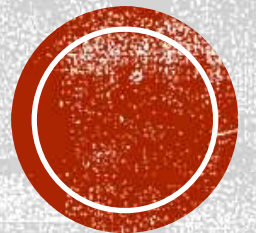


# **HCV TREATMENT ACCESS; PATIENT ASSISTANCE; GENERIC IMPORTS**

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# AN AUTHORIZED GENERIC DRUG IS...

A. a generic drug with special FDA approval.

B. marketed by a company other than the innovator.

C. the exact same product as the branded product.

D. ALL OF THE ABOVE



# AUTHORIZED GENERIC CONT...

## Generic Drug

- Manufactured by non-innovator company
- Same: active ingredient, indications, dosage form, strength, route of administration
- Different: inactive ingredients, 85% therapeutic range
- ANDA required
- Orange book listing

## Authorized Generic Drugs

- Manufactured by the innovator company (marketing may be different)
- Brand name drug with different label
- May have different tablet markings or packaging
- May have unique name (branded generic)
  - Advair – Wixela
  - Epclusa – sofosbuvir/velspatavir (10/2018)
  - Harvoni - Ledipasvir-Sofosbuvir (1/2019)



# THE LEAST EXPENSIVE DAA TX COURSE COSTS ...

A. \$100 per day

B. \$500 per day.

C. \$1000 per day.

D. NONE OF THE ABOVE



AWP = Average Wholesale Price  
WAC = Wholesale Acquisition Cost

# COST OF DAA THERAPY

Medication	Trade Name	Manufacturer	Length of therapy	AWP for 1 day	“Cash price” for 1 day
Elbasvir-Grazoprevir	Zepatier	Merck & Co, Inc.	One tab daily for 12 to 16 weeks	\$312	\$268
Ledipasvir-Sofosbuvir	Harvoni	Gilead Sciences	One tab daily for 8 to 24 weeks	\$1350	\$1161
Ledipasvir-Sofosbuvir	Ledipasvir-Sofosbuvir	Gilead Sciences	One tab daily for 8 to 24 weeks	\$514	\$442
Glecaprevir-Pibrentasvir	Mavyret	AbbVie	Three tabs daily for 8 to 16 weeks	\$566	\$487
Sofosbuvir	Sovaldi	Gilead Sciences	One tab daily for 12 to 48 weeks	\$1200	\$1106
Sofosbuvir-Velpatasvir	Epclusa	Gilead Sciences	One tab daily for 12 to 24 weeks	\$1068	\$985
Sofosbuvir-Velpatasvir	Sofosbuvir-Velpatasvir	Gilead	One tab daily for 12 to 24 weeks	\$343	\$295
Sofosbuvir-Velpatasvir-Voxilaprevir	Vosevi	Gilead Sciences	One tab daily for 12 weeks	\$1068	\$985



# 340B



- Price calculated based on Average Manufacturer Price (AMP) less:
  - Mandatory discount
    - 23% for brand name medications
    - 13% for generic medications
  - Inflation Penalty
    - Added if AMP increases faster than inflation
    - Results in “penny pricing”

Without 340B				With 340B			
The FQHC loses \$80, all due to the sliding fee discount.	<i>Sliding Fee Patient</i>			The FQHC loses only \$20. Their net cost for the uninsured patient is reduced \$50, and they retain \$30 savings on the insured patient.	<i>Sliding Fee Patient</i>		
	Drug Cost	\$100	<b>FQHC loses \$80</b>		Drug Cost	\$70	<b>FQHC loses \$50</b>
	<u>Sliding Fee</u>	<u>\$20</u>			<u>Sliding Fee</u>	<u>\$20</u>	
	Net Cost	\$80			Net Cost	\$50	
	<i>Insured Patient</i>				<i>Insured Patient</i>		
	Drug Cost	\$100	<b>FQHC breaks even</b>		Drug Cost	\$70	<b>FQHC retains \$30 savings</b>
	<u>Insurance Pays</u>	<u>\$100</u>			<u>Insurance Pays</u>	<u>\$100</u>	
Net Cost	\$0	Net Savings		\$30			

