WHO GETS THE CURE?

REGULATING HEPATITIS C DRUGS IN A STATE OF MEDICAID NON-COMPLIANCE

by

LEAH D.B. CARTER

(Under the Direction of David Mullis)

ABSTRACT

Using the Hepatitis C Virus (HCV) as a focal point and newly approved Direct-Acting Antivirals as the impetus for change, this thesis explores the course of events when states fail to adhere to the federal mandates regarding Medicaid beneficiaries' access to outpatient pharmaceuticals. The researcher analyzed how pressure against restrictive regulatory violations generates momentum to create and find alternative means of funding and procurement. Beginning with federal healthcare policy and moving to state implementation, the researcher used state Medicaid prior authorization restrictions on new, innovative cures for Hepatitis C as an example to argue that the Medicaid system, in its current form, is tolerating blatant non-compliance and failing to provide the federally mandated care for its beneficiaries suffering from Hepatitis C. The researcher concluded with a recommendation to model supplemental federal support in a manner similar to the Ryan White CARE Act.

INDEX WORDS: Regulatory Affairs, Medicaid, Hepatitis C, Direct-Acting Antivirals, Ryan White

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DEDICATION

To Zac, my love

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ABBREVIATIONS

WHO	World Health Organization
SVR	Sustained Virologic Response
CMS	Centers for Medicare and Medicaid Services
DAA	Direct Acting Antiviral
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
DUR	Drug Use Review
AIDS	Acquired Immune Deficiency Syndrome
SVR	Sustained Virologic Response
AMP	Average Manufacturer Price
URA	Unit Rebate Amount
ACA	Affordable Care Act
RWHAP	Ryan White HIV AIDS Program

INTRODUCTION

A recent survey of state Medicaid programs by the Senate Finance Committee revealed that of 68 million reported Medicaid enrollees in 44 states, nearly 700,000 are positive for the Hepatitis C virus (HCV).[1] Medicaid, a program designed to assist in providing healthcare for individuals and families with low income and few resources, is a joint federal and state program with federal mandates but state administration. In contrast, Medicare is designed for individuals over the age of 65 and/or with certain disabilities, and is solely a federal program.

Using HCV as a focal point and newly approved Direct-Acting Antivirals as the impetus for change, this thesis explores the course of events when states fail to adhere to the federal mandates regarding Medicaid beneficiaries' access to outpatient pharmaceuticals and then goes on to suggest a supplemental model which addresses the shortcomings of the current Medicaid system. The researcher analyzed how pressure against restrictive regulatory violations generates momentum to create and find alternative means of funding and procurement. Beginning with federal healthcare policy and moving to state implementation, the researcher used state Medicaid prior authorization restrictions on new, innovative Direct-Acting Antiviral cures for Hepatitis C as an example to argue that the Medicaid system, in its current form, is tolerating blatant non-compliance and failing to provide the federally mandated care for its beneficiaries suffering from Hepatitis C. The researcher concluded with a recommendation to model supplemental federal support in a manner similar to the Ryan White CARE Act (now known as Ryan White HIV/AIDs Program, or RWHAP).[2]

Hepatitis C, a liver disease caused by the blood-borne Hepatitis C virus, affects nearly 3.5 million Americans and 130-150 million worldwide, over three-quarters of which will develop a chronic infection.[3] These patients face significantly higher rates of liver cancer, liver transplant, and early mortality.[4] Deaths due to Hepatitis C related liver diseases alone total 500,000 per year globally, now surpassing HIV and AIDS as the seventh leading cause of death.[3 and 5] At the same time that Hepatitis C surpassed HIV and AIDS in number of deaths, the first of several new Direct-Acting Antiviral (DAA) drugs was approved by the FDA for the treatment of Chronic Hepatitis C.[6] This new class of Direct-Acting Antivirals did not just offer treatment without the devastating side effects of interferon. It offered a cure to Hepatitis C in more than 95% of patients with just one tablet a day over the course of 12 weeks.[7]

For the purposes of this thesis, the researcher defined cure as the clinical endpoint of Sustained Virological Response (SVR), or the absence of Hepatitis C virus RNA, at 12 or 24 weeks. [7] The World Health Organization (WHO), the United Nations, and the World Health Assembly have each made the eradication of Hepatitis C a priority, and access to DAAs is an undeniable piece of that equation. [8] As a measure of reality, WHO acknowledges that a non-zero target is necessary and considers a 90% reduction in incidence and 65% reduction in mortality by 2030 to be a success.[8] The success rate of DAAs alone more than surpass the expectations of WHO. Even with a 95% cure rate and success exceeding WHO standards, non-compliant state Medicaid plans maintained policies of restricted access to DAAs; and the federal government did little to enforce their own policies.

In Chapter One, the researcher discusses the reimbursement process by first exploring the federal regulations of the Social Security and Medicaid Acts as well as details of the Medicaid Drug Rebate Program and then looking more broadly at how states tackle implementation of

Medicaid reimbursement programs. Traditionally, where regulations exist, so do violations of those regulations. So, in chapter two, the researcher addresses the timely issue of ways in which state programs are limiting access to innovative cures under the auspices of prior authorization programs and keeping their budgets in check. The research indicates that states are failing to comply with the federal regulations that entitle patients to federally funded treatment of Hepatitis C virus. Using the state of Illinois as a case study, the researcher reviewed prior authorization programs for Direct-Acting Antivirals (DAA) as a cure for Hepatitis C virus (HCV). The researcher compared and discussed the use of restrictions among several states and the implications of these restrictions. Chapter Two concludes with an analysis of the data indicating that many of the restrictions are unduly prohibitive according to the Social Security and Medicaid Acts.

In Chapter Three, the researcher discusses and analyzes different methods of appeal available to providers, patients, and states when medical care is denied or is largely inaccessible due to regulatory violations. Moving away from federal policy and to state implementation, the question changes from "What constitutes compliance?" to "Who can be held accountable in cases of non-compliance?" When providers and patients are denied reimbursement and treatment, or when states feel coerced into particular payment programs or excluded from others, what recourse do they have? Utilizing the Supreme Court case of *Armstrong vs. Exceptional Child Center*, the researcher offers insight into current legal thought regarding a Medicaid care provider's ability, or lack thereof, to sue a state over reimbursement rates. [31] Likewise, some patients have threatened suit against their state Medicaid program for denial of care. In New York, the Attorney General opened an investigation into the prior authorization practices of sixteen health insurance companies which put pressure on the state's own Medicaid programs.[9]

Chapter Three concludes by exploring these avenues of appeal and how they impact compliance and accessibility.

In Chapter Four, the researcher looks at how the current disconnect between the state and federal administration of Medicaid creates an environment where states are blatantly violating federal policy with little accountability and no ramifications. Specifically, the research explored which avenues of recourse are available to CMS when dealing with state's non-compliance and details compliance efforts such as state reporting of budgets, disbursements, reimbursements, and drug oversight boards. The researcher also discusses requests for information from CMS and any response given to date. CMS requires frequent and voluminous reports on program specifics, reimbursement details, and enrollment numbers, yet very little seems to be done with that data in regards to enforcement. On November 5, 2015, CMS issued a letter specifically regarding HCV treatment prior authorization programs and asked for insight into pricing structures.[10] In said letter, CMS offered suggestions for compliance and promised monitoring; but, to date, they have never ventured so far as to take punitive action on state Medicaid violations. It can even be argued that the only recourse available to CMS is a so called 'nuclear option' of revoking state funding, which no one believes will ever happen.[11 and 12]

In the fifth and final chapter, the researcher discusses the disconnect between federal and state administrations and how some states have managed to change the tide and pull their programs into compliance. Given the high prevalence of states with remaining violations, the researcher recommends supplemental federal funding modeled after the Ryan White CARE Act as a means to grant access to cures and innovative treatments.[51] The researcher also briefly discusses the additional recommendations of increased federal oversight and the incorporation of 'treatment as prevention.'

CHAPTER ONE

REGULATORY FOUNDATIONS

Medicaid was brought into law in 1965 as Title XIX of the Social Security Act to provide healthcare benefits to low-income individuals. Now the single largest health insurer in the country, Medicaid offers its enrollees state specific programs consisting of comprehensive benefits packages subsidized by a collaboration of state and federal funding. The goal is to share the costs of providing healthcare for low income individuals in the hope that the uninsured, marginalized, and those without recourse to other means would avail themselves of treatment which had previously been out of reach. The funding comes as an agreement to comply with federal policy regarding aspects of care, coverage, and reimbursement. Established on a foundation of shared interests, states develop their own enrollment eligibility standards, determine the nature of the care provided, establish rates of payment, and have the privilege of administering their program quite autonomously while the federal government retains oversight. Implementation of excessive restrictions on access to that care would certainly go against the defacto goal of Medicaid and further widen any gaps in disparity of care. In fact, Section 1927 of the Social Security Act (also known as 42 U.S.C. 1396r-8) gives only five scenarios in which restrictions on prescription drugs are permissible.

1. Prior Authorization, provided it complies with paragraph 5 of Section 1927, is allowed for any covered outpatient drug.
2. A state may exclude or restrict coverage if the prescribed use is not for a medically accepted indication as stipulated in FDA approved labeling.

3. A state may exclude or restrict coverage to any drug listed in paragraph 2 of 7(d). This includes drugs for weight loss or gain, fertility, cosmetic purposes, symptomatic relief of cough and colds, smoking cessation, vitamins and minerals, nonprescription drugs, barbiturates, benzodiazepines, and drugs used to treat sexual or erectile dysfunction.
4. A state may exclude or restrict any drug which is also the subject to restrictions under an agreement between a manufacturer and state.
5. A state may exclude a drug from its formulary provided it was done so in accordance with paragraph 4 of 7(d).

The researcher dealt exclusively with the first two of these scenarios: that of Prior Authorization and the provision regarding medically indicated use.

It is important to note here that coverage for outpatient prescription drugs is *not* a requirement by federal or state mandate. Rather, it is a decision left entirely up to each state. However, despite being optional, every state has chosen to participate and nearly all of the nation's 72.4 million Medicaid enrollees now receive prescription drug coverage.[13] This number includes the 700,000 Medicaid beneficiaries who test positive for the Hepatitis C virus. Because all states and the District of Columbia have chosen to cover outpatient drugs, they are all accountable to the regulations set forth in the Social Security Act, title XIX above. The problem is that up to 88% of states, as shown in Chapter Two, are establishing and implementing restrictive prior authorization policies which potentially violate the Social Security Act.

