While you're waiting for us to start, check out the results of HRSA's health center survey… (there is no audio for this slide)

51% of NC health centers responding

Testing Capacity	NC
Health Centers with COVID-19 Testing Capacity	100%
Health Centers with COVID-19 Drive-Up/Walk Up Testing Capacity	75%

Average Turnaround Time for COVID-19 Test Results	
Less than 1 Hour	5%
12 Hours or Less	0%
24 Hours	20%
2-3 Days	60%
4-5 Days	15%
More than 5 Days	0%

Operations	NC
Health Center Weekly Visits Compared to Pre-COVID 19 Weekly Visits	73%
Health Center Sites Temporarily Closed	15
Staff Tested Positive for COVID-19	14
Health Center Staff Unable to Work (due to site/service closure, exposure, family/home obligations, lack of PPE, etc.)	6.5%
Average Percent of Health Center Visits Conducted Virtually	35.25%

Latest Data from August 21st
https://bphc.hrsa.gov/emergency-response/coronavirus-health-center-data/nc

While you're waiting for us to start, check out the results of HRSA's health center survey... (there is no audio for this slide)

51% of NC health centers responding

Number of Patients Tested for COVID-19	NC
Patients Tested	3601
Patients Tested Positive	338

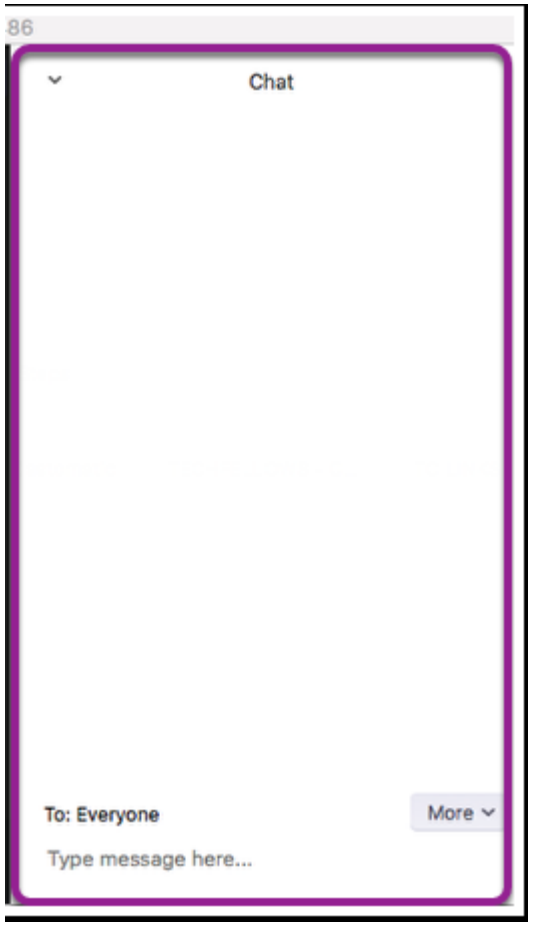
Race/Ethnicity	Patients Tested	Tested Positive
White, Non-Hispanic/Latino	24.94%	23.88%
White, Hispanic/Latino	12.25%	24.48%
Black, Non-Hispanic/Latino	36.68%	18.81%
Black, Hispanic/Latino	0.89%	1.79%
Asian	0.95%	1.19%
American Indian/Alaska Native	0.28%	0.90%
Unreported/Refused to Report	5.65%	4.48%

Latest Data from August 21st
https://bphc.hrsa.gov/emergency-response/coronavirus-health-center-data/nc

CHC Task Force Meeting

September 4, 2020

Zoom Help



You can also send questions through Chat. Send questions to Everyone or a specific person.

Everyone will be muted. You can unmute yourself to ask questions by clicking on the microphone or phone button.

Agenda

- **Welcome**, Chris Shank, President & CEO, NCCHCA
- **Quest Diagnostics Foundation's Initiative to Reduce Health Disparities in Underserved Communities**, Ron Coursey, Executive Director, Quest Diagnostics
- **Contracting Basics**, Marcie Zakheim, Partner, Feldesman Tucker Leifer Fidell
- **BAA Template**, Mel Goodwin, General Counsel, NCCHCA
- **Keeping Kids Well Program**, Jaimica Wilkins, Senior Program Manager, NC Division of Health Benefits
- **NCCHCA Updates**
- **Closing**

Slides & Other Info will be available on our website:
www.ncchca.org/covid-19/covid19-general-information/

Welcome from Chris Shank, President & CEO, NCCHCA

Ron Coursey,

Executive Director, FQHCs, Quest Diagnostics

https://newsroom.questdiagnostics.com/2020-08-24-Quest-Diagnostics-and-Quest-Diagnostics-Foundation-Launch-Initiative-to-Reduce-Health-Disparities-in-Underserved-Communities

