genotype) which according to our analysis varied by payer type, age and sex. In addition, we made the following adjustments in the HCV prevalence to consider these unique populations not represented in NHANES.

- Adjustments in the HCV prevalence were made to the Medicaid and Dual Eligible population to reflect the institutionalized HCV patients (long term care) in the Medicaid population has an HCV prevalence rate of 4.5%.[20]
- The HCV prevalence rate for individuals with health insurance sponsored by the Department of Veteran Affairs (VA) is 5.4%. [21]
- The HCV prevalence rate for the uninsured was adjusted to reflect the portion of uninsured that are homeless who have an HCV prevalence rate of 30%. [3]
- The HCV prevalence rate for the prison population is 30%.[3]

We then applied these adjusted HCV prevalence rates to the U.S. Population to obtain the number of HCVRNA+ in each payer type as shown in Table B-1.

Table B-1: Estimated Number of HCVRNA+ for the 2011 U.S. Population

Health Insurance Type	U.S. Census Pop (Thousands)	Estimated Prevalence of HCV	Number of HCVRNA+ (Thousands)
Uninsured	48,600	2.08%	1,012
Veteran Affairs	5,600	5.40%	302
Commercial	164,200	0.47%	779
Dual Medicare and Medicaid	6,900	2.91%	201
Medicare	37,600	0.31%	117
Medicaid	43,300	0.87%	377
Other Military	2,200	0.47%	10
Prison	1,500	30.0%	450
Total	**310,000**	**1.05%**	**3,249**

To adjust the HCV prevalence for each individual to account for differences in age and sex by payer type, we used the MarketScan and Medicare 5% databases. For the commercial and Medicare populations, we used the prevalence rates as calculated by MarketScan 2010 and Medicare 5% 2010 respectively. Because the NHANES sample size was small for the dual and Medicaid payer populations, we adjusted the prevalence rates of both payers using the base prevalence rates found in MarketScan for the under 65 population and the rates found in the Medicare 5% sample to adjust the over 65 population. Individuals with one or more claims coded with an ICD9 code in Table B-2 were identified as an HCV patient.

Table B-2: Coding Logic used to identify the HCV infected population

Code	Code Description
070.51	Acute hepatitis C w/o mention of hepatic coma
070.41	Acute hepatitis C with hepatic coma
070.54	Chronic hepatitis C w/o mention of hepatic coma
070.44	Chronic hepatitis C with hepatic coma
070.70	Unspecified Hepatitis C w/o hepatic coma
070.71	Unspecified Hepatitis C with hepatic coma
V02.62	Hepatitis C carrier

The prevalence rates were also adjusted to reflect the following observations.

- HCV prevalence is higher among low income individuals.
- HCV is more prevalent in the Black population.
- HCV prevalence varies by geographic location; particularly the southwest region has a higher prevalence rate than expected based on demographics.

After applying these adjustments by age, sex, race, income-to-poverty ratio, and State, the final number of HCV RNA+ was adjusted to match the number of HCV RNA+ found in Table B-1.

Based on the NHANES question HCQ030: “Was the test result in our letter the first time you were told you had Hepatitis C?” we developed a ratio of the number of diagnosed HCV infected to the number of undiagnosed HCV infected. According to our analysis, we found that this ratio varied significantly by income and payer. Using this ratio, we split the HCV infected population into undiagnosed and diagnosed.

We identified stage of HCV as those HCV patients with one or more claims coded with the ICD9 codes noted in Table B-3. Those without coding for cirrhosis or ALD were considered mild/moderate.