Prior Authorization requirements are quite common in general and are certainly no different in the case of new DAAs. In fact, only one state (Nevada) claims to have no prior authorization requirements for Sofosbuvir (brand name Sovaldi® - one of the more common

DAAs).[14] Prior authorization criteria range from co-diagnosis, history of alcohol and drug use, to requirements on who can prescribe the drug and severity of disease. The implementation and ramifications of these criteria are the subject of Chapter Two. However, the fact that prior authorization *is* allowed should not be confused with the idea that any and all restrictions are permitted.

According to (7)(d)(5) of the Social Security Act, prior authorization should not act as a formulary.[4] In other words, the intent behind seeking prior approval of a drug is to afford the State time to confirm that the drug is medically indicated and that other legitimate requirements are met. In reality though, it is not uncommon for 50% to 80% of Medicaid DAA prior approvals to result in a denial. [16 and 17] Such staggering numbers seem more like DAAs are failing to make the formulary rather than an individual case not meeting prior authorization criteria. (There are specific criteria for formularies as well, but since DAAs are listed on nearly every state formulary, the focus here will remain prior authorization). In particular, a comparative survey by Lo Re showed 46% of Medicaid patients received a denial compared to 10% of private insurance and 5% of Medicare patients being denied. [17] In October of 2014, the first month in which the state of Illinois tracked their HCV drug denials, 43 out of 50 Medicaid DAA requests were denied. [16]

There are two more pieces of legislation under the fold of Title XIX that play heavily into the landscape of restricted access to innovative drugs. Both Drug Utilization Review (DUR) boards and the Medicaid Drug Rebate Program were introduced with the Omnibus Budget Reconciliation Act of 1990. Working separately, they serve similar roles in spelling out the particulars of how Medicaid is managed on the state level in terms of coverage and reimbursements. The establishment of DUR boards addresses adherence to FDA labeling

indications and hints at supplemental rebates. The Medicaid Drug Rebate Program covers a variety of compliance issues including general accessibility, consistency in reporting, and further discusses supplemental rebates. While the complexities of pricing factor heavily into how aggressively a state may decide to restrict access to extremely expensive drugs, the minute details of calculations and larger economic ramifications lay beyond the scope of this thesis.

The Omnibus Budget Reconciliation Act of 1990 introduced Drug Utilization Review (DUR) boards to state Medicaid programs in an effort to allow states even more control over their program's formularies and benefit programs. DUR boards generate lists of FDA approved drugs which have been vetted to be equal in terms of safety and effectiveness. These decisions are made by panels of independent physicians and pharmacists, for whom there should be no financial interest, and with the backing of both public comment and scientific data. In the absence of evidence showing reduced effectiveness or lack of safety, a drug should be made available to plan beneficiaries via the state formulary. For any listed drug, a prescription should be covered by Medicaid provided it meets compliant prior authorization requirements and it is written for use in accordance with the FDA's approved labeling. Federal policy is very clear in its definition of 'medically accepted indication':

> The term "medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(1).[15]

The burden of screening for safety and effectiveness is rightly placed upon the FDA. The role of the DUR board is to refer to FDA approval and to look for drugs of equal footing to offer to their beneficiaries. FDA labeling will list medically accepted indications. To deny coverage for a drug which has already passed FDA's stringent testing and labeling requirements is a direct violation of the Social Security and Medicaid Acts.

Once a drug is listed on the state's formulary, it may be eligible for additional distinction as a 'preferred drug.' The benefit of being a 'preferred drug' brings the honor of increased preference from the state since these drugs often come with additional non-disclosed rebates. These further rebates are legal according to federal law. The same provision that allows these non-disclosed rebates also mandates that the public does not have the right to know the exact amount of rebates negotiated. Consequently, a 'preferred drug' status means more access and is discussed further in Chapter Five. Three issues remain to be addressed in this chapter: How are drugs which are on a state's formulary being denied with such frequency? What are the valid limitations on coverage of prescription drugs? And, what qualifies as non-compliance?

The Medicaid Drug Rebate Program steps in at this point and stipulates the specifics of pricing and reimbursement for the more than 600 drug manufacturers that choose to offer their drugs to Medicaid beneficiaries.[18] See Figure 1.0 for an illustrated overview of participation in the Medicaid Drug Rebate Program. The program, a collaboration between CMS, state Medicaid offices, and participating drug manufacturers, is designed to reduce the financial impact of outpatient prescription drugs to Medicaid beneficiaries. While participation in the Medicaid Drug Rebate Program is optional for drug manufacturers just as it is for states, it is the only way for a manufacturer to have their drugs covered under Medicaid. In other words, if a manufacturer doesn't agree to CMS's rebate rates and rules, doctors and hospitals who provide to Medicaid patients won't be able to prescribe that manufacturer's drugs. Consequently, the promise of a large state/federal contracts lures drug manufacturers in, and in exchange, the manufacturers agree to supply product and pricing data along with participation in a national rebate agreement. Essentially, the manufacturers tell the state Medicaid programs about which new drugs are available for coverage and then pay a rebate for every time their drug was utilized under the state

plan. If a state chooses to participate in the Medicaid Drug Rebate Program, they must submit all of their drugs to Medicaid's Drug Data Reporting database (DDR), thereby agreeing to pay a rebate for all instances of coverage under Medicaid. Rebates are then paid by the manufacturer quarterly and shared between states and the Federal government.

For manufacturers choosing to participate, there are two more required agreements which must be entered into: Section 340B Pricing Program and a master agreement with the Secretary of Veterans Affairs for the Federal Supply Schedule. A Section 340B pricing agreement means that the manufacturer will provide their drugs at a sharp discount to approved nonprofit healthcare organizations such as Ryan White Care Clinics, specialized children's hospitals, and tuberculosis clinics.[19] The VA Federal Supply Schedule (FSS) master agreement is a manufacturer's promise to offer their drugs within set pricing structures for federal contracts.

Once all three of these agreements (submission of all drugs to the DDR, 340B Pricing Program, and the Federal Supply Schedule) are entered into, the drug manufacturer can calculate their Medicaid rebate amount. Since DAAs are currently innovator drugs, the researcher focused solely on the Innovator Drug formulary though there are many formularies from which to choose. The Unit Rebate Amount (URA) calculation proceeds through a series of steps based upon the manufacturers reported pricing. The result of the first three steps is then compared with Average Manufacturer Price (AMP). The URA then becomes the greater of 23.1% of the AMP per unit or the difference between the AMP and the best unit price as adjusted by the Consumer Price Index-Urban above.[20] For reference, non-innovator drugs have a standard URA of 13% of AMP regardless of drug classification, and paragraph (7)(c)(2)(D) prohibits the URA from ever exceeding 100% of the AMP. The definition of 'best price' should not be overlooked either, especially for single source or multi-source innovator drugs, since manufacturers can quite

obviously price their products at whatever level they feel the market can support. However, the lowest price made available to *any* wholesaler, retailer, healthcare provider, nonprofit, or government entity serves as the 'best price' with a few, very significant, exceptions. These exceptions are prices offered under the Federal Supply Schedule and prices offered under Medicare's Part D Prescription Drug Plans or state pharmaceutical assistance and drug discount card programs.[15]

The relevant sections of the Act go on to stipulate reporting requirements and obligations on the part of both the states and the manufacturers entering into the rebate agreements. These aspects of oversight will be discussed in detail in Chapter Four. Once a drug manufacturer becomes a participant in the Medicaid's Drug Rebate Program, their products become eligible for coverage under state Medicaid programs, but that is not a guarantee that they will be prescribed nor approved by every state program. As we will see with the DAAs for HCV, even with the rebate agreements, the cost of some drugs remains so high that state plans often implement a system of checks to keep the higher cost drugs from depleting their entire funding - which brings us right back to prior authorization, indicated use labeling, and the ways in which states bypass these regulations.

Most recently, the Affordable Care Act (ACA) came into effect in 2014 and greatly expanded Medicaid eligibility thereby adding significantly to the number of HCV patients calling upon their state Medicaid programs for coverage of the new DAAs. The ACA also implemented prevention and wellness programs and encouraged the coordination of care between Medicaid and Medicare for individuals who are eligible for both.[21] Together these provisions further increased awareness of HCV and later DAAs in the public eye. Combined with the general and timely push to promote testing for HCV among Baby Boomers, insurers and

state Medicaid programs nationwide faced a new sense of urgency to monitor and control the growing expense of the new HCV cures. The ACA essentially added so much volume that regulatory foundations set out by the Social Security Act, and the provisions of the Omnibus Budget Reconciliation Act of 1990 were stressed and their limits tested. Chapter Two will explore the ways in which states have tested these limits and exploited the resulting disconnect to the detriment of Medicaid beneficiaries nationwide.

