



2022 NCCMP Annual Conference

Healthcare Regulatory Update

September 20, 2022 Kathryn Bakich

| Agenda

COVID-19 Challenges

No Surprises Act Update

Transparency Requirements

Nondiscrimination rules

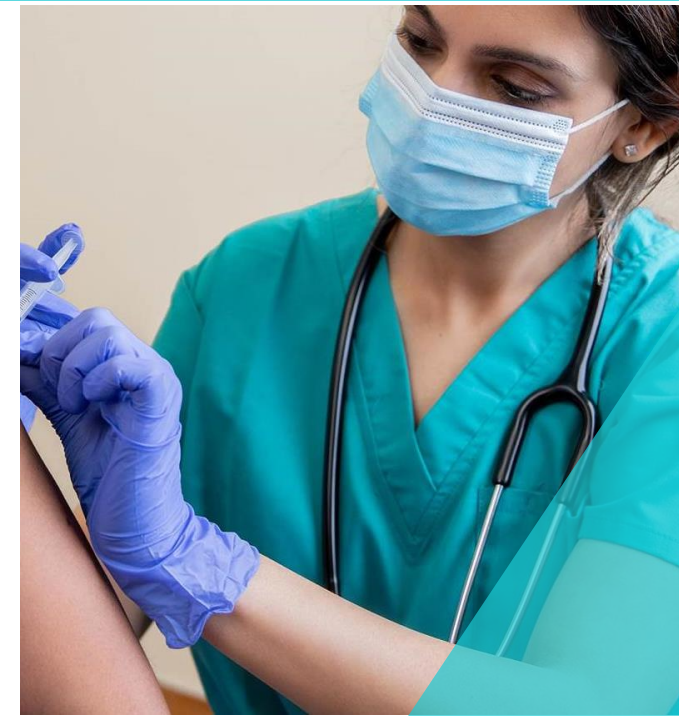
Hearing Aids



COVID-19 Challenges

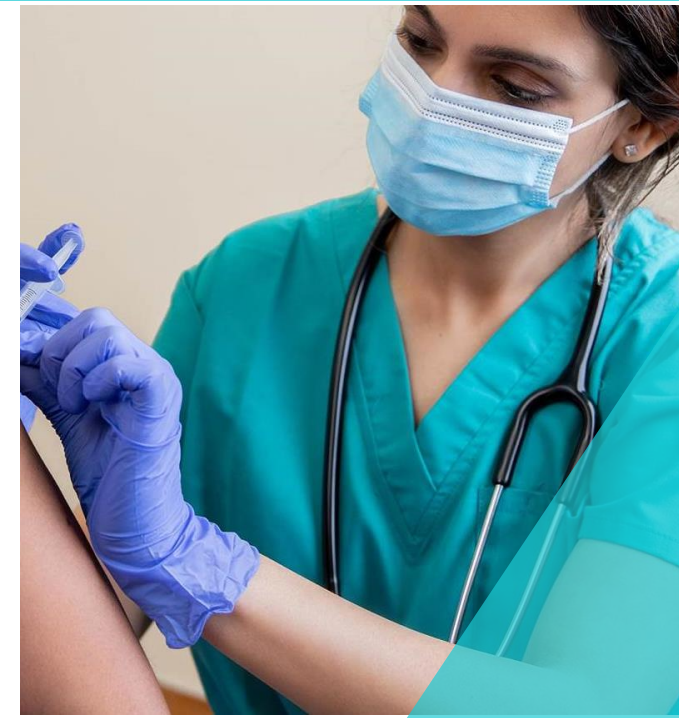
COVID-19 Challenges

- The COVID-19 Public Health Emergency (PHE) has been extended to October 2022
- Likely to be extended at least once more, through January 2023
- Department of Health and Human Services (HHS) will give at least 60 days' notice of expiration
- Requirements that sunset with the expiration of the PHE include paying for COVID tests without cost-sharing, covering OTC COVID tests with safe harbors, and non-grandfathered plans paying for vaccines in and out of network



COVID-19 Challenges

- On August 30, 2022, HHS [announced](#) that:
 - More than three in four Americans have received at least one COVID-19 vaccine shot; therapeutics are available within 5 miles of 90% of Americans; and testing is readily accessible
- Federal government will transition responsibility to the private sector to pay for:
 - Vaccines (early 2023)
 - Therapeutics, including Lagevrio (early 2023) and Paxlovid (mid-2023)



