

## Communicable Disease Reporting Changes

The Michigan Department of Health and Human Services (MDHHS) made some changes to the list of reportable conditions in Michigan for 2019, including changes to some hepatitis conditions. Both hepatitis D virus (HDV) and hepatitis E virus (HEV) were removed from the reportable disease list. These two conditions are relatively rare, not nationally notifiable, and have no standardized case definition or guidelines for case follow-up. Cases of HEV seen in Michigan are often the result of international travel and not local transmission. The infrastructure to report both HDV and HEV in the Michigan Disease Surveillance System (MDSS) will remain; however, reporting lab results for these two conditions will be voluntary.

In addition, there was a change to hepatitis C virus (HCV) reporting. MDHHS is requesting that all laboratories reporting to MDSS via HL7 messaging report the results of all HCV tests. This request means that both positive **AND** negative HCV antibody, RNA, and genotype results are reported for those submitted via electronic lab reporting. Reporting negative HCV antibody lab results can help public health staff at the state and local levels capture seroconversions that may indicate acute HCV infection. Since HCV is curable, either spontaneously or via treatment, reporting of negative RNA or genotype results can help the State and local health departments to identify HCV viral clearance. This allows us to obtain a better picture of HCV prevalence in the state of Michigan and can help better identify clients who could benefit from patient navigation services, including HCV treatment. Please see the following documents to assist with these changes.

- [De-duplicating Hepatitis C Reports in MDSS](#)
- [2019 Hepatitis C Case Classification Table](#)
- [2019 Michigan Reportable Diseases List – by Condition](#)
- [2019 Michigan Reportable Diseases List – by Pathogen](#)



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# Welcome New Staff!

We are pleased to welcome Macey Ladisky, Brandon Hool and Seth Eckel to the team. Macey is working as our new Viral Hepatitis Patient Navigator, and was previously working in the CD Division as the Hepatitis A Outbreak Epidemiologist. Her new role consists of developing patient navigation models to increase testing, linkage to care, and treatment for hepatitis C and HIV coinfecting clients with the intent to expand to mono-infected clients in the future.

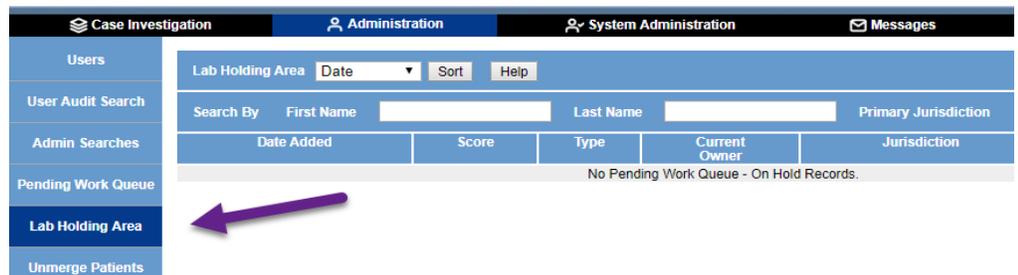
Brandon Hool is working as our new Harm Reduction Specialist. Brandon has extensive knowledge through his previous work at the Grand Rapids Red Project on harm reduction activities and will be a great resource to our unit and stakeholders. His new role with us consists of providing support and technical assistance to harm reduction projects as well as consulting with programs on best practices for implementation.

Seth Eckel has recently returned to the Viral Hepatitis Unit after a four year hiatus spent conducting influenza surveillance at MDHHS. As the new Viral Hepatitis Unit Manager, he will now be coordinating the unit's surveillance and prevention activities.

We are all excited to have these talented folks join our team!

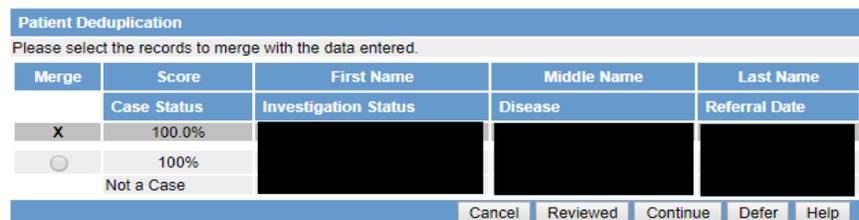
# Michigan Disease Surveillance System (MDSS) Updates

There have been some changes to the Michigan Disease Surveillance System (MDSS) to accommodate the new implementation of negative HCV lab reporting via HL7 messaging. The biggest change is the creation of the Lab Holding Area, a de-duplication queue that houses incoming negative labs that do not match to cases already in the MDSS. This queue is located within the Administration tab and follows the same de-duplication algorithm as the Pending Work Queue.