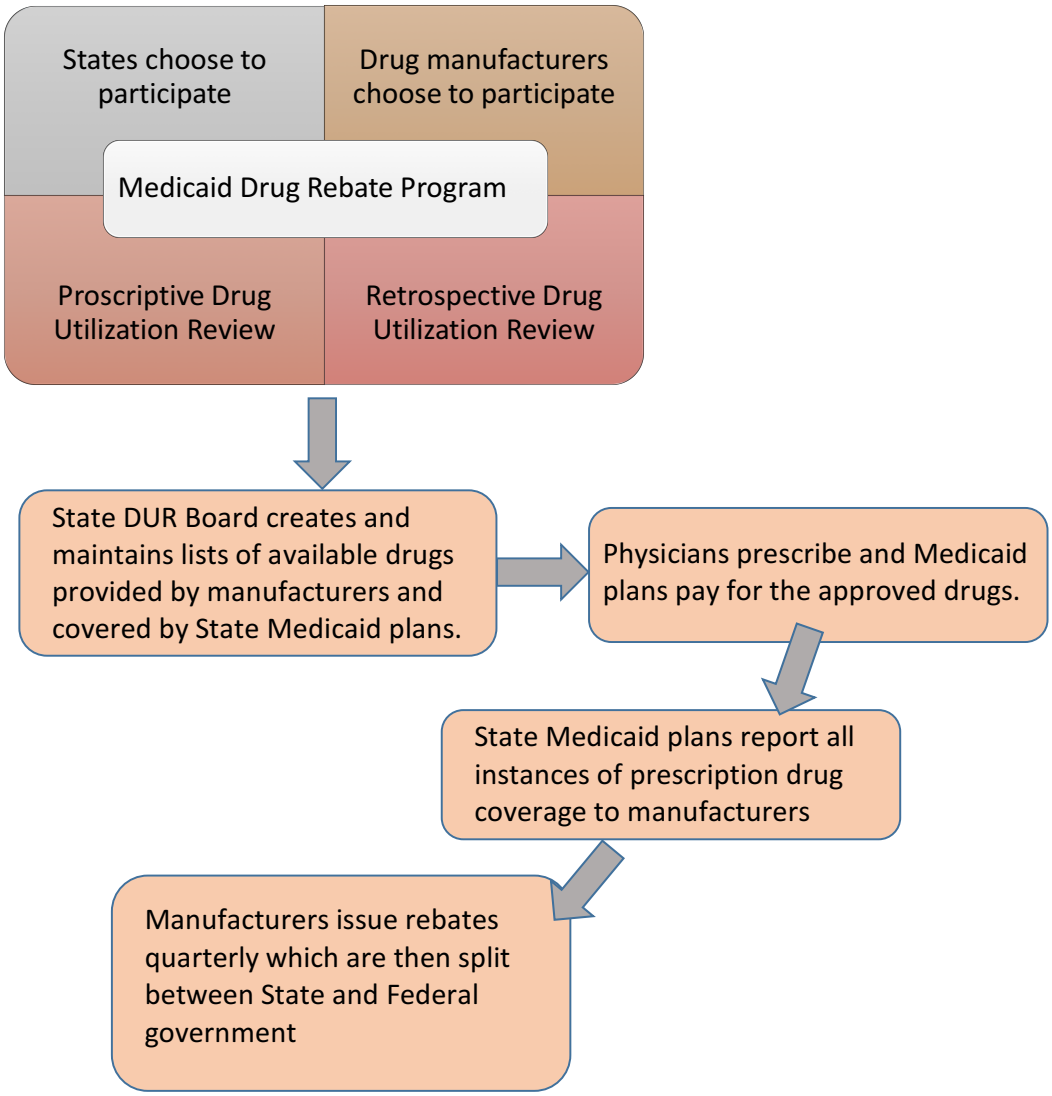


Figure 1.0 Medicaid Drug Rebate Program Participation

CHAPTER TWO

STATE IMPLEMENTATION

Federal policies are the foundation upon which states build and administer their individual Medicaid plans. With their afforded operational autonomy, states are free to develop and implement prior authorization programs to control and monitor which drugs are provided, to whom, and for which indications. The fact that states utilize prior authorization is not at issue. The problem arises when prior authorization is used in direct violation of federal policy to severely restrict access to care which is otherwise effective, clinically appropriate and medically necessary.

As established in Chapter One, when a state enters into an agreement to provide coverage for outpatient prescription drugs, they are contractually bound to provide coverage for the drugs of manufacturers who have also entered into rebate agreements. Yet, the reality and frequency of DAA denials indicates that not all clinically appropriate and medically necessary treatments are being covered. On November 5, 2015, the Centers for Medicaid and Medicare (CMS) issued a Medicaid Drug Rebate Program Notice to all participating states stating: "CMS is concerned that some states are restricting access to DAA HCV drugs contrary to the statutory requirements in section 1927 of the Act by imposing conditions for coverage that may unreasonably restrict access to these drugs."[10] CMS goes on to highlight three specific types of criteria which should be examined for compliance: disease stage, history of substance use or abuse, and specialist care. Both the Senate Committee on Finance and the team of Barua et al. collected comprehensive

data to systematically evaluate the state Medicaid policies of all 50 states and the District of Columbia.[1 and 14] Their reports include data on prior authorization/reimbursement criteria for all three of CMS's areas of concern. In reviewing data and reports, the researcher used the most current numbers when possible, often checking one against the other for discrepancies. The researcher also pulled data on the state of Illinois, considered one of the most restrictive states, specifically to use as a reference point. See Tables 2.1, 2.2, 2.5, and Figures 2.1 and 2.2.

Liver Disease Stage

Prior Authorization criteria based on liver disease stage is the most prevalent of the three main criteria as most professional organizations recognize the value of a scoring system in prioritizing care.[14] The European Association for the Study of the Liver (EASL) presented widely accepted treatment guidelines in 2015 which prioritized, not restricted, treatment to patients with Metavir scores of F3 and F4. Scores of F2 are also encouraged for treatment, though perhaps not the first priority.[22 and Figure 2.0]

Yet when funds are absolutely limited, prioritizing can easily lend itself to serving as a cut off point for care rather than the suggested triage for which it was intended. Using Sofosbuvir as an example of DAAs, of the 42 states with reimbursement/coverage restrictions, 31 limit benefits to patients with advanced fibrosis or cirrhosis (Metavir scores of F3 or F4).[14] See Table 2.1. A Metavir score of greater than or equal to 2 means that fibrosis is present; 3 indicates advanced liver disease without cirrhosis; and a score of 4, the highest level, means that cirrhosis is present.[23] The scoring system was developed to aid in understanding how far the disease has advanced in an individual and to guide predictions on the rate at which the disease might progress in the future. It is not an indicator of how well a patient is expected to respond to treatment. In fact, as illustrated later in this chapter, disease stage has very little to do with DAA

success rate. Additionally, seven states do not cover treatment to patients with decompensated cirrhosis (advanced Metavir F4). See Figure 2.4 for details on compensated vs decompensated cirrhosis. Like so many other restrictions, this one is not just without supporting evidence; it is in direct contrast to the latest studies showing SVR success regardless of disease progress.

Table 2.1 Disease Stage / Metavir Score Criteria by State

Criteria	Number of States	Illinois
No Fibrosis Score Indicated	8	
At Least F2 (moderate fibrosis)	3	
At Least F3 (significant fibrosis)	27	
Must be F4 (cirrhosis)	4	✓
Ineligible due to Decompensated Cirrhosis	7	
Mandatory Liver Biopsy	6	
* based on 42 states who provided prior authorization criteria data		
See Figure 2.1 for an illustrated chart		

Limiting treatment to those patients with the most advanced liver disease dramatically reduces financial outflow in the short-term, but there are several factors to consider in deciding whether or not such restrictions are in compliance with federal policy. (Not to mention non-regulatory considerations such as 'affordable vs. cost effective,' Quality Adjusted Life Year, and the growing concept of 'treatment as prevention' which is discussed in Chapter Five.) According to 1927(d) of the Social Security Act, a covered outpatient drug should not be excluded so long as it is prescribed as indicated on FDA approved labeling. DAAs such as Sovaldi® (Sofosbuvir) are approved by the FDA for use in patients with "HCV genotype 1, 2, 3 or 4 infection, including those with hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation) and those with HCV/HIV-1 co-infection."[24] The labeling indications do *not* include any reference to liver disease stage or disease progress.

It is also not the case that scientific data exists to indicate lower success rates on patients with more advanced fibrosis or cirrhosis. To the contrary, a study of 2,432 patients, 82% of whom were F3 or F4, showed a 90.4% success rate of achieving SVR when treated in compliance with EASL guidelines of prioritized treatment for Metavir scores of F3 and F4.[25] Similarly, a UK study of 467 patients, 88% of whom had current or past decompensation, showed early and significant improvements in liver function over those who went untreated. Those treated with DAAs achieved SVR 80% of the time, had more frequent score improvements, fewer decompensation events (18 vs. 28%, $p = .0006$), and total adverse outcomes were reduced by 12% over those patients not receiving treatment ($p = .004$).[26]

Early treatment, even in the most severe cases, has been shown to improve liver histology, decrease fibrosis score, and stop the disease progression such that once SVR has been achieved, the American Association for the study of Liver Disease and the Infectious Disease Society of America recommends no further monitoring.[7]

Substance Use and Abuse Limitations

Of the 42 states with known criteria, 37 (88%) have at least some alcohol or drug use restrictions making it the most widely used of the three prior authorization criteria. See Table 2.2. Testing before treatment and a period of abstinence are the most common requirements with half of the states requiring both. Illinois's required period of abstinence is the longest on record at 12 months.

Table 2.2 Substance Use Criteria by State

Substance Use Criteria	Number of States	Illinois
Asks about or requires treatment for person with a history of abuse	17	
Allows exemption if currently in treatment	6	
Requires drug or alcohol testing of everyone before treatment	21	✓
Requires testing only for those with history of abuse	6	
Requires period of abstinence for all	21	12 months
Requires period of abstinence for those with history of use	9	
* based on 42 states who provided prior authorization criteria data		
See Figure 2.2 for an illustrated chart		

With criteria this stringent, it would seem that there is solid evidence backing the assumption that drug and alcohol use seriously hinders either compliance with, or the success of, treatment. This is not the case. Grebely et al. conducted a study of 865 patients at 99 sites to assess the impact of illicit drug use on treatment outcomes.[27] The percentage of patients who adhered to treatment and completed treatment remained nearly identical regardless of whether or not the patient used illicit drugs during the course of HCV treatment with DAAs. Similarly, the percentage of patients who achieved SVR12 was only slightly less in patients who also used drugs during treatment.

Tables 2.3 and 2.4[27] Drug Use Impact on Outcome

Adherence to Treatment

Patients, n (%)	No Illicit Drugs n=657	Cannabinoids Only n=126	Any Illicit Drugs +- Cannabinoids n=70
>= 80% adherence	598 (91)	116 (92)	64 (91)
p-value vs no illicit drug use		0.86	1.00
Completed treatment	643 (98)	124 (98)	68 (97)
p-value vs no illicit drug use		1.00	0.66

Virologic Outcome

Outcome, n (%)	No Illicit Drugs n=657	Cannabinoids Only n=126	Any Illicit Drugs +- Cannabinoids n=70
SVR12	652 (99)	123 (98)	68 (97)
p-value vs no illicit drug use		0.12	0.14

While patients who use drugs are not any less likely to stop treatment than a non-drug user and DAA treatment has been shown to be equally safe and effective for both populations, it is true that transmission rates may be higher in patients who also inject drugs. Higher transmission rates affect predominantly new cases of HCV as re-infection after SVR is exceedingly rare at 1-5% per year.[28] The National Institutes of Health (NIH), the Infectious Diseases Society of America (IDSA), EASL, the American Association for the Study of Liver Diseases (AASLD), and WHO have all acknowledged the lack of documented evidence to support drug and alcohol use restrictions on care. Each of these world respected organizations now recommend treating HCV infection in people who use drugs.[28] The logical question then becomes: Why don't states do the same?

Specialist Care

Two thirds of the states reviewed require treatment or authorization by a specialist. See Table 2.5. This may not seem like a particularly restrictive requirement and certainly it isn't as controversial as those revolving around drug or alcohol use. However, it is important to remember that many, though not all, of those infected with HCV are already marginalized and denied at the hands of their healthcare system. They may not have the support and encouragement to seek help and may fear having to admit addiction or unsafe sexual practices. Getting this unique population to avail themselves of Medicaid is a feat in and of itself. But

getting them to then seek a referral, meet with a new doctor, and divulge all their information again can be a challenge especially when the reasoning behind the requirement is unclear. Any concerns regarding decreased safety or effectiveness of the HCV cure when prescribed by primary care physicians rather than by specialists was disproved in a study called ASCEND.[29] Sarah Kattakuzhy of the University of Maryland ran a phase 4, open-label trial with 600 subjects at two urban primary care centers between May and November 2015. The results showed that primary care patients achieved similar completion and success rates as patients who were treated exclusively by specialists:

> The ASCEND investigation demonstrates that HCV treatment administered independently by primary-care physicians and nurse practitioners is safe and equally effective as care observed with experienced specialists, inclusive of challenging sub-populations of the epidemic, and within the largest black cohort described to date.[29]

Keeping the cure as close to the intended population as possible is a huge step in easing access particularly when restrictions based on type of provider have been proven to be medically unnecessary and unduly burdensome.

