


REGULATORY ENVIRONMENT IMPACTING CLINICAL HEALTHCARE SERVICES



1

AGENDA


- Government Structure
- Pharmacy Benefit Managers
- 340B
- HIV Prevention
- Home Health



2

AGENDA

- Insulin Emergency Renewal
- Remote Dispensing
- Roles of Trade Associations



3

DR. GALLOP FRANKLIN, II

4

GOVERNMENT STRUCTURE

Federal and State


- Executive
- Legislative
- Judicial

5

FEDERAL LEGISLATIVE BRANCH

- Speaker of the House
- Senate President
- United States Rep. 435 members
- United States Senator 100 members
- Each of the United States Representatives represents the same amount of people
- Each State has 2 United States Senators regardless of population.
- States gain and lose members based on population shift (mirrors electoral college)


6



FEDERAL EXECUTIVE BRANCH

- Office of the President
- Office of the Vice President
- Secretaries of Departments


7



FEDERAL JUDICIAL BRANCH

- United States Supreme Court
- Circuit courts
- Federal Judges

8



STATE LEGISLATIVE BRANCH

- Speaker of the House
- State Rep. 120 members (185,00 people per rep)
- Senate President
- State Senate. 40 members


9



FEDERAL & STATE LEGISLATIVE BRANCH

- House Leadership roles
- Pro Tempore
- Chairs and Vice Chairs of committees
- Floor and Committee Whips
- Majority and Minority leaders
- Ranking Members


10



STATE EXECUTIVE BRANCH

- Governor
- Lt. Governor
- Secretaries of Agencies

11



STATE JUDICIAL BRANCH

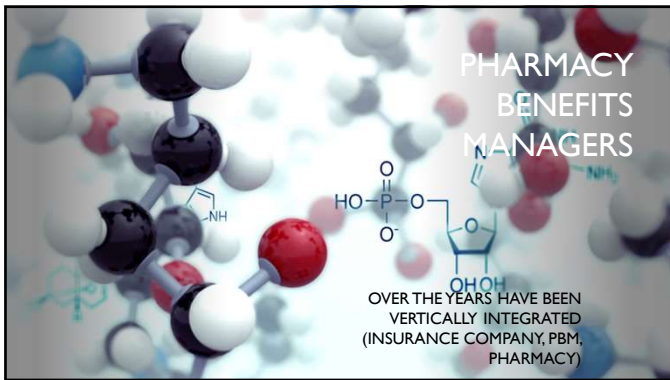
- State Supreme Court
- County Judges
- State Judges

12

PHARMACY BENEFITS MANAGERS

- MANAGE THE PRESCRIPTION BENEFIT FOR INSURANCE COMPANIES
- NEGOTIATES WITH THE PHARMACEUTICAL COMPANIES FOR PRICING AND REBATES (FORMULARY PLACEMENT)
- NEGOTIATES WITH PHARMACIES FOR PRICING


13



PHARMACY BENEFITS MANAGERS

OVER THE YEARS HAVE BEEN VERTICALLY INTEGRATED (INSURANCE COMPANY, PBM, PHARMACY)

14



PHARMACY BENEFITS MANAGERS

- Claw backs
- Maximum Allowable Cost (MAC) pricing
- Contract negotiations with Pharmacies
- Network management
- Specialty Pharmacy conditions

15

EXCLUSIVE CONTRACTS
DIRECT PATIENTS TO PARTICULAR PHARMACIES.

PHARMACY BENEFITS MANAGERS

16




WHITE BAGGING

- Medical and Pharmacy Benefit design
- Consider opening your own Specialty Pharmacy (don't outsource long term)

17

SELF FUNDED PLANS

- Not intended to change self-funded plans (340b pricing can be helpful for these plans)



18



340B

- Special program that allows certain entities such as Federally qualified health center, or DISC to purchase medications for a much lower price than the wholesale acquisition costs.
- Covered entities are Pharmacies that dispense 340b medications who have a contract with a 340b eligible facility.
- 340b programs have become a source of revenue for hospitals, clinics, and covered entities

19



340B

- 340b lower priced medications can only be dispensed to 340b eligible patients
- 340b eligible patients must have received care from a 340b facility
- 340b eligible patients could be under insured or uninsured or have Medicaid, Medicare, or private commercial insurance
- All insurances reimburse the covered entity the full price for the 340b eligible medication even though the covered entity purchased the medication for a very low price.

20



340B

- Recently Pharmaceutical companies have begun to legally challenge the 340b programs and are lobbying the federal government to amend or get rid of the program.
- Recently Pharmaceutical companies have begun to only allow one covered entity per 340b eligible healthcare facility.

21

HIV PREVENTION

- Florida has the 2nd highest HIV infection prevention rate in the United States
- Florida's HIV Infection prevention Rate
- Florida HIV heat map.

