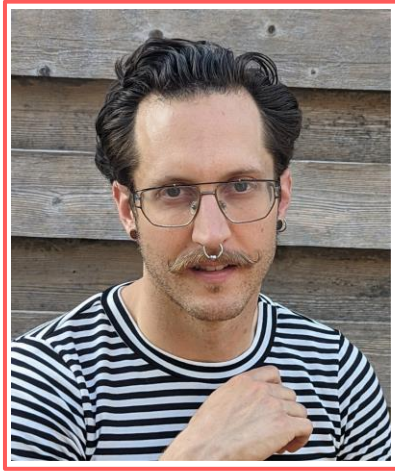


Have you prescribed
PrEP before?

Pre-Exposure Prophylaxis (PrEP) Implementation & Coverage Update





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Meet your
presenters!

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No relevant financial disclosures.

Session Agenda and Objectives

- Define PrEP
- PrEP History & Current Need
- PrEP Update
- PrEP Options Side by Side
- Barriers
- Case Studies
- Resources
- List currently available forms of PrEP and differentiate between them
- Communicate how the Affordable Care Act (ACA) establishes access to preventive services without cost-sharing—and discuss related challenges
- Help clients determine if PrEP would work for them and discuss other HIV prevention strategies

PrEP = Pre-Exposure Prophylaxis

PrEP is a biomedical HIV prevention strategy/intervention where an individual receives medication (daily oral, incident-based oral, or long acting injectable) to protect against and prevent HIV acquisition.



This is different than post-exposure prophylaxis (PEP or nPEP) which is an emergency biomedical intervention meant to be used immediately following a potential HIV exposure.

How effective is PrEP?

PrEP can reduce HIV from sex by >90%

PrEP can reduce HIV transmission from injection drug use by >74%

PrEP efficacy is highly dependent on adherence

PrEP is safe and effective for individuals with renal disease* , pregnant persons, transgender persons using hormone therapies, and adolescents

How long until it starts working?

PrEP requires approximately 7 days of daily use for maximum protection from HIV for receptive anal sex (bottoming)

PrEP requires 21 days of daily use for HIV from receptive vaginal sex or injection drug use

2-1-1 or On-Demand PrEP is only recommended for adult MSM as it has not been studied in other populations

Candidates for PrEP

All sexually active adults and adolescents should be offered info about PrEP

Possible Candidates for PrEP

Adolescents—All forms of PrEP have been approved for adolescents, so long as they meet weight requirements of 77 lbs (35 kg).

History of nPEP (Post-Exposure Prophylaxis)

Someone who is pregnant

Have an active hepatitis B infection

Have a medical condition that affects kidney function

People who may not currently be sexually active but plan to be soon

Are **NOT** Candidates for PrEP

People already living with HIV

People with symptoms of acute HIV infection

People who weigh less than 77 lbs (35kg)

Pre – Exposure

PrEP:

- Taken **before** exposure
- Daily pill for HIV negative people to prevent HIV
- Suitable for sexually active or IV drug using HIV negative persons
- Most effective when used with condoms or other prevention methods

Post – Exposure



nPEP:

- Taken **after** exposure
- Time sensitive; must be started within 72 hours
- 28 day regimen
- Intended for single-event exposure (not the best choice for those with repeated or ongoing exposure)
- Appropriate for exposure that happens from a needlestick, sexual assault, sharing injection equipment, or sex
- Most effective when started as soon as possible