Quest Diagnostics

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Quest Diagnostics and Quest Diagnostics Foundation Launch Initiative to Reduce Health Disparities in Underserved Communities

Quest to dedicate more than $100 million to expand access to testing, partner to help those hit hardest by COVID-19 and fund Foundation initiatives

SECAUCUS, N.J., Aug. 24, 2020 /PRNewswire/ -- Quest Diagnostics Incorporated (NYSE: DGX), the world's leading provider of diagnostic information services, and the Quest Diagnostics Foundation, today announced a wide-ranging initiative to address and reduce health disparities in underserved communities, including those impacted by COVID-19. The multi-year initiative will provide a combination of donated testing services, education programs, partnerships, and financial support.

"Through our role providing testing to the nation, Quest has seen how underserved populations have been disproportionately impacted by COVID-19 with tragic consequences. This major initiative is designed to address health disparities in the communities hardest hit by the pandemic," said Steve Rusckowski, Chairman, President and CEO of Quest Diagnostics. "This values-based commitment builds on existing work we have done with Federally Qualified Health Centers (FQHCs) and others. Quest plans to donate testing services and fund a range of initiatives estimated to total more

Quest Diagnostics

Vendor Contracting Basics: What To Look For

Marcie H. Zakheim, Esq.
Partner

DISCLAIMER

This training has been prepared by the attorneys of Feldesman Tucker Leifer Fidell LLP. **The opinions expressed in these materials are solely their views.**

The materials are being issued with the understanding that the authors are not engaged in rendering legal or other professional services. **If legal advice or other expert assistance is required, the services of a competent professional should be sought.**

AGENDA

- Preliminary Considerations: Contract versus Direct
- Step 1: Preparing For Negotiation
- Step 2: Evaluating the Contract
  - "Assemble" the team and documents
  - "Assess" the contractor
  - "Review" the key terms
- Step 3: Negotiating the Contract

SERVICE-RELATED FLEXIBILITY

- When developing the scope of services, health centers have discretion to determine:
  - Level and intensity of in-scope services and the service delivery methodology for each, based on factors such as need, capacity, etc. (non-financial factors)
  - Whether to offer additional and specialty services
  - Whether to prioritize the availability of in-scope additional services to individuals who use the health center as their primary medical home
- How you make these determinations may be influenced by (or may influence) mode of delivery

OTHER CONSIDERATIONS

- Costs-Effectiveness: Is contracting the most cost-effective way to provide service (versus providing service directly)?
- Contracting partner: Do missions align? Does the health center have experience with this partner or is he/she/it "new" to the health center and its patients? What are the partner's expectations?
- Scope of services: Can the contractor meet all needs in terms of access and availability, or will the health center be required to establish additional arrangements for the same services? Is the contract a means to supplement existing services provided directly or is it the only way in which patients can access a specific service?

"PROS" OF CONTRACTS V. DIRECT

- May be more cost-effective (no employment-related benefits)
- Can be used to fill immediate and temporary shortfalls in capacity (not tied into employment situations for which the center may not have ongoing need)
- Provides flexibility to determine if service is appropriate before fully committing
- Can be used to fill "gaps," e.g.,
  - While awaiting full implementation of a program that health center will be providing directly
  - To supplement direct provision of a service

"CONS" OF CONTRACTS V. DIRECT

- Less control (regardless of degree of oversight and monitoring) because other provider is furnishing services
- If included on Form 5A, MUST meet all HRSA requirements
- If included on Form 5A and arrangement is terminated, still need access to provide or have to request change in scope to delete the service
  - Consider how contractor could exercise right to terminate and potential impact on scope
  - Make sure contracts are "air tight" when working with another provider for scope purposes

STEP 1: PREPARING FOR NEGOTIATIONS

- Know your leverage points for negotiation (i.e., regulatory requirements, market power, and timing)
- Know legal considerations that could impact negotiation **
  - Procurement
  - Federal Tort Claims Act Coverage
  - Anti-Kickback and Federally-Funded Health Center Safe Harbor
  - Stark

** these also come into play when evaluating terms

PROCUREMENT

- Health center must have and utilize written procurement procedures **for purchases paid for in whole or in part with federal funds**, which comply with applicable federal and state laws and regulations, and federal procurement standards (including a process to ensure that costs attributable to the federal grant award are allowable under the "Federal Cost Principles")
- Must have access to contractor's records and reports related to health center activities in order to ensure that all activities and reporting requirements are being carried out in accordance with the provisions and timelines of the related contract

PROCUREMENT

- 45 CFR § 75.329: Three levels of purchases – items, not aggregate purchase orders (e.g., medical supplies)
  - Micro-purchases – less than or equal to $10,000 – grantee can determine if price is reasonable, no backup files required (changes so check periodically)
  - Small purchase procedures ($10,001 to $250,000) – simplified price checking and bids from an "adequate number" of sources
  - Procurement by competitive proposals or sealed bids (>$250,000 – in excess of the "Simplified Acquisition Threshold) – formal advertising, receipts of sealed bids, etc.

