

PROVIDING  
INCLUSIVE CARE AND  
SERVICES FOR THE  
TRANSGENDER AND  
GENDER DIVERSE  
COMMUNITY:

---

# A PHARMACY RESOURCE GUIDE

MARCH 2021



HUMAN  
RIGHTS  
CAMPAIGN  
FOUNDATION™



**APhA**

“ I think pharmacists play an incredibly vital role in my healthcare. They help me manage my health, offer a wealth of information, and are key in my overall well-being. Walking into a pharmacy and having the people behind the counter validate my identity as a transgender man and walk me through my testosterone prescription as easily as they would penicillin makes the entire experience truly positive. Knowing my pharmacist is educated about my community and is invested in my care is invaluable. ”

—Rowan,  
a transgender man

## ABOUT THIS GUIDE

The transgender and gender diverse community faces bias and barriers in the healthcare system that contribute to health disparities compared to the general population. Efforts to improve the health of this community include increasing provider knowledge and support to enhance the patient-provider relationship and regular use of care.<sup>1</sup>

### The pharmacist's role

Transgender and gender diverse patients seek care at the pharmacy both for gender-affirming care, such as hormone therapy, as well as managing general health concerns. By creating an inclusive and welcoming pharmacy environment, pharmacists and pharmacy staff can take steps to better serve their transgender and gender diverse patients and make an impact on their health and well-being.

### About the Human Rights Campaign Foundation

The Human Rights Campaign Foundation is the educational arm of the Human Rights Campaign, the nation's largest lesbian, gay, bisexual, transgender and queer (LGBTQ) civil rights organization. The Human Rights Campaign Foundation improves the lives of LGBTQ people by working to increase understanding and encourage the adoption of LGBTQ-inclusive policies and practices. The Human Rights Campaign Foundation's Health and Aging Program oversees the Healthcare Equality Index (HEI), the Long-Term Care Equality Index (LEI) and other projects related to LGBTQ health and aging.

### Acknowledgments

We would like to thank Sam J. Miller, PharmD, RPh, who developed this guide as part of their rotations with the University of Washington School of Pharmacy Class of 2020. In addition, we would like to thank CVS Health for their assistance in reviewing and providing feedback on this resource. Finally, we would like to thank the American Pharmacists Association for sharing their expertise in pharmacy practice and patient care.

Download this guide and quick guides for each quality of a gender-affirming pharmacy at: [thehrfoundation.org/TransPharmacyGuide](https://thehrfoundation.org/TransPharmacyGuide)

<sup>1</sup>Healthy People 2020, "Lesbian, Gay, Bisexual, and Transgender Health," <https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health>

# SIX QUALITIES OF A GENDER-AFFIRMING PHARMACY



## Knowledge of key LGBTQ terms

Pg. 4-6

- Understand and reflect the language patients use to refer to themselves
- Avoid outdated or derogatory terms



## Inclusive communication

Pg. 7-9

- Ask all patients how they would like to be addressed (name & pronouns)
- Address mistakes sincerely
- Use a two-step question on forms to determine administrative gender and gender identity



## Gender-related data management

Pg. 10-12

- Incorporate preferred name and gender pronouns into profile data and processes
- If existing EHR systems cannot be updated, utilize pop-up and notes fields to document name, gender and pronoun information
- Ensure staff are trained on managing gender-related data



## Visible symbols of support

Pg. 13

- Post transgender and LGBTQ health-focused brochures and information
- Wear gender pronoun pins as part of staff uniforms
- Celebrate Pride and other LGBTQ awareness days
- Provide all-gender restrooms
- Post the pharmacy's non-discrimination policy



## Staff training

Pg. 14

- Train all staff on your pharmacy's standards
- Implement policies to reduce bias and discrimination
- Ensure all staff know transgender status is protected health information



## Knowledgeable and patient-centered care


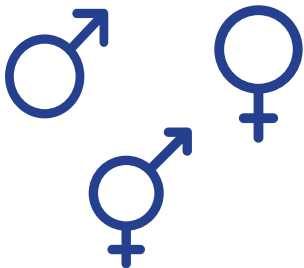


Pg. 15-17

- Review health information and guidelines for gender-affirming care
- Understand the challenges that exist for pharmacists in providing care to this community
- Serve as a resource and advocate for your patients

# QUALITY 1:

## KNOWLEDGE OF KEY LGBTQ TERMS

Understanding and reflecting the language patients use to refer to themselves is essential to being a gender-affirming pharmacy. This section covers the key terms that pharmacists and pharmacy staff should be familiar with in order to best serve transgender and gender diverse patients.