Table 2.5 Specialist Care / Prescriber Limitations by State

Specialist Care / Prescriber Limitations	**Number of States**	**Illinois**
Prescriber Limitations	29	✓
No Prescriber Limitations	13	
* based on 42 states who provided prior authorization criteria data		

To put the specific limitations into perspective, consider a timeline of prior authorization requirements put into effect by the state of Illinois's Medicaid program. See Figure 2.3. Beginning in January of 2014, Illinois was spending $1 million/week to cover hundreds of requests for Hepatitis C treatments for Medicaid beneficiaries. Between January and the end of

September, 313 requests were received and approved. However, midway through that time period, on July 10th, the state implemented 25 different prior authorization requirements for DAAs.[16] Almost all of these requirements fall into the three categories discussed previously. Others include once in a lifetime treatment and co-morbidity criteria. Once the additional criteria of July 10th were implemented, denials rose astronomically, and Hepatitis C spending dropped from $1 million/week to $200,000/week. In October alone, 43 out of 50 Medicaid requests for DAAs were denied by the state of Illinois.[16] After the 86% denial rate, Brian Edlin, professor of Public Health at Cornell cautioned: "[As] Medicaid insurers are continuing to impose these severe restrictions and onerous prior authorization processes, … this disease will become increasingly a disease of the poor, and health inequities that already exist will sharpen."[30]

The World Health Organization (WHO), the United Nations, and the World Health Assembly have each made the eradication of Hepatitis C a priority. How, though, can a global health priority possibly begin to be eradicated when access to the cure is severely restricted as seen with Medicaid's prior authorization requirements? When states are failing to provide federally mandated care, what recourse is available to patients and providers?

Treatment priority	Patient group
Treatment should be prioritized	. Patients with significant fibrosis (F3) or cirrhosis (F4), including decompensated cirrhosis . Patients with HIV coinfection . Patients with HBV coinfection . Patients with an indication for liver transplantation . Patients with HCV recurrence after liver transplantation . Patients with clinically significant extra-hepatic manifestations . Patients with debilitating fatigue . Individuals at risk of transmitting HCV
Treatment is justified	. Patients with moderate fibrosis (F2)
Treatment can be deferred	. Patients with no or mild disease (F0-F1) and none of the above-mentioned extra-hepatic manifestations
Treatment is not recommended	. Patients with limited life expectancy due to non-liver related comorbidities

Figure 2.0 EASL Treatment Guidelines

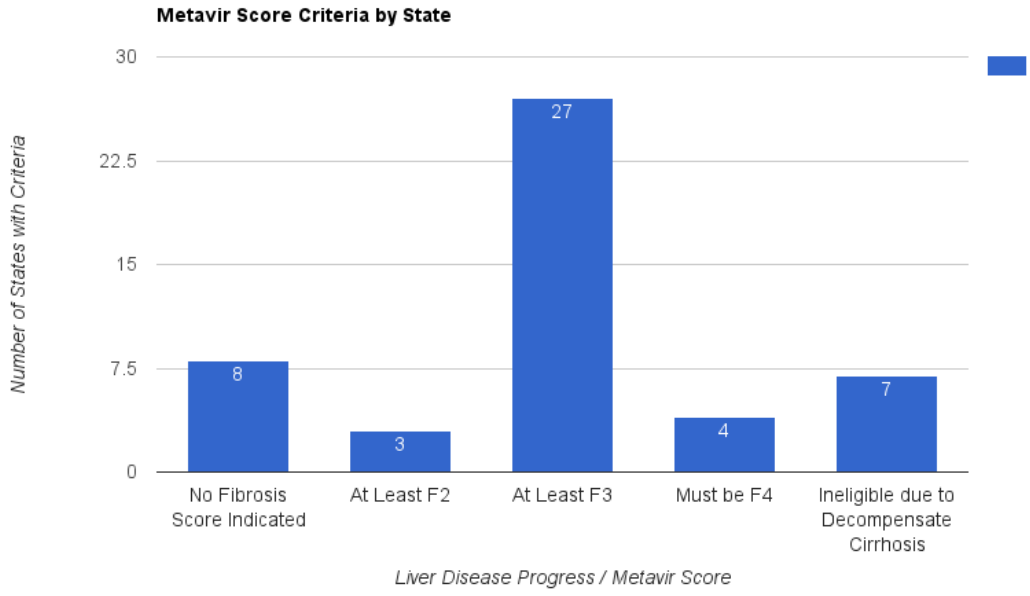


Figure 2.1 Metavir Score Criteria by State

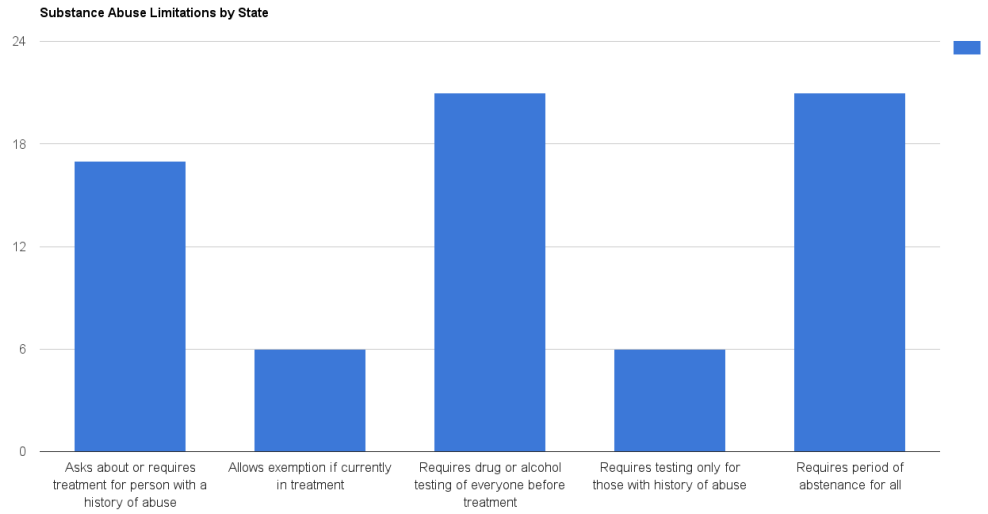


Figure 2.2 Substance Abuse Limitations by State

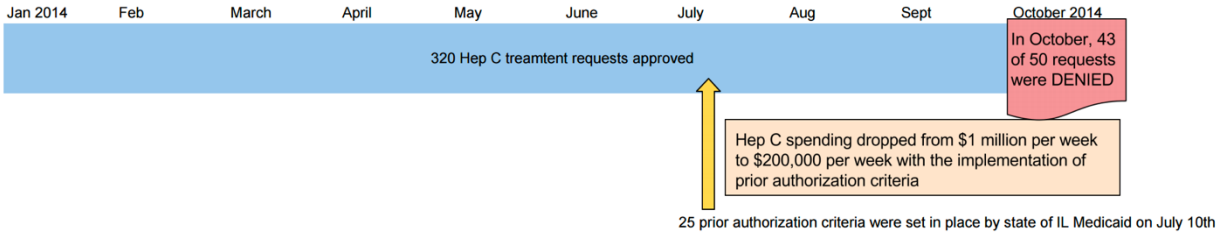


Figure 2.3 Timeline of Illinois Prior Authorization Criteria Implementation

	Compensated Cirrhosis		**Decompensated Cirrhosis**	
Stage (not Metavir score)	Stage 1	Stage 2	Stage 3	Stage 4
Clinical Indicators	No Varices No Ascites	Varices No Ascites	Ascites +/- Varices	Bleeding +/- Ascites
Death (at 1 year, without treatment)	1%	3%	20%	57%

data obtained from Reference 71

Figure 2.4 Compensated and Decompensated Cirrhosis

CHAPTER THREE

METHODS OF APPEAL FOR PROVIDERS, PATIENTS, AND STATES

The relationship between federal and state governments is a complex one especially when it comes to policy which is issued and monitored federally but implemented and administered on a state level. When beneficiaries or private parties of a State Medicaid plan feel as though violations are occurring, they often turn to the states directly, citing federal policy. Chapter Three addresses instances where state beneficiaries and parties appeal to their plan administrators to rectify violations in access to care. At least six states have had success petitioning their State Medicaid offices to lessen restrictive criteria for the coverage of Direct-Acting Antivirals (DAAs). Three were letters only, two were court cases, and one was an investigation initiated by the State Attorney General. (See Table 3.1) In all cases, beneficiaries and providers were able to petition for positive change regarding state violations of federal policy. Though not a legal suit, the letters had power because standing behind them was the threat of a lawsuit. Little did they know, the threat would soon have no teeth. *Armstrong v. Exceptional Child Center* moved up the judicial system all the way to the Supreme Court of the United States and now, as evidenced later in Chapter Three, has the potential to thwart all future petitions.[31] In it, the Supreme Court removed the power of the individual by declaring a private party unable to sue for violations of federal law.

When DAAs were introduced in late 2013, states began drafting and implementing prior authorization criteria to accommodate the forthcoming prescriptions as required by law. As discussed in Chapter Two, the criteria chosen by many states were restrictive to the point of

denying access to large portions of Medicaid beneficiaries with HCV. Within a year, many states were facing legal challenges regarding their over restrictive policies on access to DAAs. Citing violations of the Medicaid Act, the patients and providers bringing suit most commonly called on a combination of three arguments:

1. Failure to provide care which is safe, effective, and medically necessary; and
2. Reasonable Promptness; and
3. Comparable Care

The researcher has explored each of these three arguments in turn to find significant overlap and similar success via different routes as discussed in this chapter.

Table 3.1 Action Taken and Result by State

State	Date of Initial Action	Type of Action	Argument	Section Violated	Result of Action
Connecticut	2/19/2015	Letter to State Medicaid Office	Medically Necessary	42 U.S.C. 1396r-8	All restrictions were lifted within 3 months
			Reasonable Promptness	42 USC 1396(a)(8)	
Delaware	3/28/2016	Letter to State Medicaid Office threatening class action	Reasonable Promptness	42 USC 1396(a)(8)	Phasing in expanded access with all disease stage requirements removed by January 2018
			Comparable Care	42 USC 1396(a)(10)(B)(i)	
Washington	5/31/2016	Federal Court Case of *B.E. et. al v. Teeter*	Medically Necessary	42 U.S.C. 1396r-8	Judge ordered disease stage restrictions lifted. Other restrictions remain in place.