PROCUREMENT

- 45 CFR §75.329: Procurement by noncompetitive proposal ("sole source") can be used only if one of the following situations occur:
  - Item is available from only one source
  - Public exigency or emergency does not permit a delay resulting from competitive solicitation
  - Authorized by HRSA awarding agency in response to a written request (if a subrecipient, approval from the grantee)
  - After solicitation from a number of sources, competition deemed inadequate

FEDERAL TORT CLAIMS ACT COVERAGE

- Coverage is available for
  - Health center employees (full-time and part-time)
  - Individual / independent contractors practicing in the fields of adult medicine, family practice, OB/GYN and pediatric care (full-time and part-time basis)
  - Individual / independent contractors practicing in other fields must contract with the health center for an average of 32 ½ hours per week annually
- No coverage for organizational contractors

ANTI-KICKBACK LAW AND THE FQHC SAFE HARBOR

- Anti-kickback law: prohibits certain arrangements between referral sources where one party receives a benefit in exchange for federally-supported patient / business referrals, with exceptions
  - Federally-Funded Health Center Safe Harbor protects certain arrangements between health center grantees and their collaboration partners **under which the grantee receives a benefit from its partner** (*e.g.*, low cost or no cost services, low interest or no interest loans, loan forgiveness arrangements, certain donations to the health center, etc.)
  - Health center must have reasonable expectation that the arrangement will contribute meaningfully to the center's ability to maintain or increase the availability, or enhance the quality, of the services provided by the center to the medically underserved population in its service area

STARK LAW

- Federal Stark law prohibits billing Medicare and Medicaid for certain designated health services provided under an arrangement where a physician refers to another provider, entity, etc., with or in which the physician has a direct or indirect financial relationship, unless there is a specific exemption
- Under such circumstances, the referral would be considered a "self-referral" and thus payment for the services would be prohibited

STEP 2: EVALUATING THE CONTRACT

- Negotiate the timeframe for review
- Assemble your contract review team
  - Establish a "point person" and review team lead
  - Develop your in-house expertise on contract provisions
  - Assign areas of contract review to team members based on their expertise
- Assemble documents
  - Obtain entire proposed contract, including all exhibits, appendices, and addenda
  - Identify other documents cited, referenced and incorporated by reference into the contract

STEP 2: EVALUATING THE CONTRACT

- Assess the contractor's operational performance – considering past performance of the contractor is crucial
- Assess the contractor's financial and operational stability – consider contractor's background, organizational structure, operational methods, etc.

STEP 2: EVALUATING THE CONTRACT

Review the Contract

- ❑ Do you understand what all provisions mean?
- ❑ What provisions disadvantage your organization from a financial, clinical, operational, or legal perspective?
- ❑ Are responsibilities for each party clearly stated and all terms defined?
- ❑ Does the contract include all of the relevant appendices and exhibits?
- ❑ Have you reviewed any policies, procedures and documents referenced in the contract?
- ❑ Have you reviewed any references to statutes, codes, regulations to know what they say?
- ❑ Does signing the contract reflect sound business judgment?

STEP 2: EVALUATING THE CONTRACT: WATCH FOR THESE TERMS!!

- Scope of Services
- Contractor's Professional Qualifications, Credentialing, Privileging
- Application of Policies, Procedures and Protocols
- Quality Standards
- Oversight and Monitoring
- Payment to Contractor
- Billing Third Party Payors and Patients, Application of Sliding Fee
- Recordkeeping and Reporting
- Insurance
- Indemnification
- Term and Termination
- Dispute Resolution
- Post-Termination Responsibilities
- Confidentiality – Patient and Business Information
- Governing Law

HRSA-REQUIRED TERMS: COMPLIANCE MANUAL

- **Chapter 4:** assurances regarding
  - How the service will be documented in patient record
  - How the health center will pay for the service (e.g., how the center bills third-party payors and patients and provides payment to contractor)
  - NOTE: Contracts for enabling services do not need to include required provisions related to clinical services

HRSA-REQUIRED TERMS: COMPLIANCE MANUAL

- **Chapter 5:** assurances that providers furnishing services are
  - Licensed, certified, or registered as verified through a **credentialing process**, in accordance with applicable federal, state, and local laws
  - Competent and fit to perform the contracted or referred services, as assessed through a **privileging process**