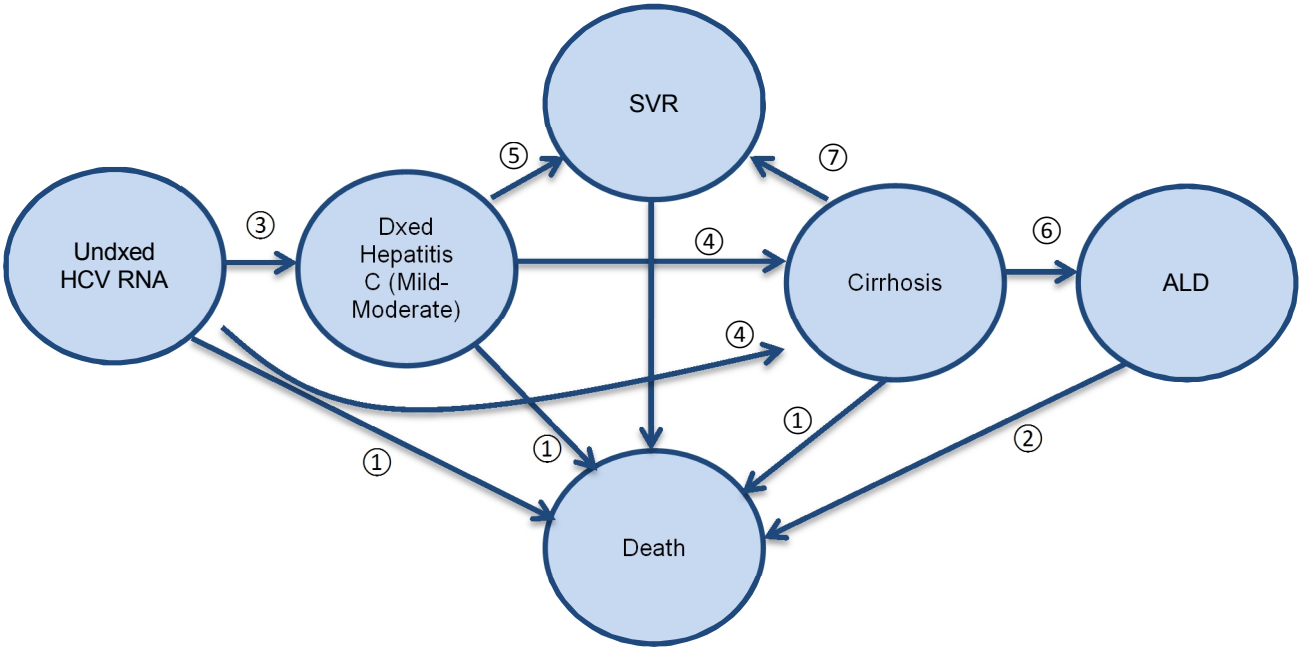
Table B-3: Coding Logic used to identify stage of HCV

Code	Code Description
571.2	Alcoholic Cirrhosis Of Liver
571.5	Cirrhosis Of Liver Without Mention Of Alcohol
571.6	Biliary Cirrhosis (This Is Cited In The Literature)
070.41	Acute Hepatitis C With Hepatic Coma (Noted In Literature To Be Used For ID Of HCV)
070.44	Chronic Hepatitis C With Hepatic Coma
348.3x	Encephalopathy Not Classified Elsewhere
456.0	Esophageal Varices With Bleeding
456.1	Esophageal Varices Without Bleeding
456.2x	Esophageal Varices In Diseases Classified Elsewhere With Bleeding
572.2	Hepatic Coma (Encephalopathy)
572.3	Portal Hypertension
572.4	Hepatorenal Syndrome
782.4	Jaundice
789.59	Ascites

Code	Code Description
V42.7	Liver Transplant
155.0	Malignant Neoplasm Of Liver Primary
47135	Liver Allotransplantation; Orthotopic Partial Or Whole, Form Cadaver Or Living Donor, Any Age.
47136	Heterotopic, Partial Or Whole, From Cadaver Or Living Donor, Any Age
50.5x	Liver Transplant

Modeling Current and Future Disease Stages of HCV

We modeled transitions of HCVRNA+ individual using the stages noted in the figure below. An individual has a probability of shifting to another disease stage including SVR or deathbased on disease progression or treatment.



The transition probabilities are described below. All transition rates are annual rates that reflect the current screening and treatment of HCV.

1. Transition Rate from Undiagnosed HCV RNA, Diagnosed Hepatitis C (mild-moderate), Cirrhosis, or SVR to Death (Mortality Rate)

   We analyzed the mortality rates of the HCV population using the 2004-2006 Medicare 5% sample data, and found that there was not a significant difference in mortality rates between mild/moderate or cirrhosis and the general population with the same demographics. We also assumed the mortality rates of the undiagnosed HCV RNA would be the same as those of the diagnosed mild/moderate or cirrhosis. Based on these findings we set the mortality rates for undiagnosed HCV RNA, diagnosed Hepatitis C (mild-moderate), cirrhosis, or SVR to the mortality rates of the United States in the CDC mortality table 23R.