State	Date of Initial Action	Type of Action	Argument	Section Violated	Result of Action
Florida	04/2016	Letters to State Medicaid Office	Comparable Care	42 USC 1396(a)(10)(B)(i)	Removed disease stage requirements but Substance Use and Abuse requirements remain in place[80]
New York	03/02/2016	State Attorney General investigated private insurers[41]	undisclosed	undisclosed	Removed disease stage requirements only
Idaho	2011 Lower Courts 2014 Supreme Court	United States Supreme Court Case	Equal Access	42 USC 1396(a)(30)(A)	Court ruled private parties may not bring suit for violations of federal law
			Supremacy Clause	42 USC 1396c	

1. Safe, Effective, and Medically Necessary

Turning to the first argument of failure to provide care that is safe, effective, and medically necessary, Section 1927 of the Social Security Act (42 U.S.C. 1396r-8 specifically) discusses payments for covered outpatient drugs and in it lies the details upon which this legal claim is based. It states that:

> A State may exclude or otherwise restrict coverage of a covered drug if –
> i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6);
> ii) the drug is contained in the list referred to in paragraph ((2)
> iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) or in effect pursuant to subsection (a)(4)[32]

Connecticut and Washington both invoked violations of this section of the Medicaid Act in their petitions for change noting that allowed exceptions are expressly defined and clearly do not include indications for which a safe and effective (FDA approved) drug is medically necessary.

As discussed in Chapter One, the Medicaid Act mandates that state programs cover participating drugs for their prescribed use when medically indicated and as stipulated in FDA approved labeling. (Noting of course that FDA approved labeling implies that the drug has already been determined safe and effective by the FDA.) There are a few enumerated exceptions in the Act, but none of those exceptions apply to current circumstances. New Haven Legal Assistance Association, Inc. summarizes the mandate quite succulently in their letter to the State of Connecticut's Commissioner of the Department of Social Services:

> … under federal Medicaid law, notwithstanding cost, if a drug is FDA-approved, subject to a rebate agreement with the manufacturer, and not in one of the few categories in which a state is allowed to exclude coverage (for adults only, none of which are applicable here), the drug must be made available wherever medically necessary, although prior authorization may be imposed.[38]

The letter was so successful that within three months DAAs were listed on the State Medicaid's Preferred Drug List, and the prior authorization process was streamlined significantly making DAAs "readily available" to all State Medicaid beneficiaries regardless of disease stage, substance abuse history, or specialty care.[33]

Medicaid beneficiaries in the state of Washington also relied on an argument citing denial of medically necessary care. In this instance, however, intervention from a Judge was necessary to bring about change. The federal court case of *B.E. et all v. Teeter* (2:16-cv-00227) resulted in the Honorable John C. Coughenour granting a preliminary injunction finding that the plaintiffs were likely to prove that the state's restrictions on DAAs were violating access requirements according to federal Medicaid policy. In his decision, Judge Coughenour states:

> "The extensive evidence provided by the plaintiffs and the lack of substantial counterevidence from the [Washington Health Care Authority] establishes that there is a consensus among medical experts and providers that the lifesaving DAAs are 'medically necessary' for all [Hepatitis C virus] infected persons, regardless of fibrosis score. … Plaintiffs have adequately demonstrated that they are likely to prevail on their claim."[34 and 35]

2. Reasonable Promptness

The second argument, that of reasonable promptness, is found in 1396(a)(8) of the Medicaid Act which states:

> A State plan for medical assistance must provide that all individuals wishing to make application for medical assistance under the plan shall have opportunity to do so, and that such assistance shall be furnished with reasonable promptness to all eligible individuals;[36]

Both Delaware and Connecticut used the argument that criteria stipulating fibrosis score or requiring advanced disease stage are a violation of federal policy which requires reasonable promptness of care. HCV is a slowly progressing infection with more severe and life threatening symptoms sometimes taking twenty years to fully develop. According to the plaintiffs, requiring patients to wait years while their disease progresses is not reasonable promptness. Prior Authorization criteria which limit DAAs to those patients with advanced stage liver disease are, in essence, requiring beneficiaries to wait for what the plaintiffs consider to be an unreasonable time span. Supporting their claim, the reasonable promptness argument maintains that if a drug made by a participating manufacturer is FDA approved and medically indicated, it should be furnished with reasonable promptness as stipulated in 1396(a)(8). State plans which require Metavir scores of F3 or F4 for authorization, as is the case with 27 states, may stand in possible violation according to this argument.

In the case of Connecticut, a series of letters were sent to the Commissioner of the Department of Social Services.[37 and 38] Delaware beneficiaries, however, took their fight beyond organized letter writing and hired formal legal counsel to threaten the State with a class action lawsuit. In Delaware's letter dated March 28, 2016, attorneys for Tycko & Zavareei with representatives from both Community Legal Aid Society, Inc. and Harvard Law School's Center for Health Law & Policy Innovation argued on behalf of Medicaid beneficiaries that Delaware's Medicaid Prior Authorization Conditions for HCV violate the Medicaid Act in at least three ways: medical necessity, reasonable promptness, and comparable care. The threatened suit included a copy of the State's required three-page Prior Authorization and Informed Consent document and CMS's November 2015 letter to all State Medicaid plans. With the violations carefully enumerated and CMS purportedly on their side, the plaintiffs requested that Delaware Medicaid remove its restrictions on DAA coverage by April 15, 2016. The letter was a success without court action and the State responded by placing DAAs on the Medicaid's Preferred Drug List as of July 1, 2016.

3. Comparable Care

The third argument, that of comparable care, is found in 1396(a)(10)(B)(i) of the Medicaid Act which states:

> A State plan for medical assistance must provide that the medical assistance made available to any individual described in subparagraph (A) shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual …[36]

In other words, a Medicaid plan may not automatically deny coverage to some beneficiaries when others with comparable needs are granted access. Of the states reviewed, only Florida and Delaware specifically mention Comparable Care. Delaware does so as the last of its three

arguments and gives it the least attention. The letters written to Florida's State Medicaid plan were not readily available to the researcher, but the revised Prior Authorization policy published on May 27, 2016 specifically makes reference to comparable care with the following statement:

> The managed care plan's prior authorization criteria and protocols may not be more restrictive than that used by the Agency as indicated in the Florida Statutes, the Florida Administrative Code, the Medicaid State Plan, and those posted on the Agency's website. (Attachment II, Exhibit II-A, Section V.A. 1.a.(25)(d)[1]) Effective June 1, 2016, the Agency will be amending its posted drug criteria for all drugs for the treatment of hepatitis C to discontinue the requirement for evidence of hepatic fibrosis.[39]

It is unclear why more states did not use the comparable care argument. It is also unclear whether or not the argument holds significant weight on its own. It is worth noting that the comparable care argument is very similar in nature to the equal access argument used in the United States Supreme Court case of *Armstrong v. Exceptional Child Center*.[31] (See Tables 3.1, 3.2, and further discussion below.) In both instances, federal policy gives a mandate that services rendered or payments offered should be comparable or equal in nature to those available to members of a like class or in the same geographic area. In *Armstrong v. Exceptional Child Center* the equal access argument eventually gave way to an underlying issue of the Supremacy Clause as discussed in the following section.

Table 3.2 Similarities between Comparable Care and Equal Access Arguments *(italics* added by researcher for emphasis)

	Comparable Care	**Equal Access Provision**
Federal Code	1396(a)(10)(B)(i)	42 U.S.C. 1396(a)(30)(A)
Wording	A State plan for medical assistance must provide that the medical assistance made available to any individual described in subparagraph (A) *shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual …*	provide such methods and procedures relating to the utilization of , and the payment for, care and services available under the plan (including but not limited to utilization review plans as provided for in section 1903(i)(4) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers *so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area*;

Armstrong v. Exceptional Child Center[31]

The cases and threats of suit discussed here bring up a larger question: What is the proper course of action for state violations of federal policy? As seen with Connecticut, Delaware, and Florida, letters to the Medicaid administrative offices can bring about swift and efficient change. When errors are carefully illuminated, the States may respond quickly and modify their criteria accordingly. But what if simple letters and threatened class action suits don't make the desired difference? What recourse is available to beneficiaries and providers if the initial request for change goes unanswered? Can a private party (such as a Medicaid recipient or a physician caring for Medicaid patients)

maintain a cause of action regarding a state law in a case before federal court? Can an individual sue over a violation of federal law? This question formed the basis for *Armstrong v. Exceptional Child Center*. While not dealing directly with DAAs or even prescription drugs, Armstrong v. Exceptional Child Center speaks to an underlying issue for any Medicaid beneficiary or private party (such as physician, therapist, or other healthcare provider) seeking legal recourse for what they perceive to be violations of federal policy which impact their own rights, care, or well-being.

In 2009, Idaho's Medicaid agency published increased reimbursement rates for providers caring for Medicaid beneficiaries. These rates and the methods used to obtain them were approved by CMS but in the end were not implemented by Idaho's Medicaid plan due to budget restrictions. A group of healthcare providers brought suit claiming that failure to implement increased rates violated the Medicaid Act's provision for equal access (42 U.S.C. 1396(a)(30)(A) - commonly referred to as 30(A)) which mandates that each state program:

> provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans as provided for in section 1903(i)(4) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area;[36]

The plaintiff's argument was that, in Idaho's failing to increase payments for care, providers had no incentive to continue offering their services to Medicaid beneficiaries. The argument goes on to state that the subsequent reduction in availability of services in the geographic area violates the Equal Access provision of the Medicaid Act.

Armstrong v. Exceptional Child Center began in the lower courts as an exercise to decide whether or not Idaho's failure to implement increased rates constitutes a violation of the Medicaid Act. The federal district court, the first to hear the case, agreed that the providers have cause of action and that Idaho was in violation of the Medicaid Act. The federal circuit's Ninth Court of Appeals then upheld the decision and suggested that the Supremacy Clause be used to defend the provider's cause of action. Accordingly, the United States Supreme Court agreed to hear the case but would decide it based solely on the procedural issue of whether or not Medicaid providers should be allowed to bring suit to enforce a federal mandate. To make their case, the providers need to call upon the U.S. Constitution's Supremacy Clause to show that when a state law and a federal law conflict, the federal law has supremacy. It is important to note here that while the Medicaid Act goes to great lengths to stipulate eligibility and reimbursement criteria, it does not formally address the role of federal courts in enforcement. It is, therefore, up to the Supreme Court to determine whether or not the omission was intentional.