HRSA-REQUIRED TERMS: COMPLIANCE MANUAL

- **Chapter 9:** assurances that fees will be discounted consistent with the Sliding Fee Discount Program requirements
  - Full discounts for individuals and families with annual incomes at or below 100% of the Federal Poverty Guidelines (FPG), unless center has elected to have a nominal fee which would be less than the fee paid by a patient in the first sliding fee discount pay class above 100% FPG
  - Partial discounts for individuals and families with annual incomes above 100% FPG and at or below 200% FPG, comprised of at least 3 pay classes based on gradations in income
  - No discounts are provided to individuals and families with annual incomes above 200% FPG

HRSA-REQUIRED TERMS: COMPLIANCE MANUAL

- **Chapter 12:** provisions addressing
  - Schedule of rates and methods of payment
  - Specific activities or services to be performed
  - Mechanisms to monitor contractor performance in accordance with contract terms and conditions and compliant with applicable federal requirements
  - Contractor's information and data reporting expectations (and intervals of reporting) necessary for the center to meet its federal and programmatic reporting requirements (such as UDS)
  - Record retention and access; audits; property management

HRSA-REQUIRED TERMS: COMPLIANCE MANUAL

- HRSA examples for monitoring contractor activities and performance
  - Periodic evaluations of performance through records, invoices, reports shared with the board and management staff
  - Documentation at time of contract completion or renewal that contractor met terms and conditions
- Additional examples from FTLF
  - Contractor compliance with health center policies, procedures, standards, etc. applicable to services provided
  - Contractor submission of financial and programmatic reports and records
  - Health center's retention of the right to replace an individual and/or terminate the contract for, among other things, breach

STEP 2: EVALUATING THE CONTRACT

- Identify and prioritize issues
  - **Red**: Critical issues that without addressing you cannot afford to proceed because the risks (not just financial) are unacceptable for the organization
  - **Yellow**: Significant issues that should be addressed before proceeding because they create undesirable risks for the organization
  - **Green**: Issues that ideally would be addressed prior to proceeding to reduce potential risks