US Public Health Service

**PREEXPOSURE PROPHYLAXIS FOR
THE PREVENTION OF HIV
INFECTION IN THE UNITED STATES
– 2021 UPDATE**

A CLINICAL PRACTICE GUIDELINE

Guidance for Apretude/injectable PrEP

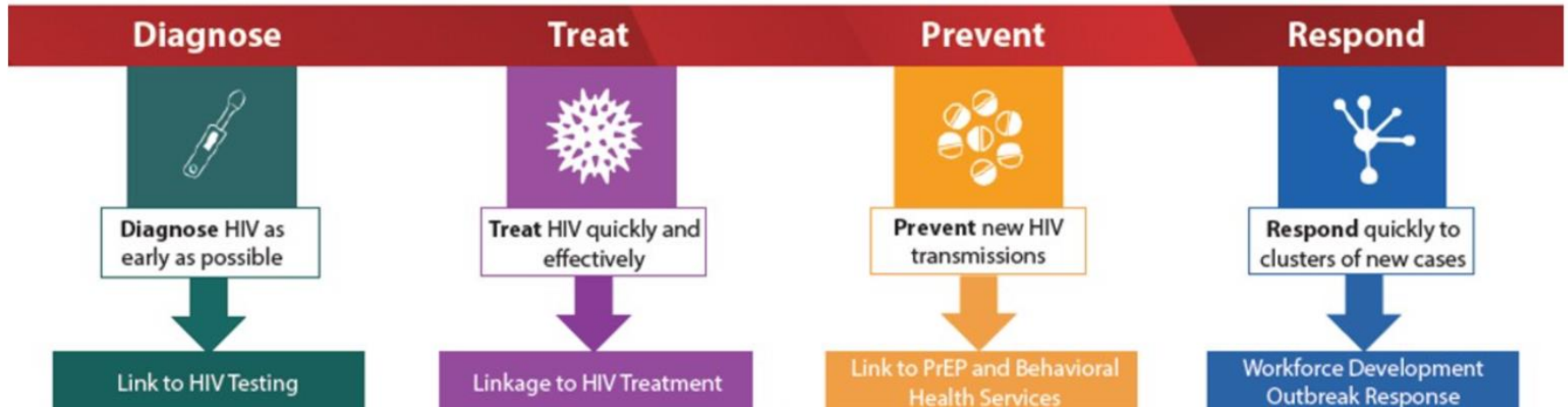
Broader indication; all sexually active persons should be counseled on the availability of PrEP

Decrease in the frequency of some monitoring labs

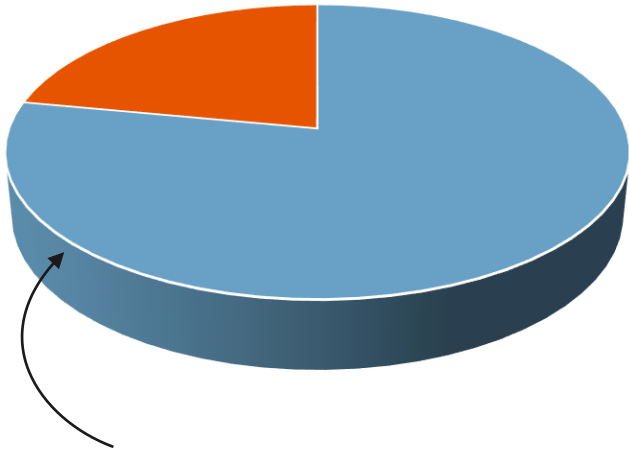
Offers guidance on Apretude®/ injectable PrEP as well as 2-1-1 / on-demand dosing

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The National HIV/AIDS Strategy (NHAS)



Iowa Progress Estimates



This is only 22% coverage when compared to the estimation of need!

At the end of 2021, Iowa reported a minimum of 1,925 unique PrEP users.

More work can and should be done to engage patients in PrEP care who would benefit from biomedical interventions, especially women, PWID, and BIPOC still underrepresented in terms of able to access PrEP.

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PrEP Options



Getting a Prescription



Counseling—Appointment with medical provider to discuss how PrEP works, assess readiness and ability to adhere to medication. Discuss side effects and screen for symptoms of acute HIV



Labs—A recent negative HIV test is required to initiate PrEP, preferably one that is > one week old. Ideally it would be an HIV-1 RNA. Oral PrEP requires additional monitoring labs such as serum creatinine. Relevant STI is recommended throughout the year.