2. Transition Rate from ALD to Death (Mortality Rate)

   For Advanced Liver Disease, we assumed the mortality rate to be a weighted average of the mortality rate of HCV individuals with Decompensated Cirrhosis, Hepatocellular Carcinoma, Liver Transplant patients which was 26%.[22]

3. Transition Rate from Undiagnosed HCV RNA to Diagnosed Hepatitis C (Diagnosis Rate)

   In our analysis of MarketScan, we identified 7% of HCV patients annually, were newly diagnosed. To calculate an annual rate of transition from undiagnosed to diagnosed, we multiplied the prevalence rate of diagnosed HCV by the 7% newly diagnosed rate and divided by the prevalence rate of undiagnosed HCV.

   Table B-4: Transition Rate from Undiagnosed HCV RNA to Diagnosed HCV by Payer

Payer	Prevalence Rate of HCVRNA+	Prevalence Rate of Diagnosed HCV	Prevalence Rate of Newly Diagnosed HCV (7% of dx)	Prevalence Rate of Undiagnosed HCV	Transition Rate from Undiagnosed HCV to Diagnosed HCV
Uninsured	2.08%	0.50%	0.04%	1.59%	2.28%
VA	5.40%	2.43%	0.18%	2.97%	5.98%
Commercial	0.47%	0.32%	0.02%	0.16%	14.62%
Dual Eligible	2.91%	1.31%	0.10%	1.60%	5.98%
Medicare	0.31%	0.14%	0.01%	0.17%	5.98%
Medicaid	0.87%	0.39%	0.03%	0.48%	5.98%

4. Transition Rate from Undiagnosed/ Diagnosed HCV RNA+ (mild-moderate) to Cirrhosis

   From published sources, we assumed an annual rate of transition to Cirrhosis from Undiagnosed/Diagnosed HCV RNA+ (mild-moderate) of 2.3%. [23]

5. Transition Rate from Diagnosed HCV RNA+ (mild-moderate) to SVR

   Based on MarketScan commercial data, we identified that 7.6% of mild moderate HCV patients received treatment annually. Based on clinical drug therapy outcome studies, we assumed a 52% SVR rate given treatment [6]. This results in an SVR rate of 3.9% for mild moderate.

6. Transition Rate from Cirrhosis to ALD

   From published sources, we assumed the transition rate from Cirrhosis to advanced liver disease (Hepatocellular cancer (HCC) plus Decompensated Cirrhosis) is 5.3%. [24] [25] [26]

7. Transition Rate from Cirrhosis to SVR

   Based on MarketScan commercial data, we identified that 13.7% of Cirrhosis patients had treatment according to MarketScan Commercial Data 2010. Assuming a 52% SVR rate given treatment [6], the SVR rate would be 7.1 %.

To test the effects of increased screening/diagnosis, treatment, and efficacy of treatment, we created 3 impact scenarios. The assumptions for the scenarios appear in Table B-5.

Table B-5: Diagnosis, Treatment and SVR Rates for each Impact Scenario

Annual Rate Assumption	Scenario			
	Base	Low	Medium	High
Diagnosis Rate of Undiagnosed HCV				
Commercial	14.6%	17.5%	21.9%	29.2%
Medicare Non-Dual	6.0%	7.2%	9.0%	12.0%
Medicaid Non-Dual	6.0%	7.2%	9.0%	12.0%
Dual-Eligible	6.0%	7.2%	9.0%	12.0%
VA	6.0%	7.2%	9.0%	12.0%
Uninsured	2.3%	2.7%	3.4%	4.6%
Treatment Rate of Diagnosed Mild-Moderate HCV	7.6%	11.3%	15.1%	22.7%
Treatment Rate of Diagnosed Cirrhosis HCV	13.7%	20.5%	27.3%	41.0%
Sustained Virologic Response SVR (SVR) Rate for Treated HCV	52%	90%	90%	90%
SVR Rate of Diagnosed Mild-Moderate HCV (=Treatment Rate of MM x SVR Rate of Treated HCV)	3.9%	10.2%	13.6%	20.4%
SVR Rate of Diagnosed Cirrhosis HCV (=Treatment Rate of Cir. x SVR Rate of Treated HCV)	7.1%	18.4%	24.6%	36.9%

APPENDIX C: HEALTHCARE REFORM MODEL METHODOLOGY

With the introduction of state Exchanges, HCV RNA+ people will switch from their current health insurance status. The population transition assumptions used in this model were largely based on the report, "Design and Implementation Considerations of ACA Risk Mitigation Programs", written by Milliman actuaries and sponsored by the Society of Actuaries.[14] We then adjusted these assumptions used in this report to reflect similar movement as predicted in the May 2013 Congressional Budget Office's "Estimate of the Effects of the Affordable Care Act on Health Insurance Coverage".