Acquired Immunodeficiency Syndrome (AIDS) Diagnoses, Rate Per 100,000 Population, 2020

22

HIV PREVENTION

- HIV treatment
- HIV Pre Exposure Prophylactic Therapy
- HIV Post Exposure Prophylactic Therapy

23

HIV PREVENTION

- HIV Pre Exposure Prophylactic Therapy (PrEP)
- Success Rate
- Who are good candidates
- Contraindications
- Common medication regimens


24



HIV PREVENTION

- HIV Post Exposure Prophylactic Therapy (PEP)
- Success Rate
- Who are good candidates
- Contraindications
- Common medication regimens


25



CURRENT MODES OF ACCESS TO PREP AND PEP

- Authorized Prescribers such as Physicians, Advanced Practice Registered Nurses, Nurse Practitioners, Physician Assistants.
- Hospital protocols for hospital employees only
- Collaborative Practice Agreement Statute with outlined requirements.

26



CURRENT MODES OF ACCESS TO PREP AND PEP

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27

HB 159 HIV INFECTION PREVENTION BECOMING A LAW

- How a Bill Becomes a Law
 - Bill submitted to bill drafting
 - Edits and changes made
 - Bill Filed

28

HB 159 HIV INFECTION PREVENTION BECOMING A LAW

- Committee Assignment and Process
 - Healthcare Regulation Sub-Committee
 - Healthcare Appropriation Sub-Committee
 - Health and Human Services (Full Committee)

29

HB 159 HIV INFECTION PREVENTION BECOMING A LAW

- Committee Process
 - House leadership
 - Senate leadership
 - Governor's office


30



HB 159 HIV INFECTION PREVENTION BECOMING A LAW

- Committee Process
 - Reasons a bill will get on the agenda
 - House leadership priority
 - Senate leadership priority
 - Governor's Priority
 - Respected member


31



HB 159 HIV INFECTION PREVENTION BECOMING A LAW

- Committee Process
 - Reasons a bill will pass
 - Stake holder engagement
 - Healthcare community
 - Business community
 - Advocacy groups

32



HB 159 HIV INFECTION PREVENTION BECOMING A LAW

- Committee Process
 - Compromise or to not compromise?
 - Healthcare community
 - Business community (currently in the business, those wanting to get into the business)
 - Advocacy groups
 - Senate Chairs with personal perspectives

33



HIV INFECTION PREVENTION BILL

- Pharmacists can prescribe and dispense HIV infection prevention PEP medications
- Collaborative practice agreement required (new section)
- Pharmacists must be certified by the Board of Pharmacy

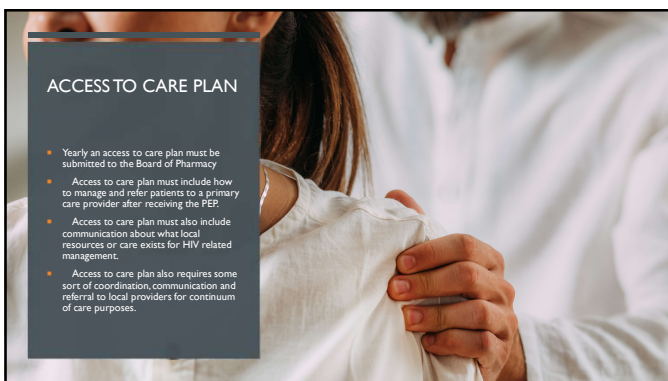
34



HIV INFECTION PREVENTION BILL

- Pharmacists will have a protocol with Physician about screening for HIV. Prescribing and dispensing appropriate medications per the CDC guidelines
- For Eligibility a Pharmacist must have practiced for 3 years or have a PharmD
- For eligibility a Pharmacist must have 250,000 of malpractice insurance
- Pharmacy must have an access to care plan approved by the board of Pharmacy.

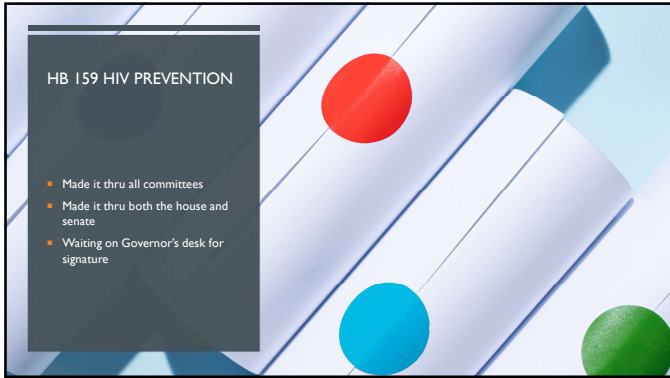
35



ACCESS TO CARE PLAN

- Yearly an access to care plan must be submitted to the Board of Pharmacy
- Access to care plan must include how to manage and refer patients to a primary care provider after receiving the PEP.
- Access to care plan must also include communication about what local resources or care exists for HIV related management.
- Access to care plan also requires some sort of coordination, communication and referral to local providers for continuum of care purposes.