Medication— Pick up prescription for oral PrEP or give first injection

Truvada®

Emtricitabine 200mg/Tenofovir Disoproxil Fumarate
300mg
(TDF/FTC or F/TDF)

Approved for use in the following populations:

- All persons weighing 35kg (77lbs) or more

Administration:

- 1 Tablet 1x/day, or
- 2-1-1 (incident based) dosing

Generic Availability

- Multiple generics available



Descovy®

Emtricitabine 200mg/Tenofovir Alafenamide 25mg
(F/TAF)

Approved for use in the following populations:

- ❑ Cisgender males—35kg (77lbs) and above
- ❑ Transgender women—35kg (77lbs) and above

Administration:

- ❑ 1 Tablet 1x/day

Generic Availability

- ❑ No generics available



There is not yet data showing the efficacy of Descovy (F/TAF) for HIV prevention that happens from injection drug use (IDU)

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Apretude®

Cabotegravir 600mg (gluteal injection)/

Optional 30mg daily oral cabotegravir 4-week lead-in (CAB-LA)

Approved for use in the following populations:

- All persons weighing 35kg (77lbs) or more

Administration:

- Initiation Injection *or*
- Optional 4-week oral lead-in
- Maintenance injections at 1 month and bimonthly thereafter

Generic Availability


- No generics available

**There is a 7-day grace period for injection administration*



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Current Forms of PrEP

	Approved for All Genders	Requires Monitoring Labs	Generic Available	Covered Under ACA Ruling	Approved for exposure from IDU
Truvada® Emtricitabine TDF	Yes	Yes	Yes	Yes	Yes
Descovy® Emtricitabine TAF	No	Yes	No	Yes	No
 Apretude® Cabotegravir	Yes	No*	No	???	Yes

Apretude® still requires regular HIV testing and continued STI testing as needed

Side Effects

Short Term

Long Term



Upset Stomach / Abdominal pain

Headache

Vomiting

Diarrhea (TAF)

Changes to Appetite (TDF—Decrease // TAF—Increase)

Fever

Irritation to Injection Site (Apretude™)

Changes to Renal Function

Changes to Liver Function

Decreases in Bone Density

Oral PrEP Regimen Management

200/300mg daily oral emtricitabine TDF

200/25mg daily oral emtricitabine TAF

Test	Initiation	Every 3 Months	Every 6 Months	Every 12 Months	Discontinuation
HIV Test	Test and screen for symptoms of acute HIV	HIV-1 RNA			HIV-1 RNA & screen for signs/ symptoms of acute HIV
Serum Creatinine Clearance	✓		If age 50 or older when eCrCl < 90 ml/ min at initiation	If age < 50 or when eCrCl > 89 ml/ min at initiation	✓
Syphilis	✓	MSM/TGW	✓		MSM/TGW
Gonorrhea/Chlamydia	✓	MSM/TGW	✓		MSM/TGW
Lipid Panel	F/TAF Only			F/TAF Only	
Hepatitis B	✓				
Hepatitis C	MSM/TGW, PWID			MSM/TGW, PWID	

Checkmark (✓) = required for all users.

Population-specific considerations denoted in text.

MSM = Men who have sex with men

TGW = Transgender women

PWID = Person who injects drugs

Heterosexual = Heterosexually active men & women



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Oral PrEP Labs

Every 3 months

HIV Testing
and medical
counseling

STI Testing
Chlamydia
Gonorrhea
Syphilis

Every 6 months

Serum Creatinine if 50 or older, or if
there is a hx of it being out of range

When starting PrEP /
Annually

Serum Creatinine
Hepatitis B panel
Hepatitis C panel



Apretude®

Cabotegravir 600mg (gluteal injection)/

Optional 30mg daily oral cabotegravir 4-week lead-in (CAB-LA)