Each year from 2011-2020, each HCV person represented in the target population will make a decision about what type of health insurance coverage (if any) they will enroll in for the upcoming year. In this model, there are 13 types of health insurance coverage (not all of which are available to any individual). An individual may fall into only one of the following 13 types:

1. Employer-sponsored benefits from Large Group
2. Employer-sponsored benefits from Small Group
3. Individually Purchased
4. Medicare Only
5. Medicaid Only
6. Dual Eligible (Medicare and Medicaid)
7. Exchange: Platinum
8. Exchange: Gold
9. Exchange: Silver
10. Exchange: Bronze
11. Veteran Affairs Health Care
12. Other Military Coverage (Tricare, CHAMPVA)
13. No Coverage (Uninsured)

An individual's choice to move from current insurance status depends on their demographic details. We use the following assumptions:

- A sicker individual will have higher costs and will more likely choose a richer, expensive plan to maximize their benefits.
- A lower income individual will receive subsidies for their health insurance if they choose to enroll in a metallic plan within the exchange market and will therefore be more likely to switch coverage.
- Based on historical analysis, young adult males are less likely to switch coverage than other age/sex groups.
- Individuals turning age 65 enroll in Medicare, and Medicaid enrollees turning age 65 will become dual eligible.

Uninsured Population
Of all coverage types, the most movement will occur from the uninsured population into the Exchanges and Medicaid. The uninsured population will be able to purchase a metallic plan from the exchange market or enroll in Medicaid with the new expansion. The most movement will occur in the first year and the movement will decrease with each passing year. We (and most forecasters) believe there will still be a significant number of individuals who stay uninsured and will choose to pay the penalty.

Individually Purchased Health Insured Population
The population who are covered by Individual Health Insurance will act in a similar manner as the uninsured with two key differences. First, they already have coverage and are not as influenced by their health status to purchase new health insurance. Second, they will not be as reactive to the introduction of the Exchange market and will act the same way in 2014 as in subsequent years.

We note that in particular states with limited underwriting (such as New York and New Jersey), the introduction of the Exchange will likely lower the premiums for individual insured, and most people with individual insurance will enter the Exchange.

Small/Large Group Population
We expect that, from 2014 to 2017, a number of small companies will decide to drop their employees' health coverage and guide them to purchase a plan in the Exchange market or enroll in Medicaid. The decision by an employer to drop coverage does not depend on the demographics of the employee, but the demographics will affect whether the employee will enroll in Medicaid or which plan they choose on the Exchange. More small group employers will choose to drop their employees' benefit plan than a large group employer.

Migration within the Exchange Market
Within the Exchange market, we expect migration among the four metallic plans; platinum, gold, silver, and bronze. The most movement will occur in the first two years of the introduction of the Exchange market but will then become more stationary. Because of annual rate increases, we have assumed that it is more likely a person will buy down to a cheaper coverage than buy up to a more expensive coverage.

Medicaid/Medicare/Dual Eligible Population
Once an individual moves into Medicaid or Medicare, we assume they will not later choose to buy commercial coverage--they will remain enrolled in Medicaid or Medicare. The only movement that will occur is if a Medicaid only individual reaches the age 65; at that time they will become dual eligible.

VA and Other Military Health Insured Population
Those who are covered by any form of Military health insurance will not switch coverage and will remain with their current coverage.

State Income Requirements for Medicaid Eligibility
Due to the Supreme Court's decision to make Medicaid expansion in each state optional, an uninsured individual's opportunity to seek coverage will be altered depending on whether or not the state they live in opts for Medicaid expansion. We vary this movement in each state based on each state's expected income requirement for Medicaid. For the states that decide to expand, the income requirement will be at least 133% of the Federal Poverty Level. The percent of children and adults eligible for Medicaid by Income Level are shown below in Table C-1 & C-2.