Arguments were heard by the Supreme Court of the United States on January 20, 2015 and on March 31, 2015 the decision of the federal circuit's Ninth Court of Appeals was reversed. Justice Scalia, with Justices Roberts, Thomas, Breyer, and Alito, delivered the opinion of the Court with respect to Parts I, II, and III. Part IV was delivered by Justice Roberts with Justices Thomas and Alito. Justice Breyer concurred in part with Part IV and with the judgment as a whole. Justice Sotomayor, with Justices Kennedy, Ginsburg, and Kagan filed a dissenting opinion.

It is the Court's opinion that *if* Congress intended for private parties to be able to sue regarding contracts between a state and the federal government, or to enforce federal law, they would have expressly provided for it. According to Justice Scalia, "… a private right of action

under federal law is not created by mere implication, but must be 'unambiguously conferred.' "[31] The Court holds that providers are more incidental beneficiaries rather than intended beneficiaries of the contract between the federal office of CMS and the State Medicaid plan.

The Supreme Court's decision in *Armstrong v. Exceptional Child Center* becomes relevant in the fight for access to DAAs if, as the researcher argues, the translation is that Medicaid beneficiaries (either as individuals or as a class) lack the opportunity to utilize the court system to address state violations which deny care for which the individuals are eligible. As seen previously in this chapter, letter writing had already proven effective. The district court case of *B.E. et al v. Teeter* in Washington also brought about the desired changes in policy. However, one concern going forward is that if the power behind letter writing was the threat of a lawsuit, what happens now that the threat is removed?

A further issue is the Supreme Court's opinion regarding a federal agency's ability and obligation to enforce their own contracts. As the researcher already noted, the Medicaid Act address only one method of federal enforcement though it does detail various means of oversight and monitoring. The sole means of enforcement granted by 42 U.S.C. 1396c is that of revocation of funds, which will be discussed in greater detail in Chapter Four. The Court notes, however, that removing funding in punishment would only further injure the plaintiffs (beneficiaries) and consequently bolster the argument that private individuals are not intended to enforce federal law. As Justice Scalia writes:

> Here, the express provision of a single remedy for a State's failure to comply with Medicaid's requirements – the withholding of Medicaid funds by the Secretary of Health and Human Services, 42 U.S.C. 1396c – and the sheer complexity associated with enforcing Section 30(A) combine to establish Congress's "intent to foreclose" equitable relief, Verizon Md. Inc. v. Public Serv. Comm'n of Md., 535 U.S. 635, 647. Pp. 6-10.[31]

The dissent views the same argument the other way around. Justice Sotomayor contends that the agency enforcement provision of 42 USC 1396c does not preclude private actions. Furthermore, Congress' use of broad language in 42 USC 1396(a)(30(A) regarding enforcement is not intended to exclude all recourse by private party. Instead, the Dissent claims:

> But mere breadth of statutory language does not require the Court to give up all hope of judicial enforcement – or, more important, to infer that Congress must have done so. … But rather than compelling the conclusion that the provision is wholly unenforceable by private parties, its breadth counsels in favor of interpreting Section 30(A) to provide substantial leeway to States, so that only in rare and extreme circumstances could a State actually be held to violate its mandate.[31]

It is the Dissent's final comment that the Court's decision was in error and has the unintended consequence of leaving federal agencies with only the drastic and counterproductive measure of withholding much needed funds.

Clearly, *Armstrong v. Exceptional Child Center* is a win for states. It removes any worry they may have in regards to who can sue for enforcement. State Medicaid plans are not, however, free from accountability. Chapter Four discusses the contractual obligations which come from both the Medicaid Act itself and with participation in the Medicaid Drug Rebate Program.

CHAPTER FOUR

RECOURSE OPTIONS FOR CMS

Despite the Supreme Court case of *Armstrong v. Exceptional Child Center*[31] ruling against an individual's right to sue for enforcement of federal policy, Chapter Three illustrated that individual parties have had success directly petitioning their State Medicaid offices for change. What happens though, when the federal agency wants to increase enforcement of their own policies? What recourse options are available to the federal government when states are not upholding their end of Medicaid agreement? Congress granted the Centers for Medicare and Medicaid Services (CMS) very specific powers in regards to oversight, penalties, and enforcements. A detailed review of Sections 1927 (also referred to as 42 USC 1396 – Medicaid and CHIP Payment and Access Commission) and 1904 (42 USC 1396c) of the Medicaid Act reveals both a series of obligations and two types of enforcements pertaining to State Medicaid program violations. After isolating the stipulated obligations, the researcher first identified the imposition of monetary penalties (both federal and civil) for direct violations of reporting requirements under Section 1927 of the Medicaid Act. These penalties, while not financially insignificant, pale in comparison to the second, more devastating revocation of funding allowed under section 1904. Both are examples of enforcement options readily available to CMS, yet data indicates that monetary fines are rarely imposed at all; and revocation of funding, while used in other (non-prescription drug) situations, has *never* been used to punish a non-compliant State Medicaid program.

When it comes to enforcement, CMS then has two avenues which they can pursue. They can focus on enforcing the oversight and reporting aspects of the Medicaid Drug Rebate program through the imposition of fines, and/or they can choose to enforce for larger, overarching policy violations with the revocation of funds. Chapter Four begins with an analysis of the Medicaid Act's reporting requirements and associated penalties. The end of the chapter reviews the aforementioned revocation of funding whereby the federal government can defund a state Medicaid program for failure to comply, which again to date has never happened.

Obligations Under the Medicaid Drug Rebate Program

As discussed in Chapter One, drug manufacturers pay a rebate for every time their drug was utilized under a State Medicaid plan. While Medicaid is funded predominantly by joint state and federal funds, additional funding is secured in the form of drug rebates from manufacturers who chose to participate in the Medicaid Drug Rebate Program. Drug rebates from manufacturers are paid quarterly and shared between the state and Federal government. Participation is mutually beneficial as Medicaid plans receive more outpatient drug options for their beneficiaries, and drug manufacturers receive the promise of large government contracts. The agreement, however, hinges upon an intricate balance of reporting and oversight. Table 4.0 below gives an overview of the obligations of the state, the manufacturer, and CMS (the federal government) with their respective details discussed in the brief sections following the table.

Table 4.0 Obligations under the Medicaid Drug Rebate Program

Responsible Party	Receiving Party	Frequency	Obligation	Code
State	CMS (Centers for Medicare & Medicaid Services)	Annual	List single source drugs & most frequently administered drugs	1927(a)(7)(A) and (B)
Manufacturer	State	Quarterly	Rebate for covered outpatient drugs	1927(a)(7)(b)(A)
State	Manufacturer	As determined	Total # units per drug, dosage form, strength, etc.	1927(a)(7)(b)(2)(A)
Manufacturer	CMS	As determined	Average Manufacturer Price or Best Price	1927(a)(7)(b)(3)
CMS	State	Periodically	Updated list of available drugs	1927(d)(3)
CMS	State	Ongoing	Make available means by which to access retail survey prices	1927(f)(1)(E)
State	CMS	Annual	Payment rates & dispensing fees	1927(f)(2)(A) and (B)
State	CMS	Annual	Utilization rates for noninnovator multiple source drugs	1927(f)(2)(C)
CMS	State	Annual	Comparative ranking & sales price data on 50 most widely prescribed drugs	1927(f)(3)
State	State	Ongoing	Drug Use Review board procedures	1927(g)
State	CMS	Annual	DUR Board Annual Report	1927(g)(3)(D)
CMS	Senate & House of Representative Committees	Annual	Fiscal Year Report on Operations	1927(i)
CMS	State	Quarterly	Funding offsets for rebate money paid to State	1927(a)(7)(b)(1)(B)

State Obligations

As can be seen in the above Table 4.0, states have a variety of reporting obligations including different criteria based upon drug classification. For single source drug utilization, data must be submitted to the Centers for Medicare & Medicaid Services (CMS) for each individual drug prescribed. For multiple source drugs, the state need only report data on the top twenty outpatient drugs identified by CMS as having the highest dollar volume.[15] Each state must then also report payment rates and any dispensing fees paid on an annual basis to CMS. Beyond these reporting requirements, a state is obligated to form a Drug Use Review Board (DUR Board) and issue an annual twenty-two-page questionnaire/report on their activities.[40] To each drug manufacturer, the state must supply details on the total number of units dispensed by dosage form, strength, and package size. The timing of these reports depends up the predetermined reporting period but must be no more than 60 days after the reporting period ends. Once the state has received a rebate from the manufacturer (discussed below), it shares that funding with the federal government by means of an offset against medical assistance. Consequently, the next allocation of funding to the state from the federal government will be less the amount owed by the state to the federal government. The details of these offset transactions are spelled out in 1927(a)(7)(b)(1)(B).

Drug Manufacturer Obligations

Drug manufacturers are required to undergo a complex calculation to determine the rebate amount offered in exchange for each unit covered. The details of the calculation are beyond the scope of this research; but, once the amount is determined, it should be reported to CMS along with details on the drug's average manufacturer price or best price (another detailed calculation based upon price after various rebates). These steps are a cost saving mechanism

designed to insure that the offered rebates are based on true, non-inflated prices. The manufacturer must then offer the agreed upon rebate to each state on a quarterly basis. The manufacturer has 30 days after receipt of the state's utilization report in which to pay.

CMS (federal) Obligations

CMS has federal reporting requirements to both the state and to various committees of the House and Senate. They have no reporting obligations with the drug manufacturers directly though they do outsource the task of surveying national retail prices. Additionally, CMS maintains an updated list of drugs available to State Medicaid plans and also makes available the results of their retail survey of average drug prices. Each year CMS then generates and distributes a comparative ranking with sales price data on the fifty most widely prescribed outpatient drugs. This report is designed to aid state plans with budgeting and forecasting. Lastly, CMS is required to transmit an annual fiscal year operating report to the Senate Committee on Finance, the House Committee on Energy and Commerce, and the House and Senate Committees on Aging. This report details costs paid out, total rebates received and the number of manufacturers providing those rebates, a comparative analysis of the rebates compared with those offered to other purchasers, the effect of inflation, price trends, and administrative costs associated with compliance to the Medicaid Act.