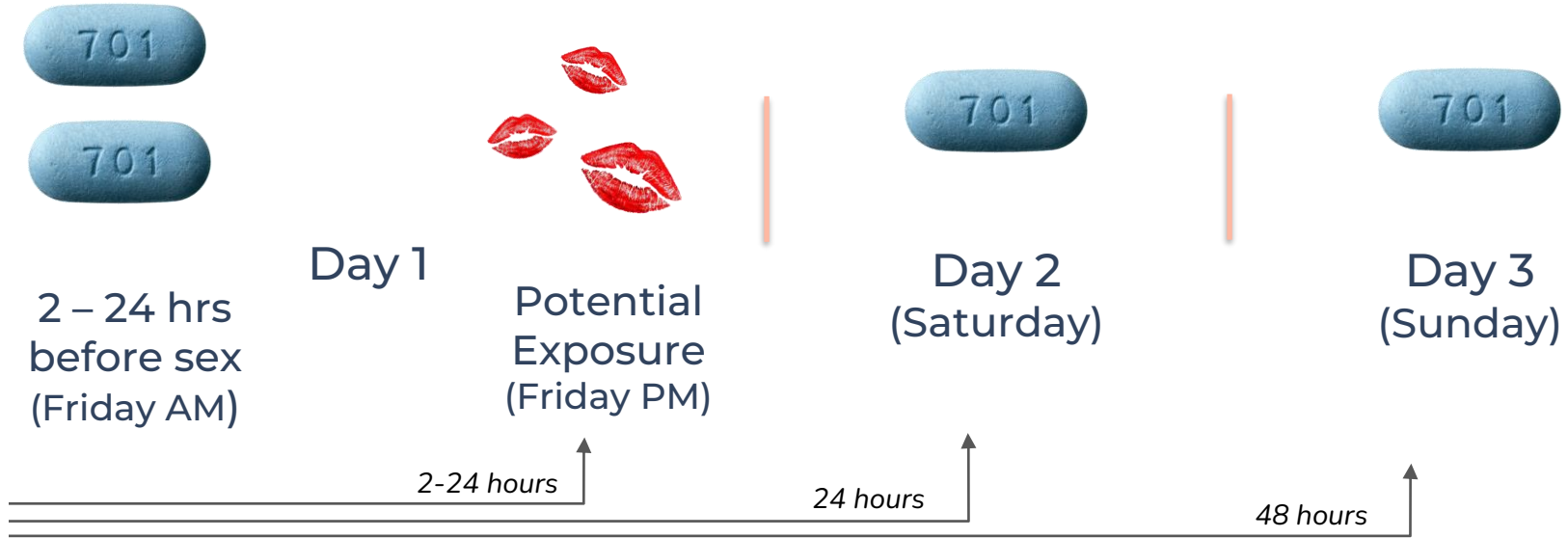
Apretude® does not require additional monitoring labs like oral PrEP however it does still require HIV testing before each injection

HIV-1 RNA testing is ideal but not always feasible

First two months are given back to back – ex Jan then Feb
Subsequent injections are every other month

Does not require refrigeration

On-Demand / 2-1-1



2-1-1 / on-demand dosing is considered “off-label” prescribing and therefore may be subject to insurance denial. It has not yet been studied specifically for injection drug use.

Currently only suggested for HIV exposure for anal sex between MSM

Barriers



PrEP Coverage Expansion



- In 2019, USPSTF gave PrEP a ‘Grade A’ rating as a preventive service. This rating triggered a **requirement that all Affordable Care Act (ACA) covered health plans provide at least one option of PrEP for HIV without patient cost-sharing.** These requirements went into effect in January of 2021.
- In July of 2021, the Federal Government issued clarifying guidance requiring these health plans to cover at **least one PrEP option AND the associated ancillary services** (office visits and recommended labs) without patient cost-sharing.

<https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-47.pdf>

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PrEP Coverage BLOCKED



On March 30, 2023, a federal district court in Fort Worth, Texas has placed a nationwide injunction on preventive services recommended by the U.S. Preventive Services Task Force (USPSTF), stating that mandating PrEP coverage is a violation religious freedom rights. This means that the mandate that requires insurers to cover USPSTF-recommended preventive services, which includes PrEP, is temporarily blocked nationwide.

Immediate Impact

- All A & B preventive care recommendations of the USPSTF made during or after 2010 are also not required to be covered by insurers
- Insurers are not required to cover HIV, STI, Hepatitis B, and Hepatitis C testing
- Insurers are not required to cover PrEP

Barriers | People aren't told about PrEP

Stigma

- May be uncomfortable disclosing sexual practices or drug use to provider

Profiling

- Services are recommended based on assumptions and often without taking a comprehensive sexual health history
- Women represent high % of new PWID but are not often told about PrEP

Location

- PrEP does not require a specialist to write the Rx, however clients are sometimes told as much
- Increased injection drug use around the country means more candidates for PrEP everywhere, including rural spaces
- “That doesn't happen here” mentality

Barriers | Possible Costs



Medical Visit—This is for the provider who writes the prescription or the health system with which they're associated. An office fee is an example.