Table C-1: Percent of Adults (Mixture of both Parents and Non-Parents) by Income Level Eligible for Medicaid in 2014

	Income Level by Federal Poverty Level				
State	<100	100-124	125-150	150-199	200-299
Alabama	6.8%	0.0%	0.0%	0.0%	0.0%
Alaska	23.5%	0.0%	0.0%	0.0%	0.0%
Arizona	100.0%	100.0%	32.0%	0.0%	0.0%
Arkansas	100.0%	100.0%	32.0%	0.0%	0.0%
California	100.0%	100.0%	32.0%	0.0%	0.0%
Colorado	100.0%	100.0%	32.0%	0.0%	0.0%
Connecticut	100.0%	100.0%	57.6%	31.9%	0.0%
Delaware	100.0%	100.0%	32.0%	0.0%	0.0%
District of Columbia	100.0%	100.0%	100.0%	100.0%	10.8%
Florida	15.4%	0.0%	0.0%	0.0%	0.0%
Georgia	13.0%	0.0%	0.0%	0.0%	0.0%
Hawaii	100.0%	100.0%	32.0%	0.0%	0.0%
Idaho	12.5%	0.0%	0.0%	0.0%	0.0%

	Income Level by Federal Poverty Level				
State	<100	100-124	125-150	150-199	200-299
Illinois	100.0%	100.0%	32.0%	0.0%	0.0%
Indiana	100.0%	100.0%	32.0%	0.0%	0.0%
Iowa	100.0%	100.0%	32.0%	0.0%	0.0%
Kansas	10.5%	0.0%	0.0%	0.0%	0.0%
Kentucky	100.0%	100.0%	32.0%	0.0%	0.0%
Louisiana	6.7%	0.0%	0.0%	0.0%	0.0%
Maine	26.7%	31.8%	31.8%	31.8%	0.0%
Maryland	100.0%	100.0%	32.0%	0.0%	0.0%
Massachusetts	100.0%	100.0%	32.0%	0.0%	0.0%
Michigan	100.0%	100.0%	32.0%	0.0%	0.0%
Minnesota	100.0%	100.0%	57.4%	37.3%	6.2%
Mississippi	11.4%	0.0%	0.0%	0.0%	0.0%
Missouri	8.0%	0.0%	0.0%	0.0%	0.0%
Montana	17.9%	0.0%	0.0%	0.0%	0.0%
Nebraska	16.3%	0.0%	0.0%	0.0%	0.0%
Nevada	100.0%	100.0%	32.0%	0.0%	0.0%
New Hampshire	10.2%	0.0%	0.0%	0.0%	0.0%
New Jersey	100.0%	100.0%	32.0%	0.0%	0.0%
New Mexico	100.0%	100.0%	32.0%	0.0%	0.0%
New York	100.0%	100.0%	53.8%	0.0%	0.0%
North Carolina	13.8%	0.0%	0.0%	0.0%	0.0%
North Dakota	100.0%	100.0%	32.0%	0.0%	0.0%
Ohio	100.0%	100.0%	32.0%	0.0%	0.0%
Oklahoma	100.0%	100.0%	32.0%	0.0%	0.0%
Oregon	100.0%	100.0%	32.0%	0.0%	0.0%
Pennsylvania	11.0%	0.0%	0.0%	0.0%	0.0%
Rhode Island	100.0%	100.0%	56.2%	23.8%	0.0%
South Carolina	27.1%	0.0%	0.0%	0.0%	0.0%
South Dakota	16.3%	0.0%	0.0%	0.0%	0.0%
Tennessee	31.7%	34.6%	1.4%	0.0%	0.0%
Texas	8.6%	0.0%	0.0%	0.0%	0.0%
Utah	14.6%	0.0%	0.0%	0.0%	0.0%
Vermont	100.0%	100.0%	100.0%	23.8%	0.0%
Virginia	8.4%	0.0%	0.0%	0.0%	0.0%
Washington	100.0%	100.0%	32.0%	0.0%	0.0%

	Income Level by Federal Poverty Level				
State	<100	100-124	125-150	150-199	200-299
West Virginia	100.0%	100.0%	32.0%	0.0%	0.0%
Wisconsin	30.1%	35.8%	35.8%	35.8%	0.0%
Wyoming	14.4%	0.0%	0.0%	0.0%	0.0%

Source: Author's analysis of Kaiser State Health Facts' "Medicaid Income Eligibility Limits for Adults as a Percent of Federal Poverty Level", July 2012 & Advisory Board Company's "Beyond the Pledges: Where the States Stand on Medicaid", Sept 2013.