Group Health Plan Requirements to Reimburse COVID-19 Tests and Vaccines (1)

<p>Items and Services relating to COVID-19 testing or diagnosis: In-Vitro diagnostic tests that are</p> <ol style="list-style-type: none"> 1. Approved, cleared, or authorized by the FDA; 2. Developer has requested or intends to request Emergency Use Authorization (EUA); 3. Developed in and authorized by certain States; or 4. Other tests determined by HHS. 	<p>Payable without cost-sharing, prior authorization, or medical management requirements</p> <p>Includes serological tests that are used to detect antibodies against the virus</p>	<p>March 18, 2020, through the Public Emergency Period (FFCRA)</p> <p>Most recent extension of PHE was January 14, 2022, for an additional 90 days</p>
<p>Items or services furnished during a provider “visit” that results in an order for, or administration of, a COVID-10 diagnostic test.</p>	<p>Payable without cost-sharing, prior authorization, or medical management requirements</p>	<p>March 18, 2020, through the Public Emergency Period (FFCRA)</p>
<p>Payments to contracted/non-contracted providers</p>	<p>Pay the negotiated rate or cash price listed on the provider’s public website</p>	<p>March 27, 2020, through the Public Emergency Period (CARES Act)</p>
<p>COVID-19 tests intended for at-home testing, when ordered by an attending health care provider who has determined that the test is medical appropriate</p>	<p>Payable without cost-sharing, prior authorization, or medical management requirements</p>	<p>June 2020 through January 14, 2022 (FAQ 43)</p>

Group Health Plan Requirements to Reimburse COVID-19 Tests and Vaccines (2)

<p>Over-the-Counter (OTC) COVID-19 tests, including tests obtained without the involvement of a health care provider;</p> <p>Test must be approved or authorized to be self-administered and self-read without the involvement of a health care provider</p>	<p>Payable without cost-sharing, prior authorization, or medical management requirements;</p> <p>Safe harbor permits limit to 8 tests per month per person</p> <p>Plans may not limit test reimbursement to only participating providers.</p> <p>Safe harbor permits plans that have a direct coverage relationship through a participating pharmacy network and a direct-to-consumer shipping program to limit reimbursement for tests obtained from non-participating retailers to no less than the actual price or \$12 per test, whichever is lower.</p>	<p>January 15, 2022, through Public Emergency Period (FAQ 51, 52)</p>
<p>Testing, (including OTC tests) for employment purposes</p>	<p>Not payable</p>	<p>FAQ 44, FAQ 51</p>
<p>Section 213(d) medical expenses include OTC COVID-19 tests, masks, hand sanitizers, wipes, and PPE</p>	<p>Payable from FSA, HRA, HSA; However, an individual cannot be reimbursed more than once for the same expense</p>	<p>IRS Guidance, FAQ 52</p>

Group Health Plan Requirements to Reimburse COVID-19 Tests and Vaccines (3)

Vaccines and Treatment

<p>COVID-19-related preventive services recommended by the USPSTF or the ACIP must be covered by non-grandfathered group health plans within 15 business days after any such recommendation is made.</p> <p>Later guidance clarified that plans are required to cover any COVID-19 vaccine authorized under an EUA or BLA immediately upon being approved</p>	<p>Non-GF plans must pay at negotiated rate or reasonable amount (Medicare rates are reasonable)</p>	<p>ACA requires coverage of vaccines in-network; CARES Act requires coverage OON through the Public Emergency Period</p>
<p>Treatment for COVID-19</p>	<p>There is no federal requirement to cover treatment</p>	<p>NA</p>



No Surprises Act Update

No Surprises Act

Enacted December 27, 2020, as part of the Consolidated Appropriations Act, 2021, Public Law 116-260