Penalties and Enforcement Actions

Penalties

The Medicaid Act details four instances of penalties which can be imposed. Three of the penalties are for violations performed by participating drug manufacturers, and one is for violations at the state level. A manufacturer can face penalties of up to $10,000 /day for failure to provide requested information. If the violation continues beyond ninety days after a stated

deadline, the participation agreement can be temporarily suspended. In other words, if a manufacturer doesn't respond in a timely manner to all governmental requests for information, including submission of details on newly approved drugs, they must pay fines and risk losing the ability to participate in the Medicaid Drug Rebate Program. In addition to the fines imposed by CMS, non-compliant manufacturers may be charged up to $100,000 in civil penalties for providing false information or for refusing further requests for information. If civil penalties are invoked, the fine can go up to $100,000 ***per*** **piece** of false information.

Table 4.1 Reporting Penalties listed in Medicaid Act

Involved Party	Offense	Penalty	Code
Manufacturer, wholesaler, or direct seller	Refusing a request for information about charges or prices	Maximum $100,000 in civil penalties	1927(b)(3)(B)
Manufacturer	Failure of manufacturer to provide information	$10,000 /day and 90 days post deadline agreement will be temporarily suspended	1927(b)(3)(C)(i)
Manufacturer	Providing false Information	Maximum $100,000 in civil penalties /item of false information	1927(b)(3)(C)(ii)
State	Substantial failure to comply	Revocation of funds	1904

Another option available to CMS, as seen in the table above, is that of revocation of funds. The researcher returns to this issue at the end of this chapter.

Warning Letters

While technically not an enforcement action, CMS is known to issue guidance and warning letters when certain matters of violation are brought to their attention. Specifically, on

November 15, 2015, CMS issued a notice to all State Medicaid programs titled: "For State Technical Contracts – Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs."[10] This letter expressed CMS's concerns that some states are restricting access to DAAs in violation of section 1927 of the Act. It went on to detail three ways in which state programs may be in violation: restrictions based on disease stage, required abstinence period from drug and alcohol use/abuse, and specialist care limitations. CMS also mentioned the need for comparable care amongst beneficiaries and briefly discussed a shared understanding of budgetary constraints. However, CMS urged plan administrators to carefully monitor requirements and to incorporate available resources such as Drug Utilization Review boards, comparative pricing analysis of previous treatment options vs. the newer cures, and to consider implementing supportive care programs for HCV patients. The letter closes with a warning: "CMS will monitor state compliance with their approved state plans, the statue, and regulations to assure that access to these medications is maintained."[10] At no point does CMS mention ramifications of non-compliance or any means of controlled enforcement. Given CMS's history of selective and light penalties which is discussed below, it is unclear how much force is behind the letter and what kind of change might come about as a result. To date, no state programs have directly responded to the letter although Massachusetts cited pressure from the federal government as one of the reasons they lifted restrictions on DAAs in MassHealth, their State Medicaid program.[41]

In an effort to obtain further information on pricing and rebates, CMS also sent letters to four DAA manufacturers: Abbvie, Gilead Sciences, Inc., Johnson & Johnson, Merck & Company, Inc.[42-45] CMS expressed appreciation for "the work that manufacturers have done to bring new curative therapies to the market for our consumers, especially when such treatments address a major public health concern such as HCV." The letters offered a brief reminder of the

Medicaid Drug Rebate program's requirements regarding "best price" but contained no advice or guidance. Instead, CMS asked for insight into each manufacturer's purchasing arrangements:

- What types of arrangements do you offer to commercial or other governmental-sponsored health insurance plans that are focused on patient outcomes and enhance access to HCV or other drugs?
- Are these arrangements offered to state Medicaid programs? If so, how are these programs typically structured? If not, what are the challenges in offering these programs to states?
- Can you estimate a monetary value of these arrangements to Medicaid, other governmental-sponsored or commercial health insurance plans? If so, how? If not, why not?
- What other ideas do you have to assist states in the affordability of these new, unbudgeted pharmaceuticals? [42-45]

The manufacturers' responses, if any, are not publically available at this time.[46]

Enforcement Actions Taken by CMS

In the Medicaid Act, the federal government established a series of checks and balances covering large amounts of data ranging from drug prices and sales statistics to utilization data and competitive trend analysis, yet there is no clear delineation of *when* enforcement measures are necessary. Indeed, the researcher found very few instances of enforcement and none were directed toward state violations. Table 4.2 provides an overview of some of the actions taken by CMS's Center for Program Integrity.

Table 4.2 Activities of CMS's Center for Program Integrity

Action Taken	**Frequency**
Revoke provider's ability to bill Medicare	>14,000 occurrences nationwide since 2011
Temporarily ceased new provider Medicaid enrollment	For 6 months in Miami, Chicago, and Houston
Report fraud prevention annually to Congress	Annually beginning in 2011
Audit Medicaid claims to identify overpayment and return funds to CMS	Ongoing

A Center for Program Integrity was commissioned in 2010 to oversee matters of Medicare and Medicaid enrollment fraud, waste, and abuse.[47] Consequently, CMS revoked the ability to bill Medicare from more than 14,000 providers nationwide since March 2011.[48] In 2013, CMS temporarily ceased new Medicaid provider enrollment for six months in the high-fraud areas of Miami, Chicago, and Houston as a further means to prevent fraud. This temporary cessation was a short term, impactful move implemented under the authority of the Affordable Care Act rather than the Medicaid Act.[48] Additionally, the Center for Program Integrity enforces Section 1936 of the Social Security Act which requires that audits be performed to identify and reclaim Medicaid overpayments.[49 and 50] Audits have resulted in over 14.9 billion dollars coming back into the Medicaid and Medicare systems.[48]

Revocation of Funding

Most relevant to this researcher's focus, though, is the enforcement action afforded to CMS when states fail to comply with the Medicaid Act on a large scale. Section 1904 of the Act stipulates the following:

> If the Secretary, after reasonable notice and opportunity for hearing to the State agency administering or supervising the administration of the State plan approved under this subchapter, finds—
> (1) that the plan has been so changed that it no longer complies with the provisions of section 1396a of this title; or
> (2) that in the administration of the plan there is a failure to comply substantially with any such provision;
> the Secretary shall notify such State agency that further payments will not be made to the State (or, in his discretion, that payments will be limited to categories under or parts of the State plan not affected by such failure), until the Secretary is satisfied that there will no longer be any such failure to comply. Until he is so satisfied, he shall make no further payments to such State (or shall limit payments to categories under or parts of the State plan not affected by such failure).[11]

If the state fails to comply substantially in any part of the administration of their Medicaid plan, CMS has the power to revoke funding (in full or in part) after giving reasonable notice and opportunity for a hearing.

The researcher found no examples of CMS revoking state funding, a fact also noted by an attorney representing Idaho healthcare providers in *Armstrong v. Exceptional Child Center*: "The federal government has few options to sanction states other than cutting off a state's federal Medicaid funding - the so called 'nuclear option,' which CMS has never used."[12] If individuals and private parties have no legal recourse and CMS's only method of enforcement is extreme, self-defeating, and unlikely to be utilized, how is the Medicaid Act being enforced? What happens when there is no enforcement? These questions are the subject of Chapter Five.

CHAPTER FIVE

BRIDGING THE GAP

As evidenced in Chapter Four, the Center for Medicare and Medicaid Services (CMS) is not without power to enforce its policies. They have been doing so for years. Why, though, are violations of Medicare billing and the Affordable Care Act being punished while violations on access to outpatient prescriptions and the Medicaid Drug Rebate Program are being tolerated without recourse? Evidence indicates that a complex system of federal and state interests, combined with little federal enforcement and no legal enforcement power for individual citizens, renders a healthcare structure vulnerable to blatant violations of policy and care. Having reviewed the intricate Medicaid relationship between state and federal governments, along with their obligations, violations, and legal challenges, the researcher identified a disconnect between the federal and state administrations. The data presented in Chapters Two, Three, and Four illustrates how the disconnect puts patients at risk for not getting the treatments and cures to which they are federally entitled and allows for egregious violations to stand as acceptable course. Bridging that disconnect is the focus of this chapter.

The researcher identified two paths which may begin to bridge the gap between federal and state administrations in regards to Medicaid access. Ideally, administrators of State Medicaid plans would see the existing disconnect, identify the ways in which their own policies are in violation, and begin to implement change. And in fact, as discussed below, some states have done this. The second path is that of bypassing state involvement and relying instead on a federally funded and federally administered support program which distributes care and

resources nationwide much like the Ryan White CARE Act (now known as the Ryan White HIV/AIDS Program, or RWHAP).[51]

Recent State Medicaid Program Changes

The first half of 2016 has resulted in at least seven states revising, or declaring their intent to revise, restrictions on access to Direct-Acting Antivirals (DAAs) for the treatment and cure of the Hepatitis C Virus. (See Figure 5.0) Of special note, only Massachusetts directly referenced CMS's November warning letter as an impetus to their policy change.[41] Delaware, Washington, New York, and Connecticut changed their policies in response to legal pressure, at least in part.[51,35,30,9,52] Pennsylvania's proposed change was suggested by a state advisory committee though definitive action has not yet been taken.[53] And, New York's Drug Utilization Review board played a role in that state's decision to lessen restrictions.[52] Lastly, Florida revised their policies for reasons not specified.[39]

The lifting of overly restrictive prior authorization requirements, for whatever reason, is a positive step toward bridging the gaps in access to outpatient pharmaceuticals. Those that have, did so swiftly and responsibly. The majority of states though have yet to publically address their own potential violations with regard to prior authorization and access. Presumably, all fifty states received the warning letter from CMS in November of 2015 advising them to monitor and correct their program's limitations to drug coverage. However, as evidenced above, the researcher was only able to identify seven states that have made modifications to DAA access since then. As shown in Chapter One, prior to the warning letter, at least thirty-seven states had known Substance and Alcohol Abuse criteria which CMS considers an area of possible violation. Thirty-four states had restrictions based on liver disease stage, which CMS also mentions as an area of concern. CMS's third focus of possible violations was that of requiring specialist care,

and at least twenty-nine states had such criteria. Regardless of which potential violation is the focus, with just seven states making adjustments, there remains a gap between what CMS requests in terms of compliance with federal Medicaid policy and what is actually occurring at the state level. When states fail to bridge this gap themselves, what other options make the cure for Hepatitis C available to those for whom it is medically indicated?