GENDER IDENTITY	SEX ASSIGNED AT BIRTH	GENDER EXPRESSION	SEXUAL ORIENTATION
<p>Your internal sense of being a man, woman, both, or another gender.</p> 	<p>Classification at birth based on external anatomy.</p> 	<p>The way you demonstrate your gender to others.</p> 	<p>Who you love and/or are attracted to in reference to your own identity.</p> 

## SEX

**Sex** refers to a set of characteristics associated with reproduction and biology that generally assign individuals into categories of “male” and “female.” Since sex can incorporate a spectrum of genotypic and phenotypic diversity but is often used as a discrete category, the term **sex assigned at birth** is preferred terminology (not “biological sex” or “natal sex”).

**AFAB** (Assigned Female at Birth) refers to someone whose sex was assigned as female when born, typically based on their external genitalia. While many transgender and non-binary people are comfortable identifying as AFAB, some prefer not to use this term to describe their experience or the experiences of others.

**AMAB** (Assigned Male at Birth) refers to someone whose sex was assigned as male when born, typically based on their external genitalia. While many transgender and non-binary people are comfortable identifying as AMAB, some prefer not to use this term to describe their experience or the experiences of others.

**Intersex** is an umbrella term used to describe those who are born with natural biological variations that differ from those classically thought to be typical to either men or women. In some cases, these traits are visible at birth, while in others they are not apparent until puberty. Some chromosomal variations of this type may not be physically apparent at all. Intersex individuals are diverse across gender identity and sexual orientation, and may or may not identify as LGBTQ. For more information, visit [interactadvocates.org](https://interactadvocates.org)

## GENDER IDENTITY

---

**Gender identity** refers to one's innermost concept of self as man, woman, a blend of both, neither or another gender – how individuals perceive themselves and what they call themselves. An individual's gender identity can be the same or different from their sex assigned at birth.

**Transgender** is an umbrella term for people whose gender identity and/or expression is different from cultural expectations based on the sex they were assigned at birth. Being transgender does not imply any specific sexual orientation; transgender people may identify as straight, gay, lesbian, bisexual or another orientation.

**Cisgender** is a term used to describe people whose gender identity aligns with the sex assigned to them at birth.

**Non-binary** is a term used to describe a person who does not identify exclusively as a man or a woman. A non-binary person may identify as being both a man and a woman, somewhere in between, or completely outside these categories. While many non-binary people also identify as transgender, not all do.

**Gender diverse** is a term used to describe people whose gender identity or expression does not conform to socially defined gender norms.

## GENDER EXPRESSION

---

**Gender expression** refers to how we present our gender to the world, and it may or may not be related to our gender identity. For example, women — whether transgender, cisgender or non-binary — may wear traditionally masculine clothing, altering their gender expression. Every individual expresses their gender differently, through behavior, clothing, haircuts, voice, and many other ways. Though gender expression is a deeply personal way of showing who we are, transgender and non-binary people often face significant barriers to expressing themselves authentically.

In order to have their gender expression align with their gender identity, many transgender and non-binary people will **transition**. Transitioning is a process that some transgender and non-binary people go through when they decide to live as their true gender, rather than the one assigned to them at birth. Transitioning can take place at different speeds, with different intensities and in different ways.

## GENDER DYSPHORIA AND GENDER INCONGRUENCE

---

**Gender dysphoria** is a billable diagnostic code in the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5), published in 2013. **Gender incongruence** is a billable diagnostic code in the International Statistical Classification of Diseases and Related Health Problems (ICD-11). These codes replaced the “Gender Identity Disorder” code that was used in earlier versions of both the DSM and ICD, which many felt contributed to stigmatization of transgender and gender diverse people.

Gender dysphoria and incongruence are not the same as not conforming to societal expectations of gender expression. Not all transgender or non-binary people will experience gender dysphoria or incongruence; however, these are the billing codes that are most frequently used for gender-related treatments. Treatments for gender dysphoria or incongruence are individualized and patient-specific; some patients may not wish to pursue a social or physical transition for a variety of reasons. Patients who seek to transition but are denied access to gender-affirming care, however, have a higher risk of mental health impacts and health disparities.

Understanding  
and reflecting  
the language  
patients use  
to refer to  
themselves is  
essential to  
being a  
gender-affirming  
pharmacy.

## Gender dysphoria (DSM-5)<sup>2</sup>

**A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least two of the following:**

1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics.
2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender.
3. A strong desire for the primary and/or secondary sex characteristics of the other gender.
4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
5. A strong desire to be treated as the other/alternative gender (or some alternative gender different from one's assigned gender).
6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).

**B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.**

---

## Gender incongruence (ICD-11)<sup>3</sup>

**A. A marked and persistent incongruence between the gender felt or experienced and the gender assigned to birth. This incongruity is manifested in at least two of the following criteria:**

1. Strong dislike or disagreement with primary or secondary sexual characteristics due to incongruence with the experienced gender.
2. Strong desire to get rid of some of those sexual characteristics due to the incongruence with the experienced gender.
3. Strong desire to have the primary or secondary sexual characteristics of the experienced gender.
4. Strong desire to be treated and accepted as a person of the felt gender.

