

Health Services Advisory Council



Minutes — October 9, 2014
3:00 – 5:00 p.m.
Andersen Building, St. Paul

Members Present

Don Brunnquell, Amelia Burgess, Howard Fink, Patrick Irvine, William Parham III, Alvaro Sanchez, Jeff Schiff (non-voting), Timothy Sielaff (chair), Cedric Skillon

Members Absent

Lance Hegland, Andrea Hillerud, Jim Miner, Katie Pieper

DHS Staff Present

Karen Dopson, Sara Drake, Joy Flugge, Jeanne Fromholz, Ellie Garrett, Susan Kurysh, Steve Masson, Fritz Ohnsorg, Adam Pavek, Mary Beth Reinke, Jennifer Yang

Others Present

Kelly Banyai (MAPS), Joann Foreman (ICSI), Paul Heideman (MAPS), Heather Keenan (MAPS), Murray McAllister (Courage Kenny Rehabilitation Institute/Institute for Chronic Pain)

I. Welcome, Introductions, Updates and Minutes

Tim Sielaff called the meeting to order, and members, staff and guests introduced themselves. New HSAC members Howard Fink and Cedric Skillon were welcomed.

The minutes of the September HSAC meeting were approved without corrections.

Jeff Schiff provided several updates:

- DHS and the managed care organizations contracted to cover Minnesota Health Care Program (MHCP) recipients have discussed the utility of having a common approach to coverage for Hepatitis C treatments.
- The American Academy of Neurology has issued a position paper on [Opioids for Chronic Noncancer Pain](#), which is largely consistent with the directions HSAC has previously endorsed with regard to opioid prescribing.
- Schiff and others from state government attended a National Governors Association meeting to discuss opioid strategies and legislative approaches from various states.
- DHS is working on two legislative proposals, one on opioid prescribing and one on integrated care for pregnant women at risk of delivering low birth weight babies or babies with neonatal abstinence syndrome.

- DHS is forming a comprehensive quality strategy committee. Jennifer Yang summarized the committee's purpose and time commitment and asked HSAC members to volunteer. Sielaff volunteered, and Yang indicated that she'd welcome one more HSAC member at the new committee. HSAC members are encouraged to contact her directly ([Jennifer Yang](#)) for more information.

II. Chronic Pain Rehabilitation Programs

A. Summary of MED Report

Garrett framed the discussion on chronic pain rehabilitation programs. She explained that DHS is working on multiple fronts to reduce inappropriate opioid analgesic utilization (consistent with HSAC's direction). Simultaneously, DHS is interested in examining access barriers to other pain treatments that have better risk/benefit profiles than opioids. Chronic pain programs (CPPs, also known as chronic pain rehabilitation programs or multidisciplinary pain programs) tend not to be covered by Medicaid programs, despite a long history of use in this country and elsewhere. CPPs tend to include:

- A multidisciplinary, team-based approach, including at least
 - Psychotherapy
 - Physical and occupational therapy
- A group setting
- Intensive services, often amounting to half- or full-day sessions over three – five days a week for two – three weeks, with follow-up care provided after intensive group sessions conclude
- Non-opioid based therapies, with support for tapering patients down or off of opioids, benzodiazepines and hypnotics
- Non-procedural therapies

She also summarized a MED report that was produced last year at DHS' request. The report evaluated scientific reviews of the literature pertaining to a wide array of treatments for chronic musculoskeletal, non-cancer pain. That report, which reflected several limitations due to the breadth of interventions being examined, showed the following:

- CPPs merit more research regarding effectiveness
- CPPs may improve disability but not pain intensity
- No evidence was identified that directly compared CPPs to opioid treatment

DHS has requested MED staff to conduct a deeper dive into the scientific literature pertaining specifically to CPPs, the results of which will be shared at the next HSAC meeting.

Garrett stated that DHS' goal for HSAC over the course of the next one to two meetings would be to:

- Recommend criteria for defining CPPs, leaving to DHS to determine what mechanisms will be involved (e.g., health home, behavioral health home, provider-based authorization)
- Recommend functional treatment goals and measurement criteria
- Consider coverage-with-evidence development

Garrett's PowerPoint presentation was circulated in advance of the meeting and is available on request from [HSAC staff](#).

B. Guest Presenter: Murray McAllister, PhD, Courage Kenny Rehabilitation Institute

At DHS' invitation, Murray McAllister from the Courage Kenny Rehabilitation Institute spoke. Jeannie Sperry, from Mayo Clinic's Chronic Pain Rehabilitation Program and who had also been invited to speak, was unable to attend due to a family emergency. Garrett reached out to MAPS in advance of the meeting, but had been unsuccessful in coordinating with MAPS.