When incoming negative labs match to existing cases in MDSS, they will be attached to the case in the same manner as labs in the Pending Work Queue. When a negative lab is sent via ELR to the MDSS but does not match a HCV case that has already been created, it will be moved to the Lab Holding Area. The Lab Holding Area is set up to assign each lab a matching score based on how strong of a match it is to a potential case. Only labs with a match score of 80.0 or higher are made visible in the queue.

Once a lab is in the queue, users have the option to view the lab result and resolve the potential match. The resolve action functions the same as the Pending Work Queue, with the exception of an added "Reviewed" button. This button is to be used when a lab result does not match any of the cases already in MDSS that were flagged as a potential match and hides the lab result from being seen in the holding area to avoid labs sitting in the queue for long periods of time.



Reviewed button hides labs that don't match to a case

At the end of each day, labs in the Lab Holding Area (both visible and hidden) are automatically checked with existing cases in MDSS for merging in the event there is now a match. The Lab Holding Area will be primarily managed by our Viral Hepatitis staff to prevent putting additional work onto the local health departments, but locals as well as regional epidemiologists are welcome to look at labs in this queue if they chose to do so.

# Gilead: Generic Versions of HCV Medications

Gilead Sciences recently [announced](#) they will begin offering generic versions of Epclusa (sofosbuvir 400mg/velpatasvir 100mg) and Harvoni (ledipasvir 90mg/sofosbuvir 400mg), for treatment of chronic hepatitis C virus (HCV), in the United States, through a newly created subsidiary, Asegua Therapeutics. The generic treatments will be available in January 2019 and will have a list price of \$24,000 for the most common course of therapy.

Since the launch of Gilead's medication Sovaldi (sofosbuvir) listed at a cost of \$84,000 in 2013, the average price of HCV treatment has decreased by more than 60 percent off the public list prices as multiple pharmaceutical companies released competing drugs. The company hopes the launch of these generic versions will help to increase transparency by closely aligning medications' list prices with their cost.

While some health insurance companies can negotiate discounts from pharmaceutical companies to bring down the cost of HCV drugs, state-managed Medicaid programs are unable to negotiate these lower prices. However, according to Gilead, patients in the Medicaid Part D program could save up to \$2500 in out-of-pocket costs per HCV treatment with the new generic medications.

"Launching these authorized generics is the best solution available to us today to quickly introduce a lower-priced alternative to our HCV medications without significant disruption to the healthcare system and our business," said John F. Milligan, PhD, President and Chief Executive Officer, Gilead Sciences. "Our ultimate goal is to lower the list price of Epclusa – a medication we believe is of great importance given its clinical profile across genotypes – and Harvoni. We are committed to working with all of our partners in the healthcare system to help enable list price reductions of our HCV medications and find better solutions to reduce patients' out-of-pocket costs," Milligan also stated.

In addition to their actions aiming to reduce patient costs, Gilead continues to pursue innovative partnerships and long-term financing models that may expand access and potentially help to eliminate Hepatitis C in the U.S. and worldwide.



## HCV Funding for Local Health Departments

Each year the Population Health Administration of MDHHS submits proposals for priorities for State funding in the next fiscal year. Last year the Viral Hepatitis Unit wrote a Proposal for Change, which supported the allocation of general funds to local health departments for HCV testing, case investigation, linkage to care, and follow-up. The \$4.5 million proposal was supported in the governor's budget and eventually approved by the Michigan legislature at \$1 million.

The goal was to fund each local health jurisdiction, but the reduced budget amount meant we needed to prioritize. We therefore decided to fund the 10 jurisdictions with the highest HCV case burden in 2017. A base amount of \$40,000 will be provided to each of those 10 agencies, with the remaining funds being distributed proportional to the 2017 HCV burden.

Disbursement of funds began on January 1, 2019. The health departments funded are Detroit City, Wayne County, Oakland County, Macomb County, Genesee County, Kent County, Ingham County, St. Clair County, Muskegon County and Kalamazoo County.

## New HCV Case Classification Guidance

With the implementation of negative electronic lab reporting for hepatitis C (HCV) in MDSS, some case classification and deduplication changes have been made. The main change is in the classification of cases with a positive antibody and negative RNA or genotype result. Previously, we recommended these cases be classified as “probable” for consistent case counting across all Michigan jurisdictions.

Now, with negative labs being reported across the state, we are recommending these cases be closed out as “not as case”. With the onboard of larger labs across the state sending their negative HCV results via HL7 messaging, the potential bias for some jurisdictions receiving negative labs while others do not have been eliminated. This new case classification will allow us to more accurately capture those who are currently infected with hepatitis C as well as capture those who were previously infected but have been cured or cleared of the virus.

The MDHHS Viral Hepatitis Unit is working on updating case classification and deduplication guidance documents and will share these on our [website](#) when available.