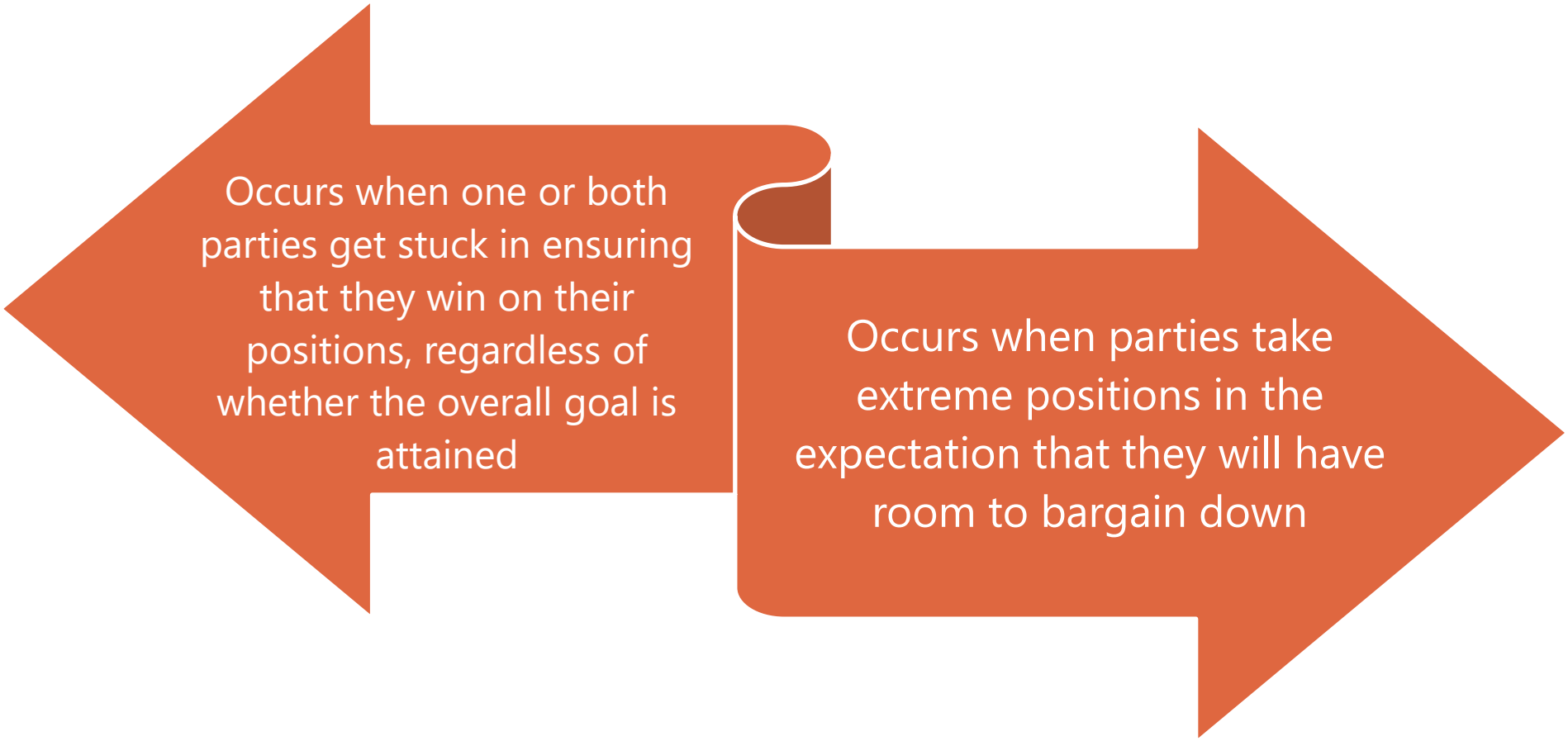
STEP 3: NEGOTIATING THE CONTRACT

Preliminary Questions

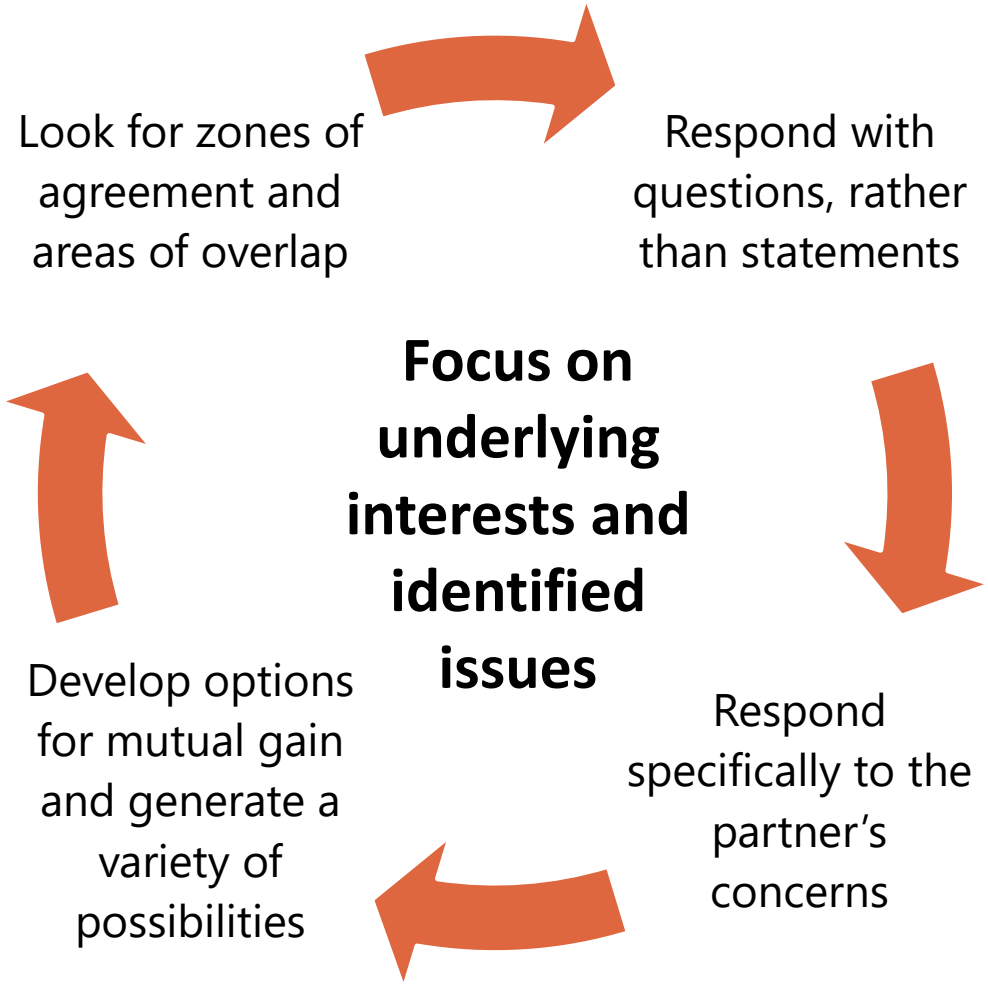
- Who will be negotiating?
  - A team?
  - An individual?
- How will issues be negotiated?
  - In writing?
  - By phone?
  - In person?