## SEXUAL ORIENTATION

**Sexual orientation** refers to an individual's inherent or immutable enduring emotional, romantic or sexual attraction to other people. Sexual orientation is independent of gender identity.

---

<sup>2</sup>Diagnostic and Statistical Manual of Mental Disorders (DSM-5), Fifth edition. American Psychiatric Association. 2013.

<sup>3</sup>M. Fernández Rodríguez et al. "Gender Incongruence is No Longer a Mental Disorder," Journal of Mental Health and Clinical Psychology, September 18, 2018.



# QUALITY 2:

## INCLUSIVE COMMUNICATION

The language pharmacies use to communicate with patients can affect how safe, included and welcome they feel. This section includes strategies that pharmacists and pharmacy staff can use to ensure that all communications with transgender and gender diverse patients are respectful and inclusive.

### AVOID GENDERED TERMS

---

Though pharmacists and pharmacy staff often use terms like ma'am and sir to show respect to patients, these terms make assumptions about patient gender and should be avoided. Similarly, when calling a patient by name in a waiting room or over the intercom, consider using just their last name. This avoids the use of gendered terms like Mrs., Ms., or Mr., and the potential of calling a patient by their non-preferred first name.

### ASK ALL PATIENTS FOR GENDER AND PRONOUN INFORMATION

---

Using the correct pronouns to refer to your patients is an important part of showing respect and creating a safe and welcoming pharmacy. It is not possible to know which pronouns someone uses simply by their appearance, and assuming can do more harm than good. The best thing to do is ask. There are many ways to do this, such as:

- What pronouns do you use?
- My name is Sam and my pronouns are they and them. How about you?
- How do you like to be addressed?

If a patient declines to answer, politely accept. Let them know that all patients are being asked so you can provide optimal care.

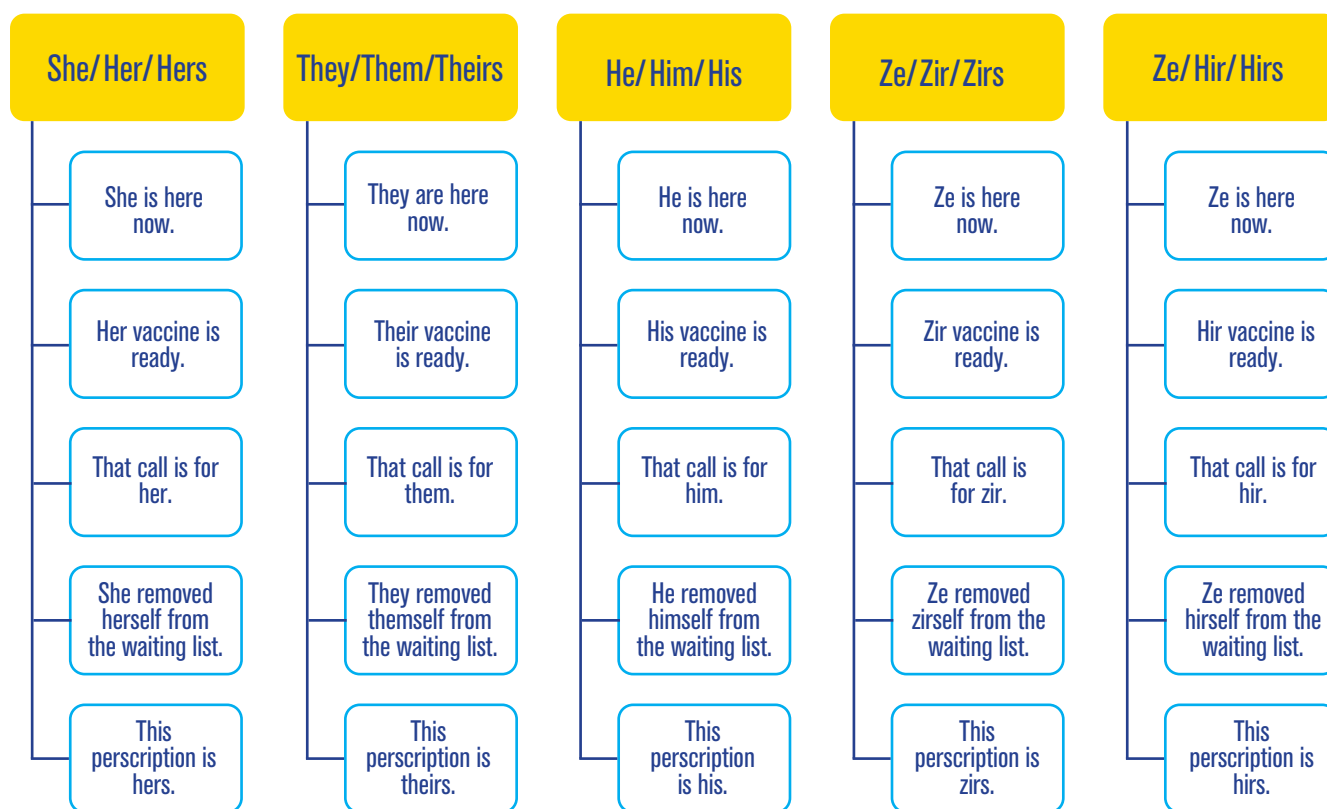
### PRACTICE USING NEW PRONOUNS<sup>4</sup>

---

It can be difficult to use pronouns that are new to you. The best solution is to practice! One way to do this is by reading a children's book and replacing familiar pronouns with those that are unfamiliar to you. The graphic shows some common pronouns and how they are used in the pharmacy context.