McAllister's PowerPoint presentation and list of references were circulated in advance of the meeting and are available on request from [HSAC staff](#). Highlights included:

- Chronic pain management dates back to the 1960s and 1970s, grounded in new science that posited that central nervous system factors influence nociception to elicit the experience of chronic pain.
- The goal is to reduce distress and impairment about pain by supporting:
 - Lifestyle changes that down-regulate the central nervous system;
 - Coping skills;
 - Exposure-based milieu that simulates work activity and reduces dependency, vulnerability and fear-avoidance.
- CPPs are empirically supported, and no other chronic pain management strategy has more empirical support. Outcomes include reduction in opioid and other health care use, improved functionality and return to work rates, and reduced pain.

C. Discussion

Responding to questions from HSAC members, McAllister provided additional information. Paul Heideman from MAPS introduced himself, and stated that MAPS, too, offered CPP therapy. Heideman joined in the discussion to respond to questions along with McAllister.

- McAllister stated that the average patient coming into Courage Kenny's program has a seven-year history of debilitating chronic pain. Patients tend to choose CPP only after they have accepted that they must learn to manage their pain. They usually try other therapies first, such as medication, surgery or other procedures. They also tend to be highly complex patients, often with co-morbid mental health conditions or other complicating factors.
- Patients on opioids must be willing to taper them. McAllister does not use medication assisted therapies (i.e., buprenorphine or methadone) to wean patients down from high-dose opioids.
- Patients with acute psychoses or who are too disruptive to participate in a group setting are not accepted into CPPs; they are treated individually.
- Patients diagnosed with chemical dependency (CD) are referred for CD treatment before commencing a CPP. Patients with a psychological dependence on opioids or other drugs to manage pain are admitted to CPP programs without first needing to complete CD treatment. Readiness for CPP is assessed during initial workups to determine a course of treatment.
- Many patients don't need the intensity of CPP. In such cases, they are referred for individual psychotherapy, PT and OT.
- Volume for these programs is fairly low. At Courage Kinney Rehabilitation Institute, therapy groups include five – twelve patients at a time. MAPS sees groups of three – six patients at a time, for an approximate total of 100 patients annually. McAllister estimated that approximately 25 people are evaluated for every person who commences CPP.

- The drop-out rate is approximately 20% of those who commence CPP; people who drop out do so within the first few days of the program.
- Programs offer after-care, including continued support for tapering opioids if patients are still taking opioids at the program's conclusion. McAllister noted that 40% of patients are completely weaned off opioids by the end of CPP.
- MAPS and Courage Kenney both report that their programs tend to be covered by commercial insurers and managed care plans, but that the fee-for-service orientation of Medicare and Medicaid programs present reimbursement barriers. Garrett interjected that it was her understanding that Mayo's program was able to bill Medicare fee-for-service.
- Providers are accredited at the institutional level, not for individual CPPs.
- CPPs build outcome expectations into their contracts with payers. Functional outcomes include a return to work, whether paid or volunteer.
- Alternatives to CPP, including chronic, high-dose medications, procedures and surgeries, are not inexpensive. A member commented that the evidence of effectiveness of many alternatives is fairly poor.

HSAC members made concluding observations:

- It would be interesting to see a compare CPP uptake and outcomes, differentiating between those who are using opioids at the start of the program and those who are not.
- We need comparative effectiveness data on alternative treatments, as well as CPP.

The meeting was adjourned at approximately 4:55.

Health Services Advisory Council



Minutes — September 11, 2014
3:00 – 5:00 p.m.
Andersen Building, St. Paul

Members Present

Don Brunnquell, Howard Fink (by phone), Lance Hegland (by phone), Andrea Hillerud, Patrick Irvine, Jim Miner, Katie Pieper, Alvaro Sanchez, Jeff Schiff (non-voting), Timothy Sielaff (chair)

Members Absent

Amelia Burgess, William Parham III, Cedric Skillon

DHS Staff Present

Sara Drake, Ellie Garrett, Adam Pavek

Others Present

Jennifer Breitinger (GSK), Rob Chose (Abbvie), Mike Gonzales (Abbvie), Mike Healy (Gilead Sciences), Daniel Jude (Fairview Specialty Pharmacy), David Lacewell (Abbvie), Paul Miner (Gilead Sciences), Cherie Moehling (Abbvie), Gina Storrs (Minnesota Gastroenterology), Baron Tisthammer (Fairview Pharmacy Service), Julie Vojtech

I. Welcome, Introductions, Updates and Minutes

Tim Sielaff called the meeting to order. Ellie Garrett reported that five HSAC slots had been up for replacement or re-appointment, four of which were due to normal term expirations and one to replace a member who resigned due to an employment change. Don Brunnquell has been reappointed. New members are:

- Howard Fink, MD, MPH, VA Medical Center
- Andrea Hillerud, MD, FCFP, Blue Cross Blue Shield of Minnesota
- Alvaro Sanchez, MD, UCare
- Cedric Skillon, MD, Hazelden Betty Ford Foundation

They replace Amy Burt, Brendon Cullinan, Tom Von Sternberg and Mark Willenbring, all of whom were thanked and recognized for their many years of service to HSAC. The new members were welcomed, and introductions were made around the room.