Applies to most group health plans and insurers, including grandfathered plans

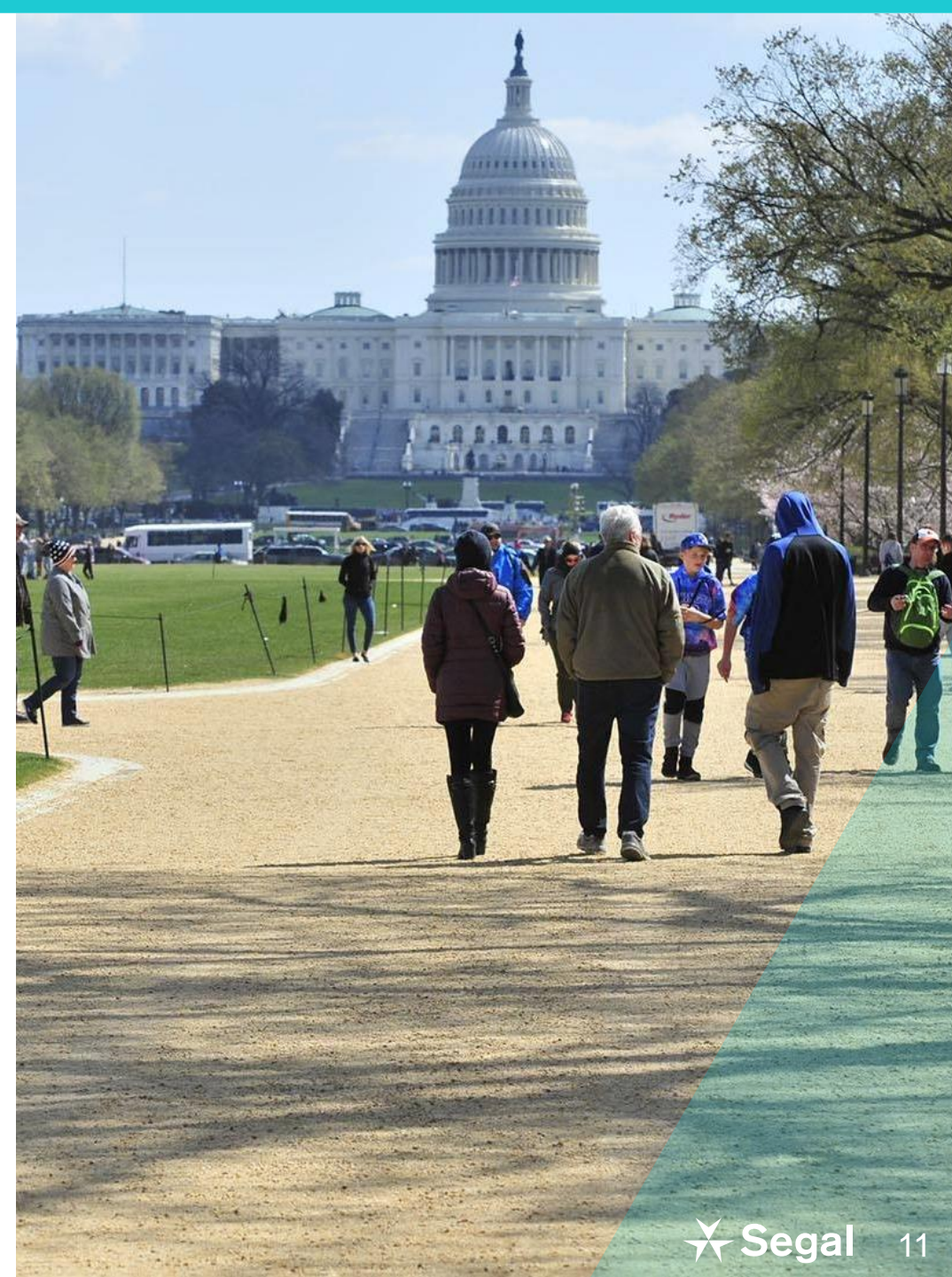
Generally, effective for plan years beginning on or after January 1, 2022

Retiree-only plans, excepted benefits, Health Reimbursement Arrangements (HRAs) exempt



Interim Final Rules

- Departments of Health and Human Services, Labor, and Treasury published an Interim Final Rule (IFR) on July 13, 2021, implementing Part I of the federal No Surprises Act (NSA)
- Part II Interim Final Rule (IFR) published on October 7, 2021, implementing the federal Independent Dispute Resolution (IDR) process
- NCCMP has provided comments on all IFRs



Final Rule – 2022

- After litigation which voided parts of the previous rules, the Administration published a Final Regulation on August 26, 2022
 - Downcoding disclosure
 - Independent Dispute Resolution (IDR) process
- Administration also released new FAQ 55
 - FAQs address application of the No Surprises Act to specific factual situations

Downcoding



Final rule finalized a definition of the term “downcode” and required that plans disclose additional information if they downcode a billed claim