---

<sup>4</sup>The Human Rights Campaign Foundation, "All Children-All Families: Pronouns 101," <https://www.thehrfoundation.org/professional-resources/all-children-all-families-pronouns-101>



## ENSURE WRITTEN FORMS ARE INCLUSIVE

The way pharmacies communicate to patients in writing, often through forms, has an impact on the extent to which they feel safe, included and welcome. Include pronouns on your forms and utilize a two-step question to gather the patient's name (ask the name they go by and their legal name) and gender (ask their gender identity and their sex assigned at birth). If possible, allow patients to write out their gender identity rather than offering predetermined categories. You can also provide written materials at pharmacy windows to help patients communicate their gender and pronoun information to providers.

## PROVIDE OPPORTUNITIES TO UPDATE PATIENT INFORMATION

A person's pronouns may change over time. In the same way that patient information such as allergies is continually updated, allow patients to update their name, gender and pronoun information. You can do this by including name, gender and pronoun fields on all forms. You can also listen for "pink flags" from patients when asked for their identifying information (e.g., "my file is listed under \_\_\_\_"). This may prompt you to ask if the patient uses a different name and/or pronouns than what you have on file.



## WHAT DOES IT MEAN TO MISGENDER SOMEONE?

Misgendering is referring to someone, intentionally or unintentionally, as a gender other than the one with which that person identifies. Persistent or unaddressed misgendering can harm the relationship of trust between you and your patient and make them feel unwelcome at your pharmacy.

*For example: Misgendering occurs when a patient who identifies as a woman is referred to using the terms like “sir,” “he,” “man” or “gentleman.”*

## MANAGING MISTAKES:

If you misgender someone and notice right away, the best course of action is to quickly apologize and correct your mistake. This models accurate and respectful use of pronouns for others who may be present and shows your commitment to addressing the error.

***“His prescription is - I’m sorry - their prescription is ready.”***

If the mistake is realized later, addressing it with a brief apology is the best practice. It is important to center the patient and not over-apologize; this can shift the focus from addressing the mistake to the patient feeling pressured to reassure you.

***“I’m sorry that I used the wrong pronoun the last time you picked up your prescriptions. I’ll be more careful next time.”***

# QUALITY 3: GENDER-RELATED DATA MANAGEMENT

Making gender-related data accessible to all pharmacy staff can facilitate respectful communication with transgender and gender diverse patients. However, managing identity information can be difficult in many pharmacy EHR systems, which are often more limited than those of large healthcare systems. Additionally, the lack of standardization in how different pharmacies manage identity information can create challenges. This section includes recommendations on how to advocate for software updates to improve gender-related data management, as well as strategies to triage existing limitations.

The image below shows one way to display preferred name and pronoun information in a pharmacy EHR system.

Jones, Michael\* E02/17/1992N\*(they/them)

Patient InfoAllergies/PMHThird PartyRx/TxNotes

Details

Legal NameSarah E Jones

Pref NameMichael

Date of Birth02/17/1992

Gender IDNon-binary (N)

PronounsThey/them/theirs

Admn GenderFemale

Contact

Address723 Rainbow Dr NW  
AmesIA50014

Phone999-999-9999

Email99999@999.com

Pref ContactPhone

Auto-Refill

Rx Image

Washington Clinic(999) 999-9999

NameMichael JonesDOB02/17/92

Address723 Rainbow Dr NWDate10/01/19

Omeprazole 20 mg caps

#301 po qd

Refills: 11

Dispense as Written

Substitution Permitted

Insurance

CarrierHusky Scripts

CardholderSarah Jones

ID #MJB07141984

Rx GroupSD040103

Admn GenderFemale

Notes

NSCNo

PCPDr. Sam Smith

Sex Asgn at BirthFemale

Save

# RECOMMENDATIONS FOR UPDATING EHR SYSTEMS

## 1. Utilize a preferred name field that is separate from legal name and searchable.

This prevents identity mismatch, which could lead to duplicate patient profiles, by filtering patient profiles by either legal name or preferred name.