Jeff Schiff provided several updates:

- DHS' Health Care Administration is proposing several legislative initiatives for the Commissioner's and Governor's consideration, including (1) a program to reduce health disparities in rates of neonatal abstinence syndrome and low birth weight and (2) an initiative to improve opioid prescribing, reflecting input received from HSAC and the Emergency Department Utilization Work Group.
- Responding to new direction from CMS, DHS is adapting its 1915i waiver application to cover early intensive interventions for autism into an application that fits under the EPSDT program.
- Garrett is forming a community of practice among DHS staff to foster best practices for the processes of engaging stakeholders in informing DHS policies and programs.

Upon motion made and seconded, the minutes of the March and May HSAC meetings were approved without corrections.

II. Presentation: Developing expectations for identifying patients most likely to complete HCV therapy successfully and for monitoring HCV care among eligible patients

Schiff and Garrett presented on hepatitis C (HCV) and HCV treatments, recent guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA), and gaps in the current guidance. The PowerPoint presentation was circulated in advance of the meeting and is available on request from [HSAC staff](#). Highlights included:

- A recap of the May HSAC presentation and discussion
- New prioritization guidance from AASLD and IDSA:
 - At highest priority are the patients who are most severely ill (Metavir F3, F4), transplant recipients and those with clinically severe extrahepatic manifestations
 - In the category of "high risk" (as opposed to "highest risk") are patients at Metavir F2, and patients with coinfections of HIV or Hepatitis B, other coexistent liver disease, debilitating fatigue, insulin resistant diabetes or porphyria cutanea tarda
 - Recommendations for treatment based in high risk of transmitting HCV to others are couched in uncertainty and calls for additional study
 - Patients who are not prioritized for treatment should receive ongoing assessment, recognizing that some patients' HCV may progress more rapidly
- There are gaps in the prioritization guidance concerning considerations such as likelihood of treatment adherence, risk of re-infection and duration of monitoring patients for sustained viral response (SVR).
- The prioritization guidance does not address continuity of care issues that may arise if there are insurance coverage changes during the treatment course.
- Summary of the Veterans Administration guidance

Schiff stated that DHS' request of HSAC was to focus on gaps in existing guidance. Specifically, HSAC was asked to provide direction on likelihood of successful treatment while also considering urgency of need, and to provide direction on monitoring of outcomes for approved cases.

A. Clarifying Questions

The chair opened the floor up to clarifying questions and comments from HSAC members. In response to a question about DHS' budget for HCV treatment, Sara Drake (manager of DHS' pharmacy unit)

stated that pharmacy costs are part of the Medicaid program, which are folded into the state's budget forecast. There is no specific cap on any specific class of drugs, but when spending on drugs increases disproportionately, ability to spend in other areas of the state budget (both health care and non-health care) is impacted. Several HSAC members agreed, observing that the cost of the new HCV treatments is exorbitant and unaffordable.

In response to another question, Schiff stated that to date approximately 71 patients in the fee for service part of the Medicaid program had been treated in the months following sofosbuvir's (Sovaldi's) FDA approval. Patients and physicians are likely awaiting the new all-oral drug regimens (which do not require interferon or ribavirin) for which FDA approval is expected in coming weeks or months.

An HSAC member remarked that current counts of HCV patients are likely understated. The availability of new treatments and increased calls for screening are likely to identify many undiagnosed cases.

Another member suggested HSAC should be considering recommending delayed treatment for patients without the most advanced disease, in order to wait for expected, improved treatments with fewer side effects.

B. Public Comments

The chair opened the floor to public comments. Paul Miner, an employee and shareholder of Gilead Sciences, spoke first. A copy of his PowerPoint presentation was distributed in advance of the meeting and is available upon request from [HSAC staff](#).

Miner stated that experience in Minnesota demonstrated that demand for HCV treatments has not been overwhelming since Sovaldi's introduction. Access to specialty care is the rate limiter to treatment.

He cautioned against restricting treatments to the sickest patients (Metavir F3 and F4), because SVR is harder to obtain among the sickest patients. Like other chronic diseases, intervening earlier produces better results. He also stated that fibrosis measures are not reliable enough to warrant treatment delays. He reported that soon-to-be-published data show the drug's efficacy among cirrhotic patients. These new studies will show expanded inclusion criteria and more real-world testing. Miner stated that SVR 48 and 72 demonstrate perfect concordance; there is no drop in SVR from week 48 to 72. All new studies are using SVR 12, because of its stability over time.

Miner stated that the VA's policy is to check for viral response at four weeks, and then again at eight weeks for those patients who showed insufficient response at week four. If there is insufficient viral response at eight weeks, then the VA recommends ceasing treatment.

Miner urged states to pay careful attention to the studies of the new drug regimens expected to be on the market soon.

He reported that the United Kingdom's National Institute for Health and Care Excellence (NICE) had provided cost-effectiveness approval for Sovaldi in the UK. He stated that Sovaldi's cost was based on pricing for prior HCV treatments.