Table C-2: Percent of Children by Income Level eligible for Medicaid in 2014

	Income Level by Federal Poverty Level					
State	<100	100-124	125-150	150-199	200-299	300-399
Alabama	100.0%	100.0%	100.0%	100.0%	100.0%	0.0%
Alaska	100.0%	100.0%	100.0%	47.4%	0.0%	0.0%
Arizona	100.0%	100.0%	32.0%	0.0%	0.0%	0.0%
Arkansas	100.0%	100.0%	100.0%	100.0%	0.0%	0.0%
California	100.0%	100.0%	100.0%	100.0%	57.2%	0.0%
Colorado	100.0%	100.0%	100.0%	100.0%	41.5%	0.0%
Connecticut	100.0%	100.0%	100.0%	100.0%	100.0%	0.0%
Delaware	100.0%	100.0%	100.0%	100.0%	0.0%	0.0%
District of Columbia	100.0%	100.0%	100.0%	100.0%	100.0%	0.0%
Florida	100.0%	100.0%	100.0%	100.0%	0.0%	0.0%
Georgia	100.0%	100.0%	100.0%	100.0%	35.2%	0.0%
Hawaii	100.0%	100.0%	100.0%	100.0%	100.0%	0.0%
Idaho	100.0%	100.0%	100.0%	68.6%	0.0%	0.0%
Illinois	100.0%	100.0%	100.0%	100.0%	0.0%	0.0%
Indiana	100.0%	100.0%	100.0%	100.0%	51.7%	0.0%
Iowa	100.0%	100.0%	100.0%	100.0%	100.0%	0.0%
Kansas	100.0%	100.0%	100.0%	100.0%	43.2%	0.0%
Kentucky	100.0%	100.0%	100.0%	100.0%	0.0%	0.0%
Louisiana	100.0%	100.0%	100.0%	100.0%	44.4%	0.0%
Maine	100.0%	100.0%	100.0%	100.0%	0.0%	0.0%
Maryland	100.0%	100.0%	100.0%	100.0%	100.0%	0.0%
Massachusetts	100.0%	100.0%	100.0%	100.0%	100.0%	0.0%
Michigan	100.0%	100.0%	100.0%	100.0%	0.0%	0.0%
Minnesota	100.0%	100.0%	100.0%	100.0%	75.3%	0.0%
Mississippi	100.0%	100.0%	100.0%	100.0%	0.0%	0.0%
Missouri	100.0%	100.0%	100.0%	100.0%	100.0%	0.0%

	Income Level by Federal Poverty Level					
State	<100	100-124	125-150	150-199	200-299	300-399
Montana	100.0%	100.0%	100.0%	100.0%	51.3%	0.0%
Nebraska	100.0%	100.0%	100.0%	100.0%	0.0%	0.0%
Nevada	100.0%	100.0%	100.0%	100.0%	0.0%	0.0%
New Hampshire	100.0%	100.0%	100.0%	100.0%	100.0%	0.0%
New Jersey	100.0%	100.0%	100.0%	100.0%	100.0%	50.0%
New Mexico	100.0%	100.0%	100.0%	100.0%	46.6%	0.0%
New York	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
North Carolina	100.0%	100.0%	100.0%	100.0%	0.0%	0.0%
North Dakota	100.0%	100.0%	100.0%	26.0%	0.0%	0.0%
Ohio	100.0%	100.0%	100.0%	100.0%	0.0%	0.0%
Oklahoma	100.0%	100.0%	100.0%	65.1%	0.0%	0.0%
Oregon	100.0%	100.0%	100.0%	100.0%	100.0%	0.0%
Pennsylvania	100.0%	100.0%	100.0%	100.0%	100.0%	0.0%
Rhode Island	100.0%	100.0%	100.0%	100.0%	49.7%	0.0%
South Carolina	100.0%	100.0%	100.0%	100.0%	0.0%	0.0%
South Dakota	100.0%	100.0%	100.0%	100.0%	0.0%	0.0%
Tennessee	100.0%	100.0%	100.0%	100.0%	58.0%	0.0%
Texas	100.0%	100.0%	100.0%	100.0%	0.0%	0.0%
Utah	100.0%	100.0%	100.0%	100.0%	0.0%	0.0%
Vermont	100.0%	100.0%	100.0%	100.0%	100.0%	0.0%
Virginia	100.0%	100.0%	100.0%	100.0%	0.0%	0.0%
Washington	100.0%	100.0%	100.0%	100.0%	100.0%	0.0%
West Virginia	100.0%	100.0%	100.0%	100.0%	100.0%	0.0%
Wisconsin	100.0%	100.0%	100.0%	100.0%	100.0%	0.0%
Wyoming	100.0%	100.0%	100.0%	100.0%	0.0%	0.0%