Labs—Oral PrEP requires monitoring labs every 3 months. In addition to the cost of the tests themselves, there may also be a facility fee, a draw fee, and (from prescribers) and fee for ordering the labs.



Medication—Most insurance plans cover at least one form of PrEP, however it is uncertain if that will change with continued challenges to ACA mandate to cover preventive health services.

Barriers | Time, Cost, and More

Housing / Residency

Health and Rx insurance provide less choice

Primary Care Providers won't prescribe

Strong aversion to needles / bloodwork

Requirement for repeated labs

Insurance is confusing/ intimidating

Don't have access to their insurance policy information

Long Commute

Time and hassle to coordinate visit and labs

Restrictions at Pharmacy (e.g., location, Prior authorizations, etc.)

Stigma / Shame



On Parent's Insurance

PRIVACY



Insurance Averse



Restrictive Work Schedule

ACCESS



Live in rural areas

Case Studies



Case Study # 1:

This person has come to clinic for an annual wellness exam

- 24 years old cisgender female
- Current partner (male) is PLWHIV
- Receptive vaginal and anal sex
- Has used condoms with previous partners but doesn't currently
- Hopes to get pregnant soon

Special Considerations

- Descovy not an option
- Is her partner virally suppressed?
- Include pregnancy test with start up labs



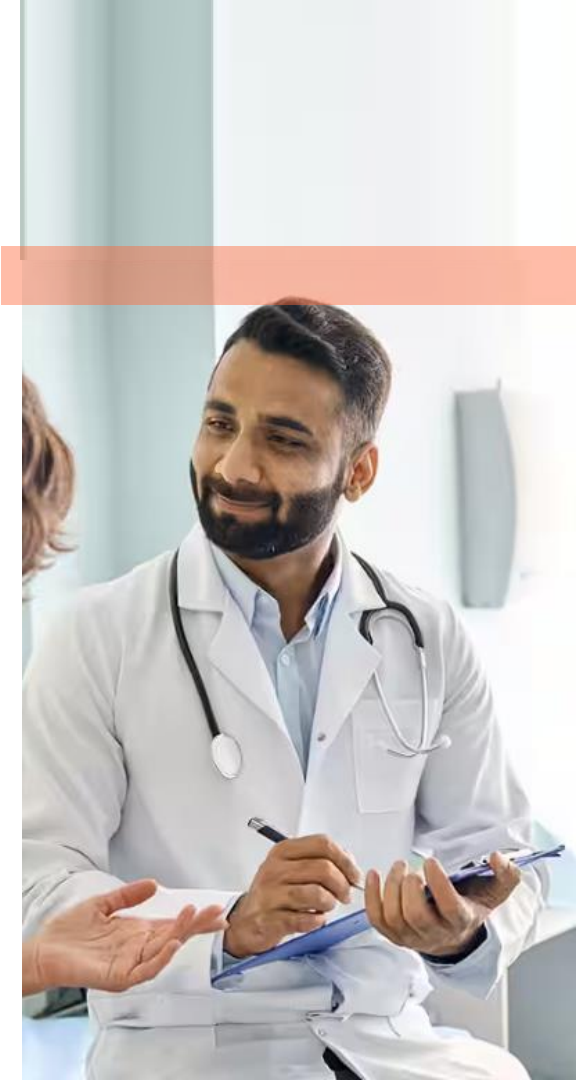
Case Study # 2:

This person asked about PrEP after one of their partners tested positive for an STI.

- 17 years old
- Identify as non-binary
- Insertive and receptive anal sex
- Uses condoms sometimes
- Will be moving to attend college soon
- On their parents insurance

Special Considerations

- Minors are not currently eligible for copay assistance
- Discuss potential privacy concerns re: insurance



Case Study # 3:

This person presents to clinic for an HPV vaccine

- 19 year old transgender woman
- Does not use condoms
- Reports oral sex and receptive vaginal sex
- Does have a history of rectal chlamydia
- Has not heard of PrEP
- Currently on gender affirming hormone therapy

Special Considerations

- Descovy not an option
- Might not feel comfortable disclosing all risk behavior
- PrEP can safely be taken with hormone therapies however 2-1-1 dosing is not recommended