Miner declined to answer a question from an HSAC member about rebate policy for Medicaid.

Gina Storrs, a nurse practitioner from Minnesota Gastroenterology spoke next. Storrs reported that she had been alerted to the HSAC meeting by a representative of Gilead Sciences. She also reported having been a paid speaker for Gilead, Genentech, Vertex, Merck, BMX and Abbvie. She further disclosed that

she or Minnesota Gastroenterology had received an unknown amount of research funding or other funding from the medical industry (including device manufacturers or biotechnology companies).

Storrs stated that this is an exciting time for HCV treatments, which are getting better, easier, shorter and more effective. She stated that while people with Metavir F0 or F1 can wait, by F2 patients should be offered treatment. Biopsies are imperfect, and a person with F3 could falsely test as someone with F2. She also stated that progression can be silent; all HCV specialists have had patients who have progressed to cirrhosis without warning. HCV symptoms are not specific and are subjective. She stated that noninvasive screening is promising. She urged against testing at four weeks of treatment, which only reveals whether a person is taking the medicine. She stated that other, less expensive blood tests could provide the same information. She views that it is her job as a practitioner as help her patients succeed in treatment, including assessing social supports. She stated that most patients would be candidates and that psychiatric patients are among the easiest for her to treat.

III. Discussion and Direction from HSAC

A member commented that there are several factors that providers should evaluate when considering patients for treatment. Common communication to providers would be helpful. Drake said that what the Drug Formulary Committee needs to hear from HSAC is advice in prioritizing patients for treatment—identifying which patient populations are at greatest need and will be most likely to benefit from and succeed in treatment. Another member agreed, stating that a checklist would be helpful, both as a decision-making and communication tool with patients and in a prior authorization process.

Another member commented that successful behavioral health treatment for those with substance abuse disorders is essential, and analogized to criteria for liver transplant candidacy.

A motion was made and seconded to endorse the following statements, which are summarized on the last two slides of Schiff's and Garrett's PowerPoint presentation:

- **Prioritize those at highest risk of severe complications, as defined by the recent AASLD/IDSA guidance**
- **With regard to heavy or binge alcohol use or IV drug use:**
 - Evaluate all patients
 - Refer for substance abuse treatment and require successful treatment for pre-determined period of time prior to HCV treatment
 - Coordinate HCV and substance abuse treatment thereafter
- **Consider stability, social supports, and behavioral health**
- **With regard to continuity of care**
 - Plan for treatment to occur within single coverage year
 - Once treatment commences, discourage patient transfers among HCV providers

The motion was discussed briefly. A member suggested that providers be consulted about how best to support these best practices and priorities. **The motion carried unanimously.**

Schiff asked members to make some recommendations about post-treatment monitoring, so that data on relapse and re-infection could be collected. One member suggested that collecting SVR 24 seems to be fairly standard. Another member suggested collecting data intensively over time as these new treatments are becoming available. If over time it becomes evident that less monitoring is needed, then the post-treatment monitoring could be cut back. Another member stated that specialty pharmacies should be

well positioned to assist with monitoring. Drake clarified that while managed care plans can make restrict dispensation to specialty pharmacies, CMS grants less flexibility to DHS. Another member suggested that providers could be required by contract to adhere to post-treatment monitoring. A member commented that monitoring is essential for multiple reasons: in the short run, to determine treatment futility and patient adherence, and in the longer term to understand safety and effectiveness.

A motion was made and seconded to endorse the concept of monitoring for futility, patient adherence and treatment effectiveness and to solicit specialists' recommendations about appropriate monitoring standards. The motion carried unanimously.

A member commented though current utilization is relatively low, it is expected to rise. When there are large increases in utilization, HSAC would be open to further discussion and offering more precise guidance about prioritization.

The meeting adjourned at approximately 5:00 p.m.

Health Services Advisory Council



Minutes — May 30, 2014
9:00 – 11:00 a.m.
Hiway Federal Credit Union

Members Present

Don Brunnquell, Amelia Burgess, Amy Burt, Lance Hegland, Patrick Irvine, Jeff Schiff (non-voting), Tom Von Sternberg

Members Absent

Brendon Cullinan, Jim Miner, William Parham III, Katie Pieper, Timothy Sielaff (chair), Mark Willenbring

DHS Staff Present

Sara Drake, Ellie Garrett, Fritz Ohnsorg, Adam Pavek

Others Present

Chad Blomgren (Gilead Sciences), Mark Boldt (Minnesota Gastroenterology), Mike Brunnquell (University of Minnesota Medical student), Sharon D'Agostino (Johnson & Johnson), Mike Healy (Gilead Sciences), Joseph Horozaniecki (Metropolitan Health Plan), Joe Llewellyn (Gilead Sciences), Christi Murphy (Gilead Sciences), Judy Rowland (Forest)

I. Welcome, Introductions, Updates and Minutes

The meeting was called to order by Don Brunnquell, who served as chair in Tim Sielaff's absence. HSAC members, DHS staff and guests introduced themselves. There was no quorum, so consideration of the minutes was postponed until the next meeting.