“Downcode” means to alter the service code to another service code or alter a modifier, if the changed code is associated with a lower QPA than the service code or modifier billed by the provider, facility or air ambulance provider



If a QPA is based on a downcoded service code or modifier, the plan must provide an explanation with the initial payment or notice of denial of payment

Independent Dispute Resolution Process

1

The Qualifying Payment Amount (QPA) must be used to calculate **participant cost-sharing** for Emergency Services at an Out-of-Network provider or facility, Non-Emergency Services at an In-Network Facility, and Non-Network Air Ambulance Services

2

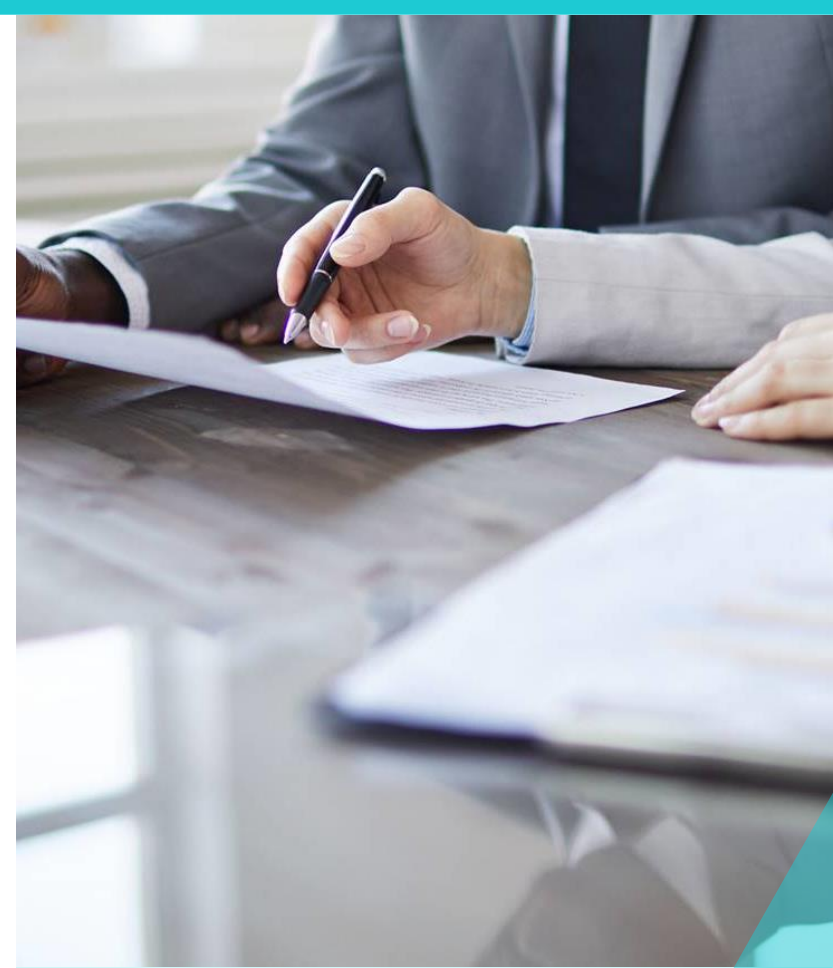
If the plan sends the provider/facility an **initial payment or notice of denial**, it must tell them what the QPA is for that service

3

NEW In **IDR**, the QPA is considered first, then additional information may be considered if it is credible and relates to the offer for payment

Additional Factors That May be Considered

- The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished the item or service;
- The market share held by the provider or facility;
- The acuity of the patient or the complexity of furnishing the item or service to the patient;
- Teaching status, case mix, and scope of services of the facility;
- Demonstration of good faith efforts (or lack thereof) made by the provider/facility or the plan/issuer to enter into network agreements;
- Additional credible information



Factors That Cannot be Considered by the IDR Entity

- Usual and customary charges
 - Including payment or reimbursement rates expressed as a proportion of UCR
- The amount that would have been billed by the provider or facility, or
- Any public payer payment or reimbursement rates
 - Including Medicare, Medicaid, CHIP, and TRICARE or rates expressed as a proportion of rates payable by public payers