Details	Legal Name	Sarah E Jones
	Pref Name	Michael
	Date of Birth	02/17/1992
	Gender ID	Non-binary (N)
	Pronouns	They/them/theirs
	Admn Gender	Female

Washington Clinic (999) 999-9999

Name	Michael Jones	DOB	02/17/92
Address	723 Rainbow Dr NW	Date	10/01/19

Omeprazole 20 mg caps

#30 1 po qd

Refills: 11

Dispense as Written Substitution Permitted

**Note:** This feature is useful for all patients, not just transgender and gender diverse patients. For example: If a patient whose legal name is “George Joseph Smith” was sent a prescription for “Joe Smith” from his prescriber, a duplicate profile could be created and impede a comprehensive drug utilization review.

## 2. Utilize a field for administrative gender (the gender listed on the patient's insurance).

This allows for streamlined communication with other entities and prevents billing errors. It also reduces opportunities for mistakes when addressing your patients.

Insurance	Carrier	Husky Scripts
	Cardholder	Sarah Jones
	ID #	MJB07141984
	Rx Group	SD040103
	Admn Gender	Female

Husky Scripts

Member: SARAH JONES

ID: MJB07141984

Grp: SD040103

BIN: 999999

PCN: TPMO

Rx

Incorporate information from preferred name and pronouns into the profile header, using an asterisk to identify differences from the legal name and administrative gender.<sup>5</sup> If possible at your site, also use the preferred name in written communications with your patient (e.g., prescriptions).

Jones, Michael\* E 02/17/1992 N\* (they/them)



<sup>5</sup>Madeline B. Deutsch and David Buchholz, “Electronic Health Records and Transgender Patients—Practical Recommendations for the Collection of Gender Identity Data.” Journal of General Internal Medicine, June 30, 2015 (pp. 843-847).

# STRATEGIES FOR TRIAGING EXISTING LIMITATIONS

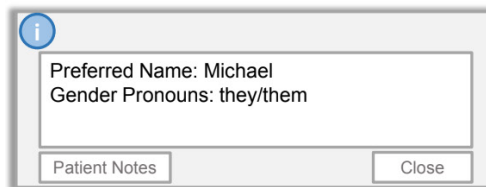
1. If the addition of separate fields is not possible at your site, utilize pop-up alerts and notes fields to document patient name, gender and pronoun information.

If possible, use the patient's preferred name and store the legal name in the notes field. This prevents routine misnaming of your patient by staff and automated systems.

**Note:** This is comparable to when an insurance company has the incorrect birth date on file – prescriptions must be processed using the incorrect birth date and the correct birth date is stored in the notes field.

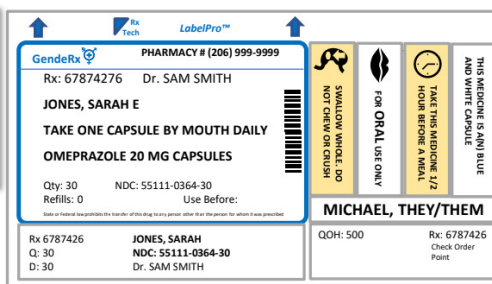
**Note:** Many insurance companies verify eligibility using the patient's ID number, birth date, administrative gender and other identifiers rather than the exact spelling of the first name. If an insurance rejection occurs due to the patient's preferred name, explain this to the patient.

## Pop-up Alert



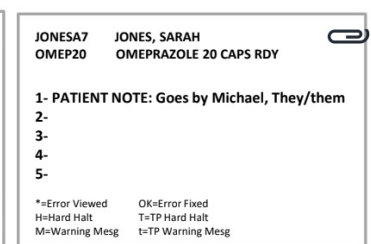
A pop-up alert dialog box with a light gray background. It has a blue information icon in the top left corner. The main text area contains "Preferred Name: Michael" and "Gender Pronouns: they/them". At the bottom, there are two buttons: "Patient Notes" and "Close".

## Prescription label (Sticker with name and pronouns)



A prescription label for Omeprazole 20 MG capsules. It includes the pharmacy name "GenderRx PHARMACY # (206) 999-9999", the pharmacist "Dr. SAM SMITH", and the patient's name "JONES, SARAH E". The label also contains the medication name "OMEPRAZOLE 20 MG CAPSULES", the quantity "Qty: 30", and the NDC "NDC: 55111-0364-30". A section at the bottom of the label displays the patient's preferred name and pronouns: "MICHAEL, THEY/THEM".

## Printable patient note (clip on bag)



A printable patient note template. It includes the patient's name "JONES, SARAH" and the medication "OMEPRAZOLE 20 CAPS RDX". The note contains a list of instructions: "1- PATIENT NOTE: Goes by Michael, They/them", "2-", "3-", "4-", and "5-". At the bottom, there are two columns of error messages: "Error Viewed", "Hard Halt", and "Warning Mesg" on the left; "Error Fixed", "TP Hard Halt", and "TP Warning Mesg" on the right.