Jeff Schiff provided several updates:

- With regard to opioid utilization, DHS and its contracted managed care organizations are coordinating their efforts. DHS staff met with representatives of the Minnesota Medical Association (MMA) recently to discuss progress toward a collaborative approach via the Institute for Clinical Systems Integration (ICSI). DHS and MDH are sharing data in order to better define the prevalence of and health disparities regarding neonatal abstinence syndrome.
- MDH has issued a report on health disparities, identifying structural barriers to health equity. DHS is represented on newly formed committees to design and implement solutions. A leadership-training group of which Ellie Garrett is a member has assessed and reported on effective engagement of stakeholders, particularly DHS service recipients, in stakeholder advisory processes. In response to the needs assessment, Garrett will be co-leading an internal community of practice for DHS staff to support high standards of stakeholder engagement.

- There are several updates regarding autism. The new autism benefit for public health care program recipients has been posted for public comment, preparatory to the filing of a waiver request to CMS. The benefit was shaped heavily by HSAC's recommendations and report of last year. The benefit is also consistent with policy requiring that people with disabilities receive services in the most accessible, integrated community setting. Coding will distinguish applied behavioral analysis services separate from other interventions. DHS is hiring a new autism research coordinator, and HSAC members are encouraged to circulate the position description to qualified candidates.
- New data are available showing that the rate of early, elective deliveries among Minnesota public health care program recipients has dropped dramatically, from approximately 5 percent to 0.25 percent. This extraordinary success is due in no small part to HSAC's recommendations, which in turn led to a collaborative quality improvement initiative among DHS and the state's hospitals.
- Schiff has been named as the incoming chair of the Medicaid Medical Directors Network. His term as chair will begin in July.
- The Legislature has revised the Minnesota Prescription Monitoring Program. The Board of Pharmacy has been directed to form a stakeholder committee that will set parameters to define potentially concerning opioid utilization. The Board will then use those parameters to establish a system by which prescribers are notified that a patient's prescribing history merits the physician's review.

II. Presentation: Hepatitis C, Emerging Therapies and Patient Selection

Brunnquell turned to the topic of the Hepatitis C virus (HCV) and directed the council's attention to its charter, which describes its guiding principles regarding quality and value of care.

Schiff presented on HCV, emerging therapies and patient selection. Copies of his PowerPoint presentation were circulated in advance of the meeting and are available on request from [HSAC staff](#). Highlights included:

- HCV is a very common condition, affecting 3.2 – 5.2 million Americans, according to the CDC. According to a 2013 study, prevalence in the Medicaid population may be twice as high as the general population. The disease progresses slowly, often with mild symptoms.
- Patients can be grouped in several ways:
 - Those whose virus does not progress to chronic liver disease and spontaneously go into remission (approximately 15 – 25 percent of people with HCV)
 - Among the remaining 75 – 85 percent, patients can be grouped by genotype, whether they have cirrhosis, severity of cirrhosis, comorbidities including comorbidities that present risk of reinfection, and whether they've been treated for HCV in the past.
 - Of those that fail to clear the virus, a small percentage will progress to decompensated liver disease and/or carcinoma.
- A new drug therapy has recently received FDA approval, and more new drugs are in the pipeline
- Independent researchers at the Medicaid Evidence-based Decision-making Project (MED) reviewed the status of the available evidence for the newly approved therapy, sofosbuvir. Limitations of the literature include:
 - Small sample sizes
 - Few patients with cirrhosis included
 - Other exclusions including co-infection, decompensated cirrhosis, severe psychiatric disorders

- No long term follow up: Published studies report outcomes of sustained virologic response at 12 weeks (SVR-12). Data on longer terms, such as 24 or 48 weeks (SVR-24 or SVR-48) are not available.
- Lack of a head to head comparison with older treatments
- Lack of studies on patients who were previously treated.
- Most studies open label, non-blinded
- Significant conflicts of interest within the professional societies that have issued guidance concerning sofosbuvir
- The cost of the new therapy in a population as large as the HCV population is unsustainable.
- Acting on recommendations from DHS' Drug Formulary Committee, DHS has already limited approval of sofosbuvir for on-label use only. The pharmacy unit is requesting HSAC's input on how to prioritize patients for treatment.
- Recognizing that new therapies are in the pipeline and that the disease progresses slowly for most patients, Schiff recommended that HSAC consider prioritizing HCV patients for treatment along the lines of other organizations such as the VA: Prioritizing those with advanced fibrosis and cirrhosis and therefore the highest risk of near-term harm in the absence of treatment; requiring a period of IV drug use abstinence; and interval SVR testing to continue treatment. Other coverage options to consider include coverage-with-evidence-development, delivery adherence mechanisms, and limitations to appropriate specialists.
- At the national level, HSAC could recommend that DHS support a common national purchasing structure and a request that the manufacturer attest to the lack of unpublished data showing negative results and/or a reason for the lack of publication of SVR-24 data.