Federal IDR Process Status Update

- Between April 15 and August 11:
 - 46,000 disputes initiated through the IDR Portal
 - Certified IDR entities decided 1,200 disputes
 - Challenges were made that 21,000 of the 46,000 disputes were ineligible, and 7,000 of those have been found to be ineligible by the Certified IDR entity
 - Eligibility challenges could be because of state/federal jurisdiction, correct batching and bundling, compliance with time periods, and completion of open negotiations

IDR Process Backlogged

Request for Information: Advanced Explanation of Benefits

- On September 16, 2022, the Administration published a Request for Information (RFI)
- Comment deadline November 15, 2022
- Under No Surprises Act, if health care provider sends plan a Good Faith Estimate regarding charges for a proposed health care service, the plan must send the participant an Advanced Explanation of Benefits (AEOB)
- Generally required within one day, depending on when services scheduled
- Rule enforcement deferred until notice and comment rulemaking



Transparency Requirements

Transparency Final Rule

Beginning July 1, 2022*

Non-Grandfathered plans must post online, machine-readable files (or links to files) that include:

- An in-network rate machine-readable file
- An out-of-network allowed amount machine-readable file
- Files must be updated monthly

Prescription drug machine-readable file
not required unless guidance is issued.



* Delayed from plan years beginning on or after January 1, 2022.

Transparency Final Rule

- Effective for plan years beginning on or after January 1, 2023, with respect to 500 items and services listed in rule
- Effective for plan years beginning on or after January 1, 2024, for all covered items and services

Internet-based self-service tool

- Real time tool a participant can use to search for cost-sharing information that is accurate at the time of request



Prescription Drug Reporting (RxDC)

- Section 204 of the CAA 2021 requires reporting prescription drug costs and other data to HHS/DOL
- Reporting delayed until 12/27/22 for 2020 and 2021 data; June 2023 for 2022 data
- Plans and vendors report on the HIOS system
- <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/Prescription-Drug-Data-Collection>