2. Use acronyms and abbreviations to efficiently use limited notes space, for example:

**AFAB** (Assigned Female At Birth)/**AMAB** (Assigned Male At Birth)

**PN** (Preferred Name)

**GP** (Gender Pronouns)

3. List both the patient's preferred name and legal name in the name field.

**Note:** This has a high risk of outing the patient to others who may or may not be providing care to them. Always explain to the patient how their information can be accessed before storing gender-related information. Since someone's transgender status is private health information, these decisions should be made in collaboration with the patient. Consider adapting the following language: "If you would like, we have the ability to add a preferred name and gender pronouns to your patient record. This will help staff to know how to refer to you respectfully in person and over the phone. However, this information may be accessible to your other healthcare providers when we communicate with them about your medications. Let's talk about some options."

## Legal and Preferred Name in Name Field



A patient information field with a light gray background. It contains the text "Jones, Sarah 'Michael' 02/17/1992 F". Below the text are five tabs: "Patient Info", "Allergies/PMH", "Third Party", "Rx/Tx", and "Notes".

4. Train all pharmacy staff on how to manage gender-related data at your site. This creates a consistent, positive and supportive experience for your patients.

## QUALITY 4:

# VISIBLE SYMBOLS OF SUPPORT



Visible symbols of support for transgender and LGBTQ people can make patients feel welcome and safe in your pharmacy. This section includes actions pharmacies and pharmacist staff can take to show support.

### Wear pronoun pins

- Provide pins for pharmacy staff to wear that say, “My pronouns are \_\_\_\_” as part of their work uniform.



### Post transgender and LGBTQ health-focused brochures and information

- Obtain informational brochures from local LGBTQ centers and make them easily accessible to patients.
- Post flyers for LGBTQ community events.
- Provide a self-injection guide tailored toward transgender patients.



### Participate in community outreach and LGBTQ awareness days

- Celebrate Pride by marching, tabling or decorating the pharmacy.
- Sign up to participate in LGBTQ health fairs and provide point of care services or health information.
- Host an HIV testing day at your pharmacy or in your community.



### Ensure access to restrooms that align with patients' gender identity

- If possible, provide access to an all-gender restroom.
- If an all-gender restroom is not available, post clear signage indicating that patients may use the restroom that aligns with their gender identity.



### Post your inclusive non-discrimination policy

- If your non-discrimination policy does not already include the terms “sexual orientation” and “gender identity and expression,” advocate for changes. Sample non-discrimination policies are available on the [HRC Website](https://www.thehrcfoundation.org/professional-resources/patient-non-discrimination).<sup>6</sup>
- Share your non-discrimination policy with patients by posting it visibly at your site.

<sup>6</sup>The Human Rights Campaign Foundation, “Patient Non-Discrimination Sample Policies & Statements,” [www.thehrcfoundation.org/professional-resources/patient-non-discrimination](https://www.thehrcfoundation.org/professional-resources/patient-non-discrimination)

# QUALITY 5:

## STAFF TRAINING

A well-trained staff is an essential quality of any gender-affirming pharmacy. Effective training can increase the likelihood that patients feel welcome, safe and included in your pharmacy. This section includes considerations for pharmacies designing training plans to improve the experience of transgender and gender diverse patients.

### **Train all staff**

---

Since patients interact with the entire pharmacy team when they seek care, train all staff on the pharmacy's standards. Training should occur at onboarding and at regular intervals. In addition to training, pharmacies should provide all staff with access to additional educational resources and transgender health guidelines.

### **Implement policies to reduce discrimination and bias**

---

It is important that all staff are aware of company diversity and inclusion policies and know how to report an incident of discrimination.

Some policies that can help reduce discrimination and bias include requiring pharmacy staff to:

- Use only the name and pronouns the patient says they currently use, even when they are not there, to discourage bias.
- Show respect for transgender and gender diverse patients by showing genuine engagement and not speaking in a way that is demeaning or derogatory.
- Ask themselves the following before requesting transition-related information from a patient: "Is it necessary to the care I'm providing, or am I just curious?"

### **Ensure gender-related data is protected**

---

Ensure all pharmacy staff understand that patient transgender status is protected health information and can only be disclosed to those providing care to the patient.



The left side of the page features a vertical decorative bar with a gradient from light blue at the top to pink at the bottom. It contains faint, white line-art icons including male and female gender symbols, a heart, a pill bottle, a syringe, and a line graph with data points.

## QUALITY 6: KNOWLEDGEABLE AND PATIENT-CENTERED CARE

Providing knowledgeable and patient-centered care to the transgender and gender diverse community requires an understanding of gender health guidelines. This section highlights some key considerations and provides links to online guidelines that can serve as ongoing resources.

### **Considerations for hormone therapy**

Many transgender and gender diverse patients come to the pharmacy for hormone therapy as part of their gender transition. Information about hormone therapy in transgender patients is missing from many clinical resource tools that you may use in practice. A list of online clinical guidelines at the end of this section will help you counsel your patients on what to expect from their hormone therapy. These resources will also help you determine if there are interactions with other medications or conditions that warrant additional monitoring.