Modeling Federal Funds After Ryan White HIV/AIDS Program

Until this point, the researcher looked within the Medicaid system for both an understanding of the problem and for a solution. Research, however, revealed a possible alternative which avoids the federal/state disconnect by relying entirely on federal funds and administration. Modeling supplemental HCV funds after the Ryan White CARE Act offers another means by which Medicaid beneficiaries can receive access to DAAs. The AIDS epidemic of the late 1980s illustrated how restrictive access to life altering medications motivated patients and their loved ones to petition the government for assistance. In response to public outcry, the Ryan White CARE (Comprehensive AIDS Resources Emergency) Act was enacted in 1990 with a federal budget appropriation of $220.6 million. Its mission was to fill the gaps in HIV/AIDS care not provided by any other means. As public dismay regarding disparities in care continued, and with mounting Congressional support, funding grew incrementally. By fiscal year 2010, federal appropriations had expanded tenfold to $2.29 billion. Today, what is now called the Ryan White HIV/AIDS Program (RWHAP) is funded at 2.32 billion for the fiscal year 2016.[54] Money from RWHAP extends to states and organizations, not individuals, to aid in the provision of primary care, essential and interventional needs, clinical training, grants, education, and other initiatives. Though HIV itself remains without a cure, lifespans have been greatly lengthened by access to treatments, enhanced preventative measures, and education

granted by RWHAP. When traditional avenues of insurance and Medicaid/Medicare were not enough, as is the case with both HIV/AIDS and HCV, RWHAP helped and continues to help HIV/AIDS patients without recourse to gain access to life changing medications and resources.

The usefulness of the RWHAP model on HCV patients is not without precedent. Many patients who are HIV positive are also positive for HCV. In fact, as many as 35% of the Americans with HIV are co-infected with HCV.[55] In the population of people who use injection drugs the percentage of co-infection rises to between 50% and 90%.[4] Consequently, organizations funded by the RWHAP have already taken great steps toward providing care for both illnesses in instances when they present together. Even as early as 2011, the Technical Assistance Resources, Guidance, Education, and Training Center (TARGET Center) remarked that:

> Ryan White-funded clinics around the Nation are responding to these needs by taking on a greater role in HCV care. Much of the work of Ryan White grantees has focused on helping clients manage HCV infection by providing, for example, alcohol counseling to co-infected clients. However, clinics are increasingly looking for ways to take the next step and deliver HCV treatment, which was once considered too toxic and risky but is less so given new and emerging HCV drug regimens.[55]

Shortly thereafter, RWHAP began a Special Project of National Significance (SPNS) Hepatitis C Treatment Expansion initiative specifically to encourage new models of care for co-infected patients which now includes the use of DAAs. [56]

Utilizing the RWHAP model, the researcher isolated three elements which translate well to the needs created by Medicaid state violations.

1. Federally funded *and* federally administered
2. Divided into 5 autonomous ‘parts’ or sections
3. Designed to be the “payer of last resort”

First, RWHAP is funded under Title XXVI of the Public Health Services Act and administered by the U.S. Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA), and the HIV/AIDS Bureau (HAB).[57 and 58] As with most funding from Congress, it is limited in time and must be reauthorized periodically. Since its inception, RWHAP has been reauthorized five times.[2] Second, the enacting legislation called for a division of funds and administration into 'Parts.' Each of RWHAP's five parts controls the administration of a particular subset of beneficiaries based upon region, population, or need.[2] For the purposes of this research, the details of the individual parts matter less than the overall concept of dividing the program into unique units. Third, RWHAP was designed to be a 'payer of last resort.'[2] In other words, RWHAP is available when no other options exist (as is the case for many Medicaid beneficiaries with HCV).

After isolating three elements which translate to the needs created by Medicaid State violations, the researcher identified four ways in which these elements address the previously discussed gaps created by the states' failure to comply with federal policy on non-restricted access to DAAs.

1. Federal administration removes the State 'middleman' thereby streamlining administration and making oversight and enforcement more manageable
2. Breaking the administration and funds into 5 parts makes oversight and enforcement more manageable
3. Well defined parts/components offer clear allocation of duties and funding, lessening the likelihood of gaps in care
4. As a "payer of last resort," funds are available to those who were denied care from other sources

In this study, the researcher has shown that states are frequently and blatantly violating federal policy in regards to offering Medicaid beneficiaries access to Direct-Acting Antivirals for the cure of Hepatitis C. The researcher has also shown that avenues to challenge those violations are either ineffective on a large scale as in the case of letter writing and legal challenges, or simply not utilized as in the case of the federal option to defund state programs.

In Table 5.0 below, the researcher correlates the identified challenges to the system, resulting gaps, and ways in which a RWHAP model may bridge those gaps.

Table 5.0 Ways in Which a RWHAP Model Bridges the Gap

Challenge to the System	**Result**	**Remaining Gap**	**How a RWHAP model bridges the gap**
Individual party suing for enforcement of a federal policy	Supreme Court ruled that an individual cannot sue for federal enforcement	Policy remains unenforced and patients untreated	Streamlined administration makes enforcement easier
			As a payer of last resort, individuals once again have options available to them
Letter writing, petitioning for change	Regional, small scale success	Most states remain non-compliant, reducing available care	Division into parts creates unique units which can be petitioned more effectively and respond more appropriately
State Attorney General investigation	One instance of success by peer pressure	Most states remain non-compliant, reducing available care	Removes the State middleman to streamline enforcement
Federally issued Warning Letters to States	Unclear due to insufficient data	Most states remain non-compliant, reducing available care	Federal funding and federal administration make enforcement threats more real
Defunding of care	Unknown as action has never been taken	Policy remains unenforced	Division into parts means defunding one program won't leave patients entirely without care.

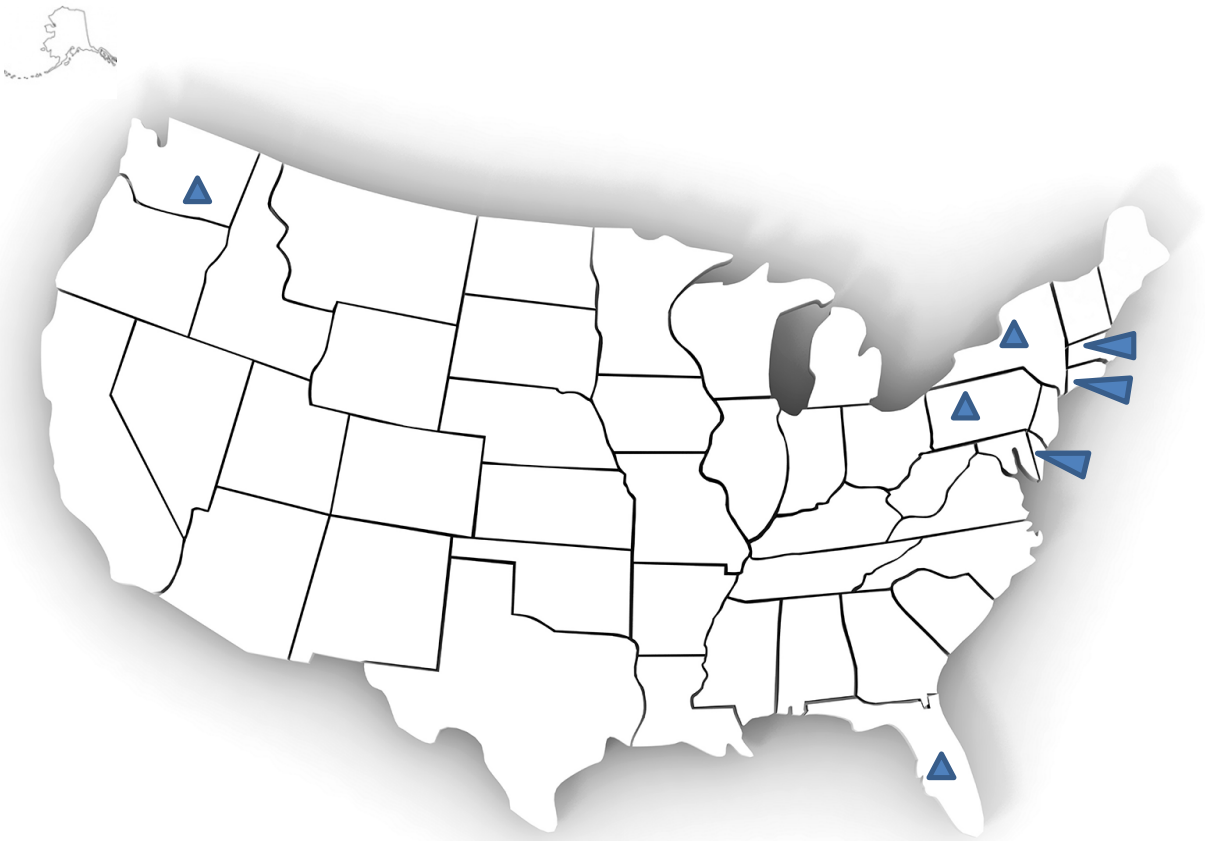
The researcher concluded that the Medicaid system, in its current form, is failing to provide the necessary care for its beneficiaries suffering from Hepatitis C. Overly restrictive requirements are in place at the state level; federal policies are not being enforced; and individual beneficiaries have little recourse to fight for the care to which they are entitled. CMS could defund state programs which refuse to comply. However, that option is both unlikely and self-defeating as the end result is even less care for those who need it. Implementing a model of federally funded and federally administered care similar to RWHAP would bridge the existing gaps in Medicaid coverage and extend the promise to one day offer the cure to everyone who needs it.

Further recommendations based on the results of this research include increasing enforcement efforts at the federal level. If CMS's Center for Program Integrity required annual reporting of denial metrics by each state and published the results, states might find the motivation to increase compliance and reduce the number of denials. Both the Prescription Drug User Fee Act (PDUFA) and the Medical Devices User Fee Act (MDUFA) had success with a similar approach by mandating the reporting and improvement of the Food and Drug Administration's (FDA) performance in regards to application approval timeliness.[59 and 60] Even if the accountability itself doesn't come with a believable threat of punishment from CMS, the knowledge that their violations are being publically tracked may encourage state compliance.

Lastly, the researcher recommends a shift in thinking to incorporate the idea of 'treatment as prevention' to realign how costs and expenses are weighted. Funding allocated toward the treatment and cure of HCV positive patients now reduces their anticipated expenses down the road and lessens the likelihood of new infections in the population. Particularly in the case of HCV, a blood borne virus where the population of patients contains a high number of people

who inject drugs, curing a significant portion of the population will reduce the number of new infections and in time reduce the overall disease prevalence.[61] As shown in Chapter Two, early treatment is successful in curing the infection *and* improving liver histology. 'Treatment as prevention' not only reduces the number of patients needing liver transplants and cancer treatment, but it aids in reducing the disease prevalence overall.

Overcoming the disconnects which leave Medicaid beneficiaries without access to DAAs will likely involve a combination of efforts. Easing prior authorization restrictions and bringing state Medicaid plans into compliance may have the largest and furthest reaching impact, but this research shows that the benefit of supplemental federal funds and renewed perspective should also be considered.



▲ = Researcher confirmed a lessening of Medicaid restrictions on DAAs

Figure 5.0 States with Changes in Medicaid Restrictions

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