A. Clarifying Questions

The chair opened the floor up to clarifying questions and comments from HSAC members. In response to a question, Sara Drake, manager of DHS' pharmacy unit, stated that on-label use of sofosbuvir requires concomitant administration of interferon. Interferon-based treatments have been long been available, and unpleasant side effects of interferon are well known. Drug treatments currently in the pipeline for FDA approval are not interferon-based.

In response to a question about longer term, patient-centered outcomes, Schiff clarified that useful outcomes to measure would include mortality, liver function and SVR for periods longer than 12 weeks. There are no direct studies linking sofosbuvir to these long-term outcomes.

B. Public Comments

Two members of the public offered comments. The first, Joe Llewellyn, PharmD, is affiliated with Gilead Sciences, the manufacturer of Sovaldi (sofosbuvir) and disclosed stock ownership in the company. His presentation was supported by PowerPoint slides, copies of which were circulated to the HSAC's distribution list and which are available by emailing [HSAC staff](#). Highlights included:

- Published studies show that sofosbuvir directly affects HCV, and that the drug has a favorable side-effect profile.
- Once patients achieve SVR-12, they do not relapse. He shared unpublished data showing that remains stable at 24, 48 and 72 weeks. Adam Pavek, a DHS clinical pharmacist interjected to state that SVR rates are highly variable in other studies, calling into question the data shown on Llewellyn's slides. Llewellyn responded that the FDA equates SVR-12 with cure.
- Discussion of the side effects of protease inhibitors

- Review of FDA labelling for sofosbuvir
- Review of response rates in subpopulations
- A summary of sofosbuvir safety data
- Genotype 3 patients require a 24-week treatment cycle for optimal outcomes

Mark Boldt, RN-CNP, of Minnesota Gastroenterology spoke next. He disclosed that he has been a paid public speaker for four medical industry companies, including Gilead. He also disclosed that he or his employer received research funding directly or indirectly from such companies. In response to the question about the amount of such funding, he stated “have no idea but would be minimal.” Boldt discounted conflicts of interest among those who developed guidelines, because providers who have such conflicts are the best providers in their fields. He stated that neuroses associated with HCV can be worse than the disease itself, and that withholding treatment would be harmful to many patients. He stated that sofosbuvir is the most efficacious, least harsh treatment available, and that it enables treatment of patients who would not have been treated before. He stated that cost projections assuming treatment of 50% of HCV patients are unrealistic, because there are not enough providers to treat that many patients. He also stated that as newer, simplified regimens become available, more providers would be able to offer HCV treatment.

HSAC members then asked questions of the presenters. Llewellyn clarified that there were no age limits (other than adulthood) imposed in the studies and stated that no treatment response differences by age were detected. There are some limitations for patients with cardiac disease.

In response to a question about pricing and cost, Llewellyn and his colleague, Mike Healy, stated that Gilead acquired the molecule by purchasing another company for \$11 billion. They were not involved with pricing decisions, but stated that sofosbuvir’s price is fair when compared to protease inhibitors. Healy circulated a table showing wholesale pricing among available HCV treatments, a copy of which is available from [HSAC staff](#).

Drake clarified that the longer a drug on the market, the greater the rebate available to Medicaid programs. New drugs, such as sofosbuvir, come with significantly smaller rebates. Older drugs like interferon are very affordable. Healy acknowledged that the table he provided does not reflect Medicaid rebates. Drake stated that rough, preliminary estimates of providing sofosbuvir for 80% of eligible HCV patients could exceed the cost of all drugs combined within Minnesota’s Medicaid pharmacy benefit.

An HSAC member asked about competition, and Drake stated that four new HCV drugs, some or all of which will not require concomitant interferon, are expected to be FDA-approved by the end of 2015.

There were no other public comments offered.

III. Discussion

The chair closed the public comment portion of the agenda and called for HSAC members to discuss. HSAC members made the following points during discussion. Because there was no quorum, no votes were taken.

- There needs to be public discussion about price fairness and a public policy change in paying for treatments such as sofosbuvir.
- No one wants to harm anyone, but current evidence is too sparse to inform patient selection.

- Gilead's choice to spend \$11 billion to acquire this molecule does not comprise the best investment for public health.
- Delivery system issues will be important considerations. DHS should consider therapeutic adherence and possibility of diversion or noncompliance.
- Requiring IV drug abstinence for a reasonable period prior to treatment should be considered. Alcohol abstinence will require more discussion.