STEP 3: NEGOTIATING THE CONTRACT

A common error is bargaining over positions.



STEP 3: NEGOTIATING THE CONTRACT



STEP 3: NEGOTIATING THE CONTRACT

If you did not resolve all of the **critical issues** to your satisfaction, consider:

- Whether this one partner is essential to your operations
- Whether the risks of contracting outweigh the risks of not contracting with the partner
- Whether you can terminate the contract early in the event that the financial or legal harm becomes too great to bear
- Whether you have any other options for achieving a better outcome, i.e., using an agent for negotiations

QUESTIONS?

Marcie H. Zakheim, Esq.

MZakheim@FTLF.com

Feldesman Tucker Leifer Fidell LLP
1129 20th Street N.W. – Suite 400
Washington, D.C. 20036
(202) 466-8960
www.ftlf.com

BAA Template, Mel Goodwin, General Counsel, NCCHCA





NC Department of Health and Human Services

Keeping Kids Well Presentation

Jaimica Wilkins, MBA, CPHQ, ICP

Senior Program Manager – Quality Management

September 4, 2020

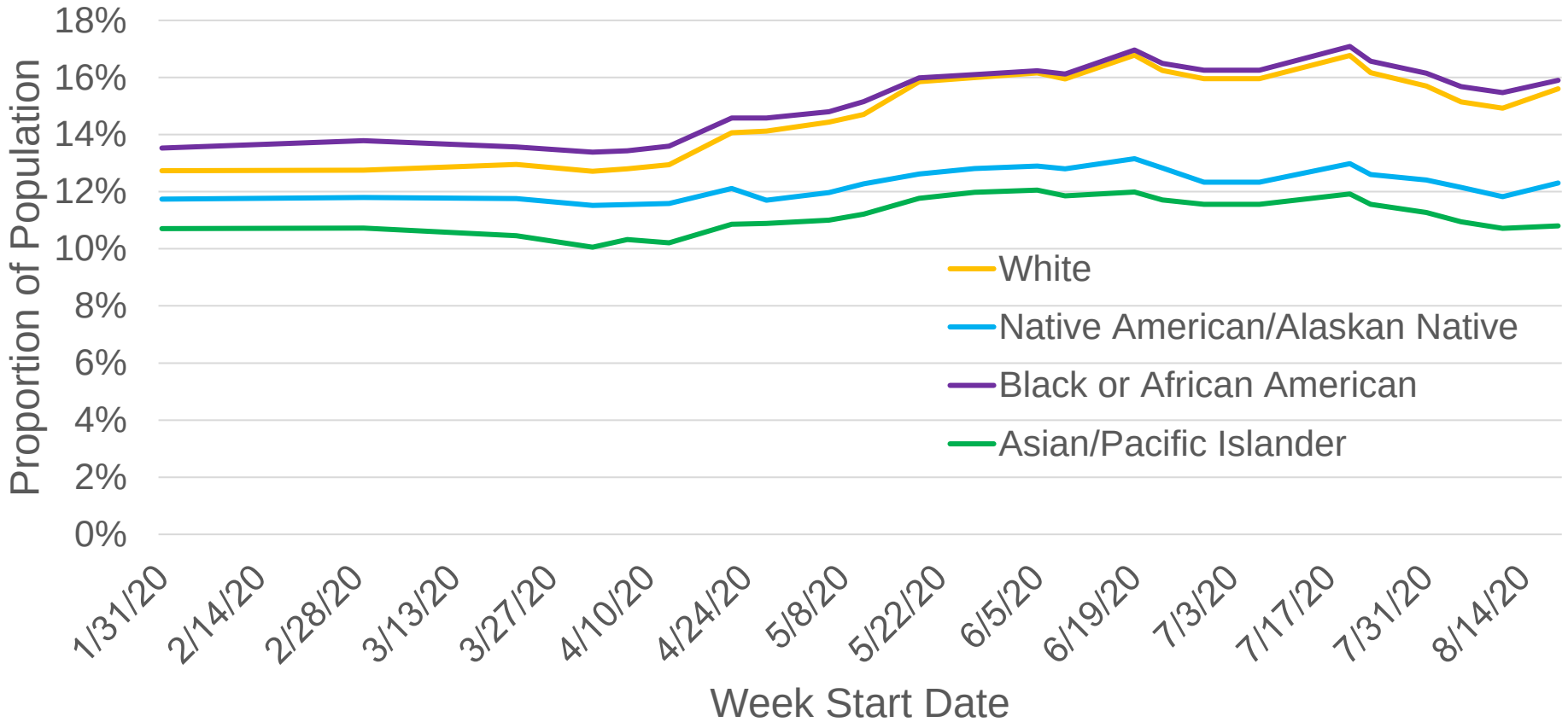
Summary

- COVID-19 has led to a measurable decrease in pediatric preventive care, especially for African-American and Latinx populations.
- Parents are not certain if vaccines are required with virtual education.