For injectable medications, there are multiple formulations available. Though rare, a patient may be allergic to the oil used to suspend their medication. Make sure your patient understands the signs of an allergic reaction and help facilitate communication with their prescriber if they need an alternate therapy or route of administration.

### **ACCESS TO HORMONE THERAPY**

There are certain situations that can create barriers to patients accessing hormone therapy. Insurance challenges, transitions of care or manufacturing shortages can result in interruptions to hormone therapy. These interruptions may result in negative physical and psychological consequences for patients. Be proactive when challenges arise by communicating with the patient and their provider. If products are on backorder, consider reaching out to other pharmacies in the area or exploring alternate therapeutic options with the patient's provider.

### **USP 797 AND DAYS SUPPLY CONSIDERATIONS**

Recent updates to standards regarding sterile medications have created a difficult balancing act between regulatory compliance, patient safety and access. Inconsistent management between pharmacies can create confusion for pharmacists, patients, and other providers.



## EXPIRATION DATE VS. BEYOND-USE-DATE<sup>7</sup>

The **expiration date** is the date after which an unopened multi-dose vial should not be used. This is designated by the manufacturer on the medication packaging.

The **beyond-use-date** (BUD) is the date after which an opened multi-dose vial should not be used. The BUD should never exceed the expiration date specified by the manufacturer.

The United States Pharmacopeia recommends the following beyond-use-date guidelines for multi-dose vials of sterile pharmaceuticals:<sup>8</sup>

- If a multi-dose vial has been opened or accessed (e.g., needle-punctured), it should be dated and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial.
- If a multi-dose vial has not been opened or accessed (e.g., needle-punctured), it should be discarded according to the manufacturer's expiration date.

## SINGLE-DOSE OR MULTI-DOSE VIAL

Even if an injectable medication contains a preservative, it may be labeled as a single-dose vial and should only be accessed one time to administer medication. This will have an impact on the days supply for the medication you are dispensing.

RX only  
1mL  
Single-dose vial

For example: If a patient injects 0.5 mL once weekly and their 1 mL vial is labeled as an SDV, this vial would have a 7-day supply and any remainder after 1 dose should be discarded.

ONE 10mL  
STERILE  
MULTIPLE-  
DOSE VIAL

If you have questions about medication labeling and how it impacts patient use, reach out to the manufacturer.

5 mL  
MULTIPLE-  
DOSE VIAL

<sup>7</sup>Centers for Disease Control and Prevention, "Questions about Multi-dose vials," June 20, 2019, [www.cdc.gov/injectionsafety/providers/provider\\_faqs\\_multivials.html](http://www.cdc.gov/injectionsafety/providers/provider_faqs_multivials.html)

<sup>8</sup>The United States Pharmacopeial Convention, "United States Pharmacopeia General Chapter 797, Pharmaceutical Compounding – Sterile Preparations," 2008.

## BEST PRACTICES FOR DISPENSING AND BILLING

- Reach out to your supervisor or district manager for your company's policies and practices when dispensing and billing for sterile injectable medications.
- Obtain an Rx for injection supplies to allow you to bill the patient's insurance. Combining Rx's may reduce cost for patients.
- Consider that injectable controlled substances such as testosterone may not be overfilled to accommodate minor self-administration errors. Patients may not be able to administer two 0.5 mL doses in full from a 1 mL vial, even with good technique.
- Be transparent with your patients about the regulatory challenges that accompany sterile injectable medications. Do not pass blame to their insurance company or prescriber. If a large vial MDV is dispensed, such as 10 mL, document that there has been a conversation about USP 797's BUD regulations with the patient and the prescriber.
- Prioritize patient safety and access to their medications. If regulatory requirements cause an increase in cost for patients, help connect them with coupon cards or financial assistance, or work with their prescriber to find a solution.
- When challenges arise, work with the patient and their prescriber to find a mutually agreeable solution.

## NEEDLE SIZING AND INJECTION TECHNIQUE COUNSELING

<b>Luer-Lok Syringe</b> 1mL	
<b>Drawing Needle</b> 18-23G 1-1 1/2 inch	
<b>Admin Needle (IM)</b> 22-25G 1-1 1/2 inch	<b>Admin Needle (SQ)</b> 25G or smaller 5/8 - 1 inch



Ensure you are providing appropriate counseling for the injection method of choice. Though manufacturers often list “for intramuscular use only” on medication packaging, there has been a recent shift to administer hormones subcutaneously that is supported both by pharmacokinetic data and patient experience.<sup>9,10</sup> Patients or their providers may have a specific preference for subcutaneous or intramuscular injection.

- If patients prefer smaller gauges, inform them that they will require a longer injection time. Counsel patients to press firmly on the plunger but inject slowly to avoid irritation at the injection site due to the increased force of the medication entering the tissue. (If 1 mL syringes are not available, discuss using 3 mL syringes with the patient. Some patients may prefer 3 mL syringes).
- Provide a patient-friendly handout, such as the [Fenway Health Injection Guide](#)<sup>11</sup>
- If possible at your site, offer medication administration services for those who have needle anxiety or technique concerns.