The chair surveyed all members present, asking them whether it is reasonable to limit focus treatments on patients with advanced disease. Each member responded individually, and all agreed that it was reasonable to prioritize patients with the greatest burden of disease in the short term. The following individual comments were made:

- It's reasonable to focus on stages three and four, to limit treatments to select providers and to consider additional patient selection criteria, such as periods of abstinence from illicit drug use prior to treatment.
- We should look for opportunities to promote patient education and learn what other supports patients might need to support successful treatment.
- It is not uncommon to consider lifestyle issues as part of treatment and coverage decision-making. For example, lifestyle issues are relevant for gastric bypass candidates.
- Patient selection criteria should not exacerbate existing health disparities within the HCV population. We should in particular consider HCV rates in populations with disparate prevalence, such as the Native American population.
- Access to treatment, particularly to specialty providers, will be a concern in rural parts of the state.
- Monitoring patients before and after treatment is part of good stewardship. The impact of treatment on overall population health should be considered.
- We will need to consider treatment for pregnant women carefully.
- HSAC needs more detailed cost estimates based on different levels or projections of use.
- It would be useful to hear how Minnesota's health plans are covering sofosbuvir.

The meeting was adjourned at approximately 11:05.

Health Services Advisory Council



Minutes — March 13, 2014
3:00 – 5:00 p.m.
Elmer L. Anderson Building

Members Present

Don Brunnquell, Amelia Burgess, Amy Burt, Lance Hegland, Patrick Irvine, Jim Miner, William Parham III, Katie Pieper, Jeff Schiff (non-voting), Timothy Sielaff (chair), Tom Von Sternberg, Mark Willenbring (by telephone)

Members Absent

Brendon Cullinan

DHS Staff Present

Sara Drake, Ellie Garrett, Judy Gunderson, Fritz Ohnsorg, Adam Pavek

Others Present

Amy Borden (University of Minnesota Pediatric Residency), Dawn Carlson (Almeida Public Affairs), David Watts (Boston Scientific)

I. Welcome, Introductions, Updates and Minutes

Tim Sielaff called the meeting to order. Upon motion, a second and unanimous vote, the minutes of the February meeting were approved as written. Introductions were made around the room.

Jeff Schiff updated members on the status of various bills before the Legislature, including the Board of Pharmacy's proposed legislation to revise the Minnesota Prescription Drug Monitoring Program and a proposal regarding the Medicaid autism benefit that was passed last year. DHS submitted its mandated report to the Legislature on dental access. Schiff also stated that DHS was working with the Minnesota Department of Health to better quantify the incidence of neonatal abstinence syndrome (NAS). Preliminary data show high disparities in NAS among the Native American community.

II. Opioid prescribing activities – updates, discussion and next steps

Ellie Garrett reviewed the latest draft of the opioid work plan. It reflects collaborative opportunities to work with the Institute for Clinical Systems Improvement and other community members on protocols for the gap between an initial, acute dose and treatment for chronic pain, along with relevant quality measures. It also calls for development of common messages and coordination on formulary policies. Discussion ensued. Several members observed potential for coordinated approaches to quality improvement. Another stated that smaller, rural providers that are not affiliated with large, statewide

systems have limited data resources; he suggested that a single measure, perhaps total amount of opiates prescribed, would be most practical. Another member suggested measuring the number of opiate overdose deaths.

A member expressed concern about uneven access to and quality of addiction treatments around the state, particularly in the methadone clinic programs. Access to suboxone/buprenorphine-assisted treatment should be improved, and there are too few buprenorphine-licensed providers in the state. Death rates can be reduced by better opiate analgesia prescribing practices and better treatment for addiction.

No public comments were offered.

III. Identification of potential topics for HSAC to address

Schiff reviewed a list of possible topics for HSAC to next address, along with a list of previous reports. Suggested topics included:

- Patient selection and related criteria for treating Hepatitis C
- Criteria for coverage of genetic tests
- Proton beam therapy
- Long-acting reversible contraception
- Outcomes measures of overall health for Olmstead Plan and/or other DHS programs
- Non-procedural/interventional pain management treatment bundling
- In-home assessment of asthma risks
- Lifestyle-related prevention for diabetic and cardiac risk
- 17-Hydroxyprogesterone for prevention of premature labor

DHS has not yet pulled utilization data to prioritize the list by size of population or cost. Each of the possible topics offers different opportunities for leverage. Depending on the topic, HSAC might recommend coverage criteria, a quality improvement approach or other change in policy.

A member suggested that spine care be added to the list and also asked if there is a relevant topic relating to mental health that merits consideration. He also suggested the possibility of evaluating the Choosing Wisely campaign topics. Schiff suggested that the CDC's Winnable Battles campaign topics also be considered.

Discussion ensued. One member observed that a mental health-related topic might offer the biggest opportunity to impact health outcomes, particularly because of how mental health also impacts lifestyle decisions that in turn influence heart disease and diabetes. Also, genetic testing needs clear guidance, and the opportunity for policy intervention is now. Measures of well-being would be useful to discuss.

HSAC will continue discussing possible topics at its next meeting.

No public comments were offered.

The meeting was adjourned at approximately 5:00.