Provider and Consumer Resources



Recap

- There are currently two forms of oral medication PrEP: Truvada ® (or generic) or Descovy ®
There is one long-acting injectable version: Apretude®
Any licensed prescriber can initiate and monitor PrEP.
 - The Affordable Care Act (ACA) establishes access to select preventive services for free, currently including PrEP (labs, visit, and medicine), however currently this ruling is being challenged
 - PrEP is effective for injection drug use. Because most PWID are sexually active they should be assessed for both sexual and injection behaviors that indicate HIV risk
 - Apretude® / injectable cabotegravir shows promise as it requires fewer monitoring labs and doesn't require daily adherence; however uptake thus far has been slow due to logistical challenges. It has not yet been studied for IDU. Additionally, some people in recovery may find injectable therapies triggering.
-

Considerations When Prescribing PrEP

Adherence

PrEP efficacy is highly dependent on adherence. Need 5 in 7 doses per week and not missing two days in a row. For event-based dosing i.e. 2-1-1, all four doses are needed

Time Commitments

Oral PrEP requires labs and monitoring appointments every 3 months; Apretude® requires bi-monthly injections

Housing and transportation

Insurance may require using specialty or mail order pharmacies. Are they able to receive mail? Also, are they able to regularly arrive to monitoring visits?

Privacy

Patient assistance programs exist to cover cost of medication but are not a good option for those with insurance but privacy concerns as they screen for active insurance coverage

Provider Resources

The Iowa Department of Health and Human Services offers several resources to support providers:

- Provider web page with reference to clinical guidelines
- Printed reference materials for providers (free)
- Linkage to local specialist for complex case consultation, upon request

STATE OF IOWA DEPARTMENT OF
Health AND **Human**
SERVICES



The National Clinician Consulting Center offers clinically-supported advice on PrEP for healthcare providers Monday-Friday from 8 a.m. to 7 p.m. CST.

- (855) HIV-PREP
- (855) 448-7737

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Questions?

When in doubt - reach out.

www.PrEPIowa.org



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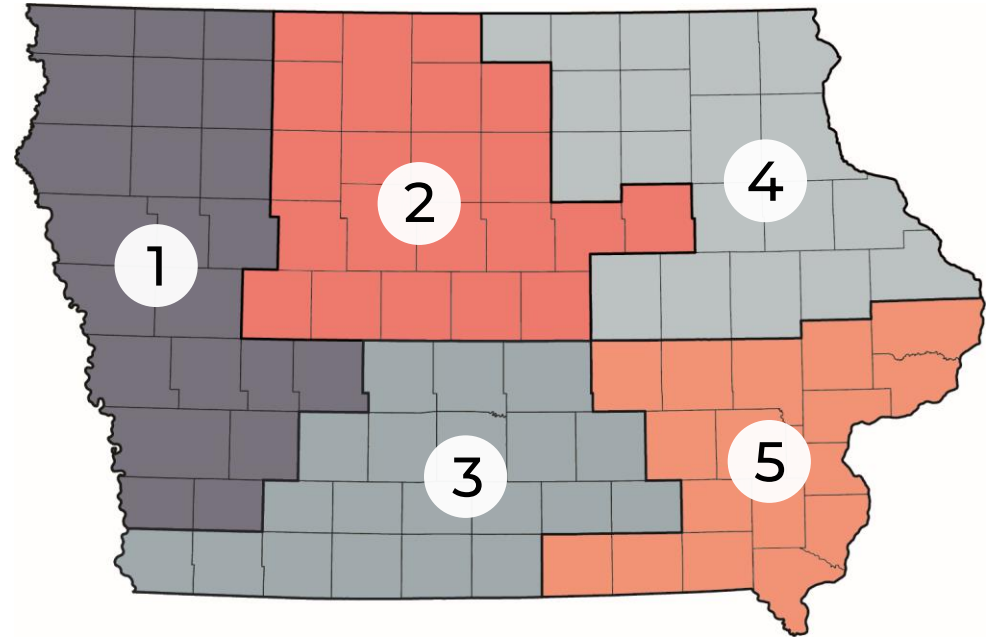
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