<sup>9</sup>David M. Wilson, et al. “Pharmacokinetics, safety, and patient acceptability of subcutaneous versus intramuscular testosterone injection for gender-affirming therapy: A pilot study,” *American Journal of Health-System Pharmacy*, March 15, 2018 (pp. 351–358). Available at: [doi.org/10.2146/ajhp170160](https://doi.org/10.2146/ajhp170160)

<sup>10</sup>Daniel I. Spratt, et al. “Subcutaneous Injection of Testosterone Is an Effective and Preferred Alternative to Intramuscular Injection: Demonstration in Female-to-Male Transgender Patients,” *The Journal of Clinical Endocrinology & Metabolism*, July 1, 2017 (pp. 2349–2355). Available at: [doi.org/10.1210/je.2017-00359](https://doi.org/10.1210/je.2017-00359)

<sup>11</sup>Fenway Health, “Transgender Health Injection Guide,” [fenwayhealth.org/wp-content/uploads/MG-6\\_TransHealth\\_InjectionGuide.pdf](https://fenwayhealth.org/wp-content/uploads/MG-6_TransHealth_InjectionGuide.pdf)

# FINAL THOUGHTS

**All pharmacists and pharmacy staff can be change agents! Never underestimate the power of your own voice when you identify barriers to providing equitable care to your transgender and gender diverse patients.**

Connect with resource centers in your community for transgender and gender diverse people, as well as provider groups and associations. These organizations can help you identify providers and community services for patient referrals.

## ONLINE GENDER HEALTH GUIDELINES AND OTHER RESOURCES

GUIDELINE	ORGANIZATION	DESCRIPTION
Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People	<b>UCSF Transgender Care</b> <a href="http://www.transcare.ucsf.edu/guidelines">www.transcare.ucsf.edu/guidelines</a>	Guidelines designed for implementation in every day evidence-based primary care  Includes a broad range of topics such as laboratory value interpretation, cardiovascular health, and fertility options
WPATH Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People	<b>World Professional Association for Transgender Health (WPATH)</b> <a href="http://www.wpath.org/publications/soc">www.wpath.org/publications/soc</a>	A professional consensus about psychiatric, psychological, medical and surgical management of care  Physician/health care provider protocols for diagnosis and assessment
Endocrine Treatment of Gender-Dysphoric/ Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline	<b>Endocrine Society</b> <a href="http://www.endocrine.org/clinical-practice-guidelines/gender-dysphoria-gender-incongruence">www.endocrine.org/clinical-practice-guidelines/gender-dysphoria-gender-incongruence</a>	Detailed recommendations and suggestions to maximize benefit and minimize risk when caring for individuals diagnosed with gender dysphoria  Hormone regimens, expected effects, and considerations for the multidisciplinary healthcare team

HEALTH EDUCATION AND PRACTICE	DESCRIPTION
The National LGBTQIA+ Health Education Center	Online educational programs, resources, and publications to optimize health care for LGBTQ people <a href="http://www.lgbtqihealtheducation.org">www.lgbtqihealtheducation.org</a>
UCSF Center of Excellence for Transgender Health	Online education courses, toolkits, and the biennial National Transgender Health Summit <a href="http://www.prevention.ucsf.edu/transhealth/education">www.prevention.ucsf.edu/transhealth/education</a>
The Q Card Project	A tool to facilitate patient-provider communication about SOGI and other health information <a href="http://www.qcardproject.com/">www.qcardproject.com/</a>

CULTURE AND UNDERSTANDING	DESCRIPTION
National Center for Transgender Equality: “About Transgender People” Resource Hub	Educational materials on a variety of cultural, legal, and advocacy topics <a href="http://www.transequality.org/about-transgender">www.transequality.org/about-transgender</a>
The Lavender Effect Oral History Projects	Video testimonies from members of the LGBTQ community and supportive allies who were integral participants or witnesses to a historic event or movement <a href="http://www.thelavendereffect.org/projects/ohp/">www.thelavendereffect.org/projects/ohp/</a>

ADMINISTRATION AND POLICY	DESCRIPTION
HRC Foundation Patient Non-Discrimination Sample Policies & Statements	Sample patient non-discrimination policies that include sexual orientation and gender identity or expression <a href="https://www.thehrcfoundation.org/professional-resources/patient-non-discrimination">https://www.thehrcfoundation.org/professional-resources/patient-non-discrimination</a>
Creating Equal Access to Quality Health Care for Transgender Patients: Transgender-Affirming Hospital Policies	Publication that provides guidance to hospitals on best practices for care of transgender patients <a href="http://www.hrc.org/resources/transgender-affirming-hospital-policies">www.hrc.org/resources/transgender-affirming-hospital-policies</a>