## Collaborating with Community Partners to Offer HCV Rapid Testing at Pride Festivals

An estimated 3.5 million people in the U.S. are chronically infected with hepatitis C; however, only 50 percent are diagnosed and aware. More efforts are needed to increase hepatitis C testing and linkage to care. According to the CDC, men who have sex with men are at increased risk for hepatitis C if they are involved in high-risk behaviors. The CDC also recommends hepatitis C testing for:

- Adults born from 1945 through 1965
- Persons who inject drugs
- People living with HIV
- Persons who were ever on long-term hemodialysis
- Persons who received clotting factor concentrates produced before 1987
- Persons with persistently abnormal ALT levels
- Recipients of transfusions or organ transplants before July 1992/were notified the received blood was from a donor who later tested positive
- Persons with recognized exposures

The MDHHS Viral Hepatitis Unit partnered with the American Liver Foundation, Wellness AIDS Services, Lansing Area AIDS Network (LAAN), and Meijer Pharmacy to offer hepatitis C testing at the Michigan Pride Festival in Lansing, Flint Pride Festival, and the Hotter Than July Festival in Detroit. The American Liver Foundation donated 200 rapid test kits for the festivals. Remaining hepatitis C rapid test kits were utilized during LAAN’s National HIV Testing week activities, Wellness AIDS Services’ National African American Hepatitis C Action Day workshop and their Syringe Treatment Exchange Program (STEP). As a result of the testing events, a total of 116 people were tested for hepatitis C. Individuals who tested reactive, which indicates detection of hepatitis C antibodies, were counseled and linked to follow-up care for secondary testing to confirm hepatitis C infection.

MDHHS is always looking for opportunities to collaborate with organizations to hold hepatitis C testing events in the community! If you are interested in hosting a hepatitis C testing event in your area, please contact [MDHHS-Hepatitis@michigan.gov](mailto:MDHHS-Hepatitis@michigan.gov).



# Changes to MI Medicaid Fibrosis Score Restrictions for HCV DAA

In April 2017, a Michigan Medicaid beneficiary filed a class-action lawsuit against MDHHS over Medicaid prior authorization restrictions for hepatitis C direct-acting antiviral (DAA) coverage. The beneficiary, who had a Metavir Fibrosis score of F0, was denied hepatitis C treatment coverage. At the time of denial, Michigan Medicaid limited treatment coverage for enrollees with a liver damage score of F2 or higher. In January 2018, both the Michigan Medicaid beneficiary and the State agreed to settle the lawsuit. A final hearing on the proposed settlement was held on August 8, 2018.



The final settlement includes changes to Michigan Medicaid's liver damage criteria for treatment coverage. Starting October 1, 2018, Michigan Medicaid expanded HCV DAA coverage for beneficiaries with a fibrosis score of F1 or higher even without the presence of other health problems. On October 1, 2019, coverage will be expanded to include beneficiaries with a fibrosis score of F0 or higher. Prior authorization forms have been updated to reflect the new changes.

To view the updated hepatitis C prior authorization forms, please visit [https://michigan.fhsc.com/Downloads/MI\\_PAfaxform\\_Hepatitis\\_C\\_Agents.pdf](https://michigan.fhsc.com/Downloads/MI_PAfaxform_Hepatitis_C_Agents.pdf)

For more information about the hepatitis C lawsuit, please visit [www.michigan.gov/HepCLawsuit](http://www.michigan.gov/HepCLawsuit).

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## Save the Date

- 3/29 [MPHA Epidemiology Conference](#)
- 4/2 [2019 MI Harm Reduction Summit](#)
- 4/18 [Communicable Disease Conference](#)  
(Registration Opening Soon!)

## Helpful Links



- [www.michigan.gov/hepatitis](http://www.michigan.gov/hepatitis)
- [www.mi.gov/HepatitisAOutbreak](http://www.mi.gov/HepatitisAOutbreak)
- [www.michigan.gov/injectionsafety](http://www.michigan.gov/injectionsafety)
- [www.michigan.gov/hepatitisb](http://www.michigan.gov/hepatitisb)
- [www.michigan.gov/cdinfo](http://www.michigan.gov/cdinfo)
- [www.michigan.gov/hai](http://www.michigan.gov/hai)
- [CDC Hepatitis](#)
- [CSTE HCV Subcommittee](#)
- [Know More Hepatitis Campaign](#)
- [Know Hepatitis B Campaign](#)
- [CDC Hepatitis Risk Assessment](#)
- [Hepatitis A](#)
- [Hepatitis B](#)
- [Hepatitis C](#)
- [USPSTF](#)
- [AASLD](#)
- [Institute of Medicine Report](#)
- [One and Only Campaign](#)
- [Injection Safety Resources](#)
- [Hepatitis Occupational Exposure Guideline](#)
- [Blood Glucose Monitoring](#)

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