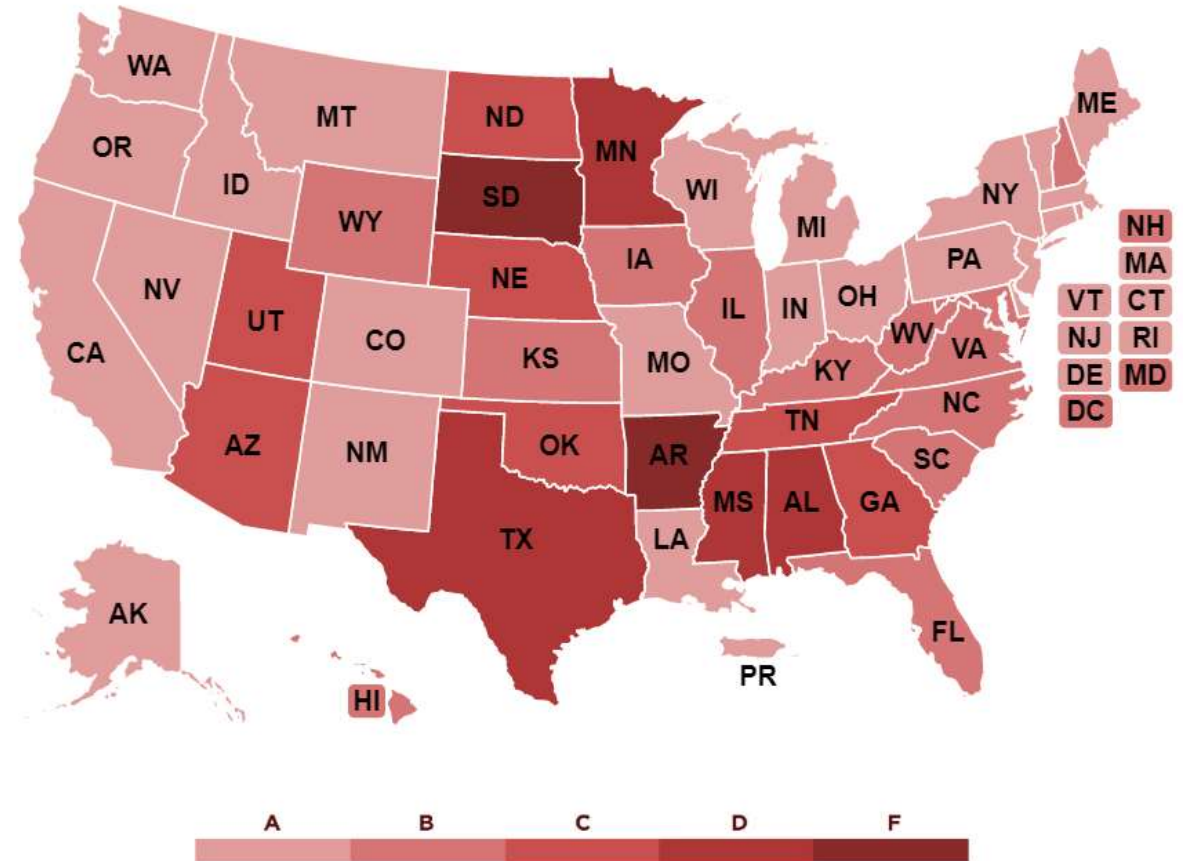


# MEDICAID COVERAGE

- November 5, 2015 CMS released guidance regarding access to HCV DAA treatment
- December 31, 2018 DHS Med-Quest guidance
  - Baseline HCV RNA within 3 months
  - All F scores eligible for tx
  - Prescribed by or in consultation with specialist or **PCP with expertise who is approved by the plan**
  - Prescriber attests to medication adherence
  - Sobriety restrictions removed

## Hawaii

State of Hepatitis C Medicaid Access: **B**



# PRIOR AUTHORIZATION PUZZLE

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Encounter  
note

Treatment  
history

HCV RNA  
(90-days)

HBV  
serology/HIV  
status

CMP/CBC

Cirrhosis  
status

Treatment  
agreement

\*\*Specialist  
Consult\*\*





# FINANCIAL ASSISTANCE OPTIONS FOR DAA MEDICATIONS INCLUDE:

A. Manufacturer-sponsored copay cards.

B. Patient assistance programs.

C. Non-profit pharmacies.

D. A and B

E. All of the above



# FINANCIAL ASSISTANCE



- Commercially insured: copay card
- Uninsured/underinsured: patient assistance
  - Number of household members
  - Household income (proof may be required)
  - F score and previous treatment
  - Medicare patients eligible
- Resources
  - Liver Foundation
  - HepFree Hawaii

Household size*	Annual income
1	\$100,000 or less
2	\$100,000 or less
3	\$109,800 or less
4	\$132,500 or less

After 4, add \$22,700 for each additional dependent family member



# MEDICATION IMPORTATION

- Importation = manufactured and intended for sale in another country
- Reimportation = manufactured in USA, exported for sale in another country, brought back to USA for personal use
- Importation for **personal use**
  - ILLEGAL
  - Medicare Modernization Act (2003) HHS Secretary waivers:
    - Serious condition
    - No effective treatment in USA
    - No commercialization of the drug in USA
    - No risk to public health and safety
    - **Significant cost savings to patient**
- Sunny Pharma: two American physicians
  - Mavyret - \$9250 for 8 weeks
  - Harvoni/Epclusa - \$777 for 12 weeks
  - Vosevi - \$15,330 for 12 weeks



# MINIMUM PRETREATMENT TESTING FOR DAA THERAPY SHOULD INCLUDE

A. HCV RNA, CMP, CBC, IMAGING.

B. HCV RNA, GENOTYPE, CMP, CBC, HBV, HIV, IMAGING.

C. HCV RNA, GENOTYPE, CMP, CBC, HBV, HIV, PT/INR, AFP, IMAGING.

D. IT DEPENDS....



# CARING FOR THE UNINSURED



## Pretreatment labs

- CBC - \$12.50
- CMP - \$19
- HCV RNA - \$90
- Genotype - \$386.50
- AFP - \$29
- PT/INR - \$9



## During treatment (?)

- HBsAg - \$20.35
- Anti-HBc - \$23.90
- HIV – free at DOH or HIHAF



## Post treatment

SVR  
Long-term HCC  
monitoring

- Liver US w/elastography - \$372
- Fibroscan (Medicare non-facility fee 91200) - \$36.19



## Imaging/Fibroscan



# REFERENCES / RESOURCES

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