Source: Author's analysis of Kaiser State Health Facts' "Income Eligibility Limits for Children's Regular Medicaid and Children's CHIP-funded Medicaid Expansions as a Percent of Federal Poverty Level (FPL)", July 2012 & Advisory Board Company's "Beyond the Pledges: Where the States Stand on Medicaid", Sept 2013.

APPENDIX D: DETAILED TABLES OF THE HCV POPULATION BY PAYER UNDER EACH SCENARIO FOR 2013-2020

Table D-1: Payer Forecast of the U.S HCV Population under Status Quo Screening and Treatment

Payer	2013	2014	2015	2016	2017	2018	2019	2020
Medicare Non-Dual	146,800	164,010	192,790	223,590	262,760	297,930	330,020	355,670
Medicaid Non-Dual	349,250	432,530	444,010	424,230	393,040	363,540	334,240	307,120
Dual Eligible	193,430	190,200	196,530	200,900	206,330	210,090	213,250	215,080
Small Group	107,630	99,190	87,800	72,550	64,850	58,000	51,190	45,140
Large Group	489,730	457,310	416,710	373,810	333,980	296,370	261,710	230,660
Individual	92,360	75,470	63,740	52,690	42,580	37,640	33,070	29,050
Exchange – Platinum	0	13,820	20,380	25,750	23,670	21,430	19,180	17,060
Exchange – Gold	0	23,780	34,390	44,540	41,000	37,070	33,270	29,610
Exchange – Silver	0	90,770	129,710	173,210	161,940	148,270	134,970	122,720
Exchange – Bronze	0	45,670	69,890	93,680	88,290	80,950	73,930	67,300
Veteran Affairs	275,770	261,860	248,110	234,470	220,970	208,040	195,480	183,380
Other Military	9,500	8,860	8,040	7,250	6,590	6,010	5,360	4,750
Uninsured	978,050	693,160	551,610	439,320	420,860	401,850	382,150	363,340
Total	**2,642,520**	**2,556,630**	**2,463,710**	**2,365,980**	**2,266,840**	**2,167,170**	**2,067,820**	**1,970,890**

Source: Milliman's analysis of NHANES, MarketScan 2010, Medicare 5% Sample, and Medicaid Contributor data.
Totals may not match due to Rounding
Does Not Include Prison Population

Table D-2: Payer Forecast of the U.S. HCV Population under a Low Impact Treatment Scenario

Payer	2013	2014	2015	2016	2017	2018	2019	2020
Medicare Non-Dual	146,800	161,080	185,700	210,810	242,600	268,680	290,660	305,730
Medicaid Non-Dual	349,250	424,270	427,320	399,990	362,710	327,820	294,210	263,550
Dual Eligible	193,430	186,370	188,810	188,990	190,130	189,620	188,390	185,690
Small Group	107,630	95,620	81,760	64,980	55,830	47,830	40,430	34,010
Large Group	489,730	441,490	387,820	334,580	286,970	244,260	206,610	173,920
Individual	92,360	73,020	59,440	47,330	36,710	31,140	26,180	21,960
Exchange – Platinum	0	13,710	19,910	24,720	22,140	19,520	16,950	14,590
Exchange – Gold	0	23,580	33,620	42,590	38,160	33,480	29,250	25,110
Exchange – Silver	0	89,950	126,790	166,570	152,110	135,250	119,270	104,910
Exchange – Bronze	0	45,240	68,380	90,330	83,160	74,210	65,760	57,810
Veteran Affairs	275,770	256,780	238,230	220,280	203,230	187,250	172,270	158,210
Other Military	9,500	8,640	7,600	6,690	5,890	5,210	4,540	3,900
Uninsured	978,050	692,160	549,960	437,230	418,110	398,390	378,080	358,760
Total	**2,642,520**	**2,511,920**	**2,375,330**	**2,235,080**	**2,097,740**	**1,962,670**	**1,832,600**	**1,708,160**