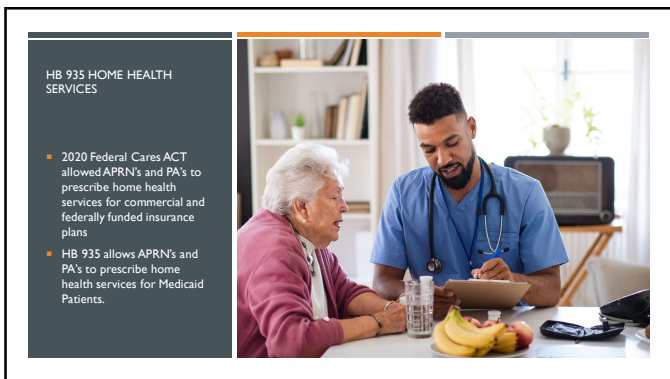
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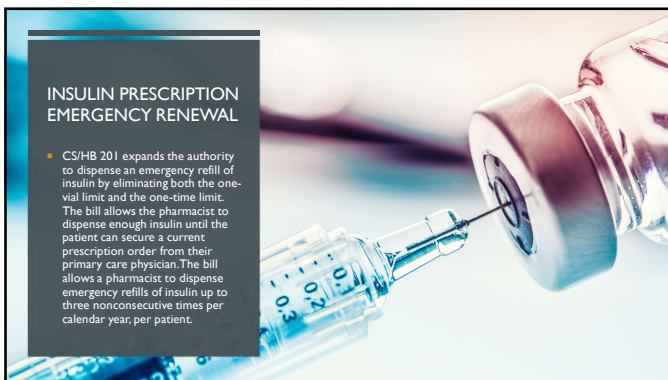
39



INSULIN PRESCRIPTION EMERGENCY RENEWAL

- In the event a pharmacist receives a request for an insulin prescription refill, but is unable to readily obtain refill authorization from a prescriber, current law allows the pharmacist to dispense a one-time emergency refill of one vial of insulin. However, current law does not authorize pharmacists to dispense insulin-related supplies or equipment as part of an emergency prescription refill, and one vial may be insufficient for some patients' emergency needs.

40



INSULIN PRESCRIPTION EMERGENCY RENEWAL

- CS/HB 201 expands the authority to dispense an emergency refill of insulin by eliminating both the one-vial limit and the one-time limit. The bill allows the pharmacist to dispense enough insulin until the patient can secure a current prescription order from their primary care physician. The bill allows a pharmacist to dispense emergency refills of insulin up to three nonconsecutive times per calendar year, per patient.

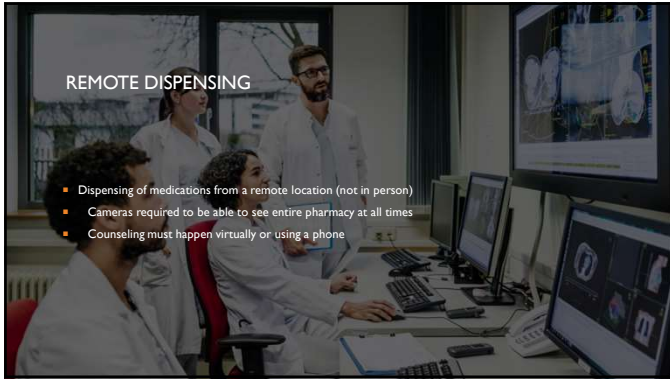
41



INSULIN PRESCRIPTION EMERGENCY RENEWAL

- The bill also authorizes a pharmacist to dispense an emergency refill of insulin-related supplies or equipment, if the pharmacist is unable to readily obtain refill authorization from a prescriber. The bill allows a pharmacist to dispense emergency refills of insulin-related supplies or equipment up to three nonconsecutive times per calendar year, per patient.

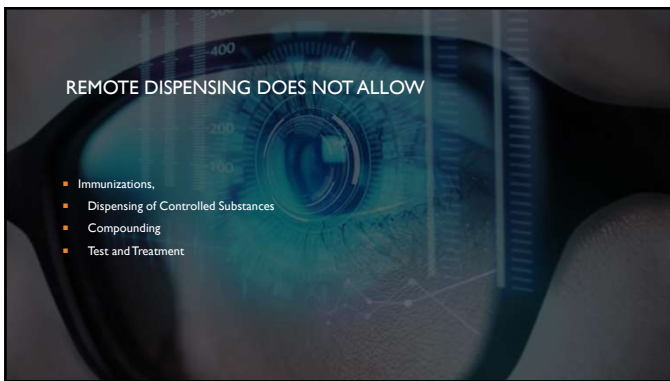
42



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