Health Services Advisory Council



Minutes — February 13, 2014
3:00 – 5:00 p.m.
Elmer L. Anderson Building

Members Present

Don Brunnquell, Amy Burt, Brendon Cullinan, Patrick Irvine, Jim Miner, William Parham III, Katie Pieper, Jeff Schiff (non-voting), Timothy Sielaff (chair), Tom Von Sternberg

Members Absent

Amelia Burgess, Lance Hegland, Mark Willenbring

DHS Staff Present

Sara Drake, Ellie Garrett, Judy Gunderson, Fritz Ohnsorg

Others Present

Howard Epstein (ICSI), Tara Erickson (MSIPP), Erin Huppert (Allina Health), Peggy Kaproth (BCBSM), Heather Keenan (MAPS), Murray McAllister (Courage Kenny Rehabilitation Institute), Dave Renner, (Minnesota Medical Association), Anne Thompson (Medtronic)

I. Welcome, Introductions, Updates and Minutes

Tim Sielaff called the meeting to order. Upon motion, a second and unanimous vote, the minutes of the November meeting were approved as written. Jeff Schiff introduced William Parham, III, as a new HSAC member.

Schiff reported that Nathan Moracco was serving as Acting Assistant Commissioner for the Health Care Administration within DHS while Scott Litz was serving as Interim Director of MNsure. Schiff also reported that DHS was moving ahead to hire a research coordinator for the autism benefit that is in the process of being designed, consistent with HSAC's recommendations.

II. Opioid Prescribing Initiatives in the Community and DHS Outline for Comprehensive, Collaborative Approach

Ellie Garrett presented a summary of opioid-related initiatives in the community, highlighting ICSI's recently completed work on acute and chronic prescribing. There is a gap between guidance for considering an initial dose of opioids and prescribing opioids for chronic pain (see ICSI's acute pain protocol and chronic pain guidance documents, respectively). There is also a need to develop common local (provider level and provider monitored) and sentinel quality measures (reported or constructed at the aggregate provider level), along with common messages for providers and the general public. Copies

of Garrett's PowerPoint presentation were circulated at the meeting and to those on the HSAC distribution list. Additional copies are available on request from hsac@state.mn.us.

Discussion ensued. Schiff reported that he and Garrett had met with medical directors from the managed care organizations that contract to cover public health care program recipients. They have expressed support for a common approach to reducing opioid overuse. DHS' pharmacists are also coordinating with the MCOs' pharmacists to develop common formulary approaches.

Members discussed how best to define the "sub-acute" space for which prescribing guidance from ICSI is currently lacking, and whether it should be defined in terms of numbers of refills or pills/day or the passage of time. They also discussed the kinds of guidance that could be useful during the sub-acute period, including average ceilings for morphine equivalence, recommendations for behavioral and chemical health assessments, non-opioid therapies, functional and pain assessments and goals, and prescriber continuity. Members also discussed the utility of mining the Minnesota Prescription Monitoring Program (PMP) to understand better individual and aggregate behavior of both prescribers and patients. Sara Drake explained that current law limits access to the PMP to providers for purposes of checking on individual patients' opioid history.

A member observed that physical symptoms of withdrawal can occur as early as 30 days from commencement of opioids. Physicians need to taper patients off of opioids during acute and sub-acute periods in order to prevent chronic use.

Several members described opioid-related initiatives that are occurring within their health plans or health systems. One member stressed that prescribing patterns are already changing as a result of individual organizations' activities. Schiff stressed the need to implement common measures that can support individual organizations' improvement efforts and measure variation among them and among providers. A member observed that health plans are well situated to monitor providers in this regard.

A. Public Comment

The chair called for public comments, and Murray McAllister (Courage Kenny Rehabilitation Institute) reminded members about the etiology of chronic pain. Most people who are in chronic pain do not use opioids. The time to screen for risk of chronic pain and opioid dependence is during the acute and sub-acute phases of pain. If opioids are prescribed, he stressed the need for setting realistic endpoints for discontinuation even if pain persists.

No other comments were offered.

B. Continued HSAC Discussion

A member queried how best to address availability of opioids for patients who don't have access to or don't follow recommendations for adjunctive therapies, such as physical and behavioral therapy. Another member acknowledged that access to adjunctive therapies in greater Minnesota is more limited than in the metro area.

Members discussed what kinds of measures might be needed to support quality improvement. They agreed that measuring the right things, asking the right questions, was essential. Not all steps in a quality improvement process will need sentinel measures. Garrett suggested that it would be useful to develop population health measures that assess, for instance, whether the ranks of new chronic users are declining and whether dosages for people who are receiving chronic opioids are appropriately low.

Members discussed whether HSAC was best situated to develop local and sentinel quality measures. Some members stated that ICSI or MN Community Measurement would be better suited to developing a community collaborative approach to quality and measurement.

Schiff asked Howard Epstein about ICSI's interest in community collaboration. Epstein responded that ICSI would be very interested in collaborating.

Action: A motion was made and seconded that HSAC staff, in coordination with other community organizations and agencies, should work together to develop measures and algorithms related to sub-acute opioid use including its relationship to acute and chronic use. The motion carried unanimously.

The meeting was adjourned.