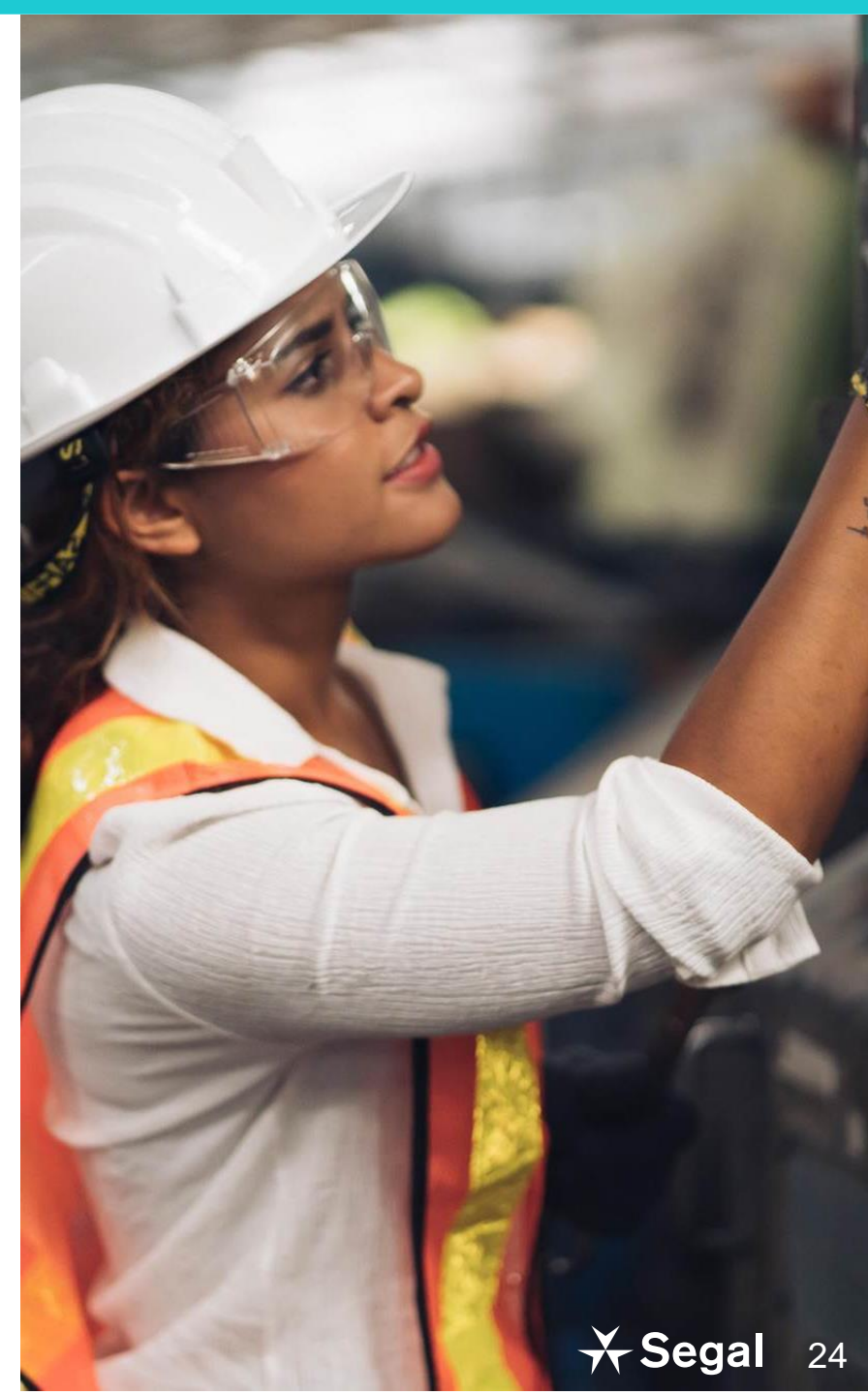




Nondiscrimination Rules

Gender Dysphoria Coverage

- Gender-affirming care includes care for transgender individuals that may include, but is not necessarily limited to, counseling, hormone therapy, surgery, and other services designed to treat gender dysphoria or support gender affirmation or transition
- Exclusions of services because of an individual's sex assigned at birth, gender identity, or gender recorded could be challenged under:
 - Americans with Disabilities Act
 - ACA Section 1557
 - Title VII of the Civil Rights Act
 - The EEOC cites the Bostock decision as it continues to take the position that employment discrimination based on sexual orientation or transgender status constitutes discrimination prohibited by Title VII



1557 Proposed Rule

Rule proposed August 4, 2022, comments due October 3, 2022

Would expand scope of covered entities

Would reinstate notification obligations concerning language assistance

Would require disability accommodation in benefits

Plans could not deny or limit health coverage to individuals based upon the individual's sex assigned at birth, gender identity, or gender otherwise recorded

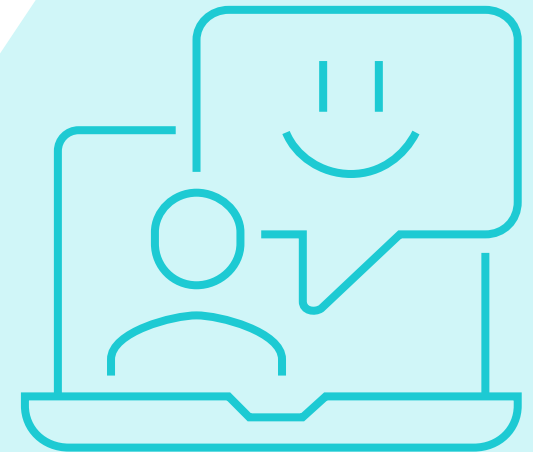
Would require written policies and procedures

Web Accessibility Under the ADA

On March 18, 2022, the U.S. Department of Justice (DOJ) issued guidance on how public entities can ensure that their websites are accessible to individuals with disabilities <https://beta.ada.gov/web-guidance/>

Examples of barriers to website accessibility:

- Poor contrast between colors of text and the background
- Use of color alone to give information
- Lack of text alternatives (“alt text”) on images
- No captions on videos
- Inaccessible online forms
- Mouse-only navigation



Web Accessibility Under the ADA

How to Make Websites Accessible:

- Color contrast in text
- Text cues when using color in text
- Text alternatives (“alt text”) in images
- Video captions
- Online forms
- Text size and zoom capability
- Headings
- Keyboard and mouse navigation
- Using accessibility checkers





Hearing Aids

FDA Approves OTC Hearing Aids

- Effective October 17, 2022, FDA established controls for a category of over-the-counter hearing aids
- Individuals will be able to buy a hearing aid in the store or online without seeing a physician or audiologist
- The OTC final rule applies to certain air-conduction hearing aids intended for people 18 years of age and older who have perceived mild to moderate hearing loss



Thank You