- Parents are apprehensive to take children in for visits due to COVID-19 or experience barriers visiting their pediatrician or family physician.
- Under-utilization of well-child visits are missed opportunities to identify physical, developmental, and behavioral concerns – many of which can be managed or treated.
- Missed vaccinations can eventually lead to community outbreaks of preventable disease during a busy COVID19 and influenza season.
- North Carolina now requires a meningococcal vaccine for kids 17 years and older.

Opportunity

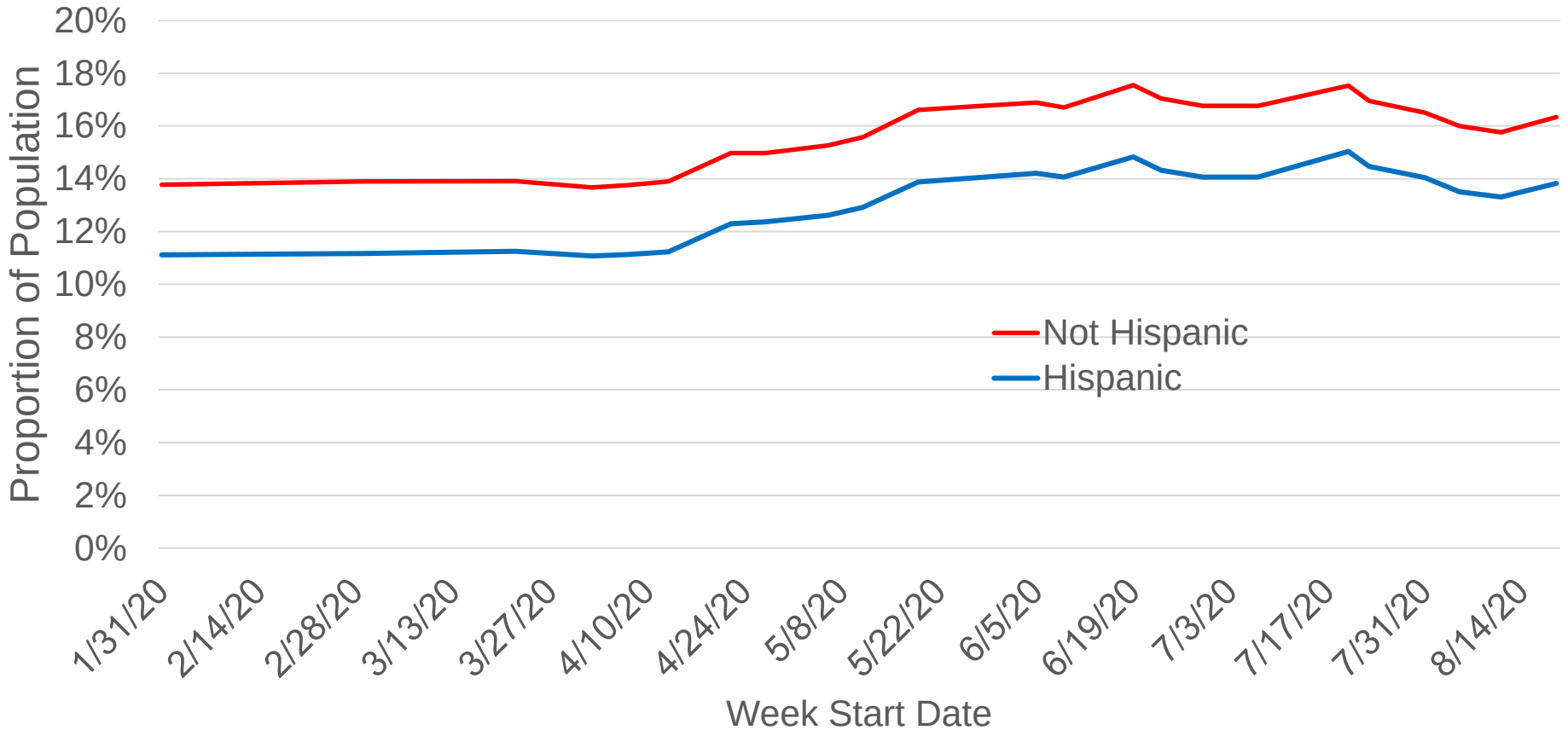
- **CCNC, NC AHEC and NC DHHS can help address this important public health concern.**
- **Can accelerate a rebound of pediatric well-care among Medicaid beneficiaries younger than 19 years of age to the pre-COVID-19 level.**
- **NC DHHS has engaged stakeholders through an Advisory Group supporting a statewide campaign to address the problem.**
- **NC AHEC and CCNC developed a strategic and coordinated approach to improving well-child and immunization rates through provider and patient interventions. Our collective work will contribute toward preparing kids for school and for a life-time of optimal health.**