Source: Milliman's analysis of NHANES, MarketScan 2010, Medicare 5% Sample, and Medicaid Contributor data.
Low Impact Scenario – 20% increase in screening, 50% increase in treatment rate, and 90% treatment efficacy
Totals may not match due to Rounding
Does Not Include Prison Population

Table D-3: Payer Forecast of the U.S. HCV Population under a Medium Impact Treatment Scenario

Payer	2013	2014	2015	2016	2017	2018	2019	2020
Medicare Non-Dual	146,800	159,260	181,470	203,540	231,390	253,020	269,980	280,270
Medicaid Non-Dual	349,250	419,660	418,540	386,960	346,180	308,580	272,850	240,880
Dual Eligible	193,430	184,400	184,740	182,720	181,510	178,760	175,250	170,480
Small Group	107,630	93,760	78,620	61,210	51,400	43,100	35,540	29,240
Large Group	489,730	433,000	372,690	314,820	264,400	219,970	181,710	149,270
Individual	92,360	71,680	57,220	44,610	33,890	28,030	23,040	18,970
Exchange – Platinum	0	13,670	19,720	24,130	21,230	18,370	15,660	13,240
Exchange – Gold	0	23,500	33,140	41,520	36,590	31,550	27,090	22,870
Exchange – Silver	0	89,440	125,010	162,360	145,730	127,080	109,750	94,510
Exchange – Bronze	0	45,020	67,480	88,100	79,650	69,710	60,480	51,960
Veteran Affairs	275,770	253,910	232,910	212,820	193,970	176,550	160,450	145,510
Other Military	9,500	8,500	7,370	6,370	5,500	4,820	4,150	3,520
Uninsured	978,050	691,620	548,910	435,980	416,360	396,260	375,610	355,990
Total	**2,642,520**	**2,487,420**	**2,327,830**	**2,165,150**	**2,007,800**	**1,855,780**	**1,711,550**	**1,576,720**

Source: Milliman's analysis of NHANES, MarketScan 2010, Medicare 5% Sample, and Medicaid Contributor data.
Medium Impact Scenario – 50% increase in screening, 100% increase in treatment rate, and 90% treatment efficacy
Totals may not match due to Rounding
Does Not Include Prison Population

Table D-4: Payer Forecast of the U.S. HCV Population under a High Impact Treatment Scenario

Payer	2013	2014	2015	2016	2017	2018	2019	2020
Medicare Non-Dual	146,800	156,080	174,080	190,770	211,980	226,150	235,620	238,810
Medicaid Non-Dual	349,250	410,770	401,390	362,150	315,580	273,580	235,290	202,090
Dual Eligible	193,430	180,390	176,760	170,860	165,730	159,380	152,650	144,830
Small Group	107,630	90,330	72,760	54,330	43,710	35,130	27,800	21,830
Large Group	489,730	416,950	344,830	279,680	225,190	179,690	142,080	111,780
Individual	92,360	68,990	53,040	39,710	29,000	23,060	18,090	14,240
Exchange – Platinum	0	13,550	19,160	22,910	19,470	16,290	13,460	10,910
Exchange – Gold	0	23,210	32,180	39,380	33,750	28,040	23,260	18,980
Exchange – Silver	0	88,550	121,270	154,380	133,760	112,280	92,740	76,590
Exchange – Bronze	0	44,580	65,660	84,040	73,190	61,610	51,280	42,210
Veteran Affairs	275,770	248,250	222,780	199,290	177,540	158,190	140,680	124,800
Other Military	9,500	8,280	6,910	5,810	4,880	4,170	3,510	2,900
Uninsured	978,050	690,490	546,760	433,200	412,540	391,670	370,180	349,830
Total	**2,642,520**	**2,440,430**	**2,237,570**	**2,036,510**	**1,846,320**	**1,669,260**	**1,506,650**	**1,359,810**

Source: Milliman's analysis of NHANES, MarketScan 2010, Medicare 5% Sample, and Medicaid Contributor data.
High Impact Scenario – 100% increase in screening, 200% increase in treatment rate, and 90% treatment efficacy
Totals may not match due to Rounding
Does Not Include Prison Population

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