Proportion of Population[1] with Overdue Well Child Visits 0-2 by Race



- [1]Sub-population denominators are for ages 1-5 whereas well visit data are for 0-2
- This version does not include the “unknown” category

Proportion of Population[1] with Overdue Well Child Visits 0-2 by Ethnicity



- [1]Sub-population denominators are for ages 1-5 whereas well visit data are for 0-2
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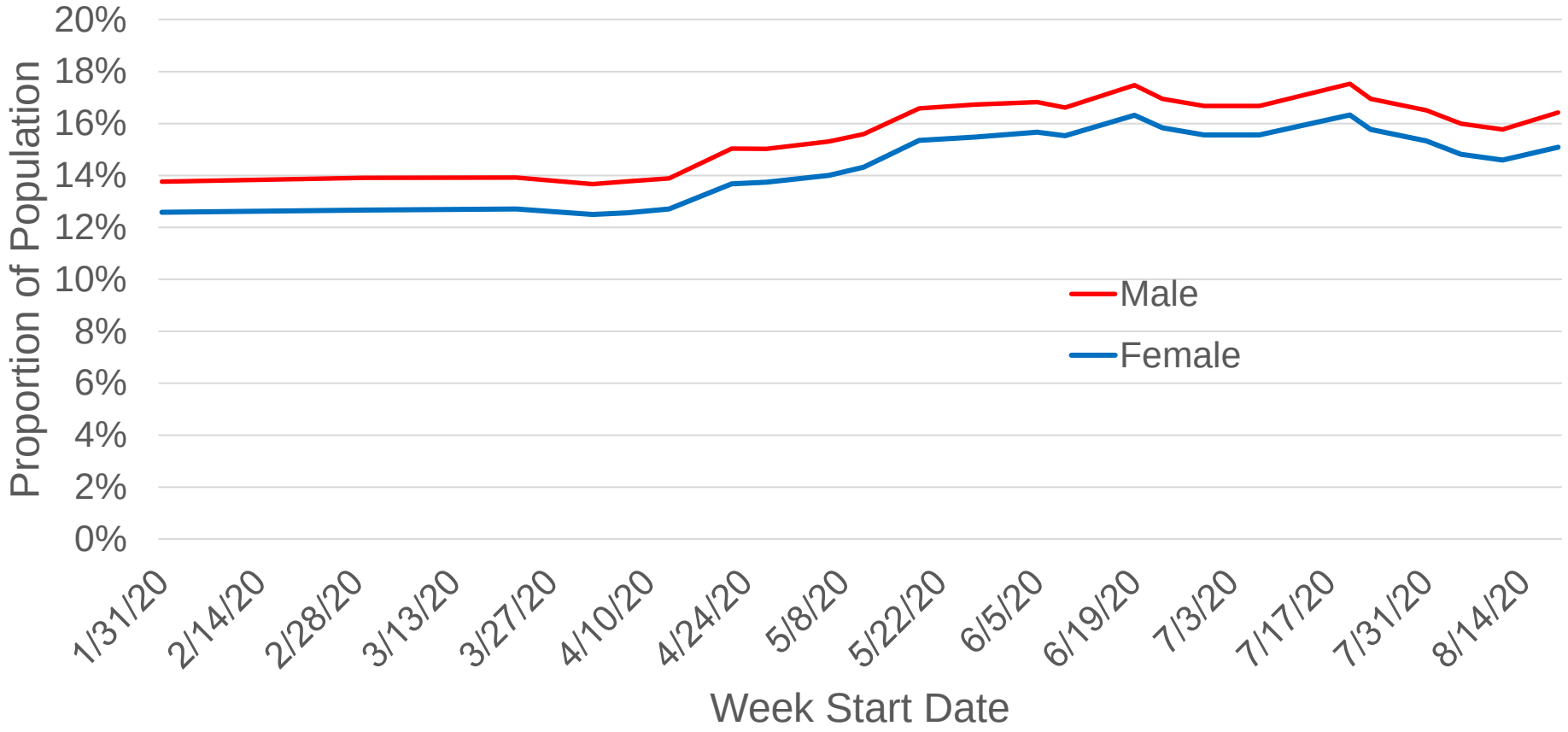
Proportion of Population[1] with Overdue Well Child Visits 0-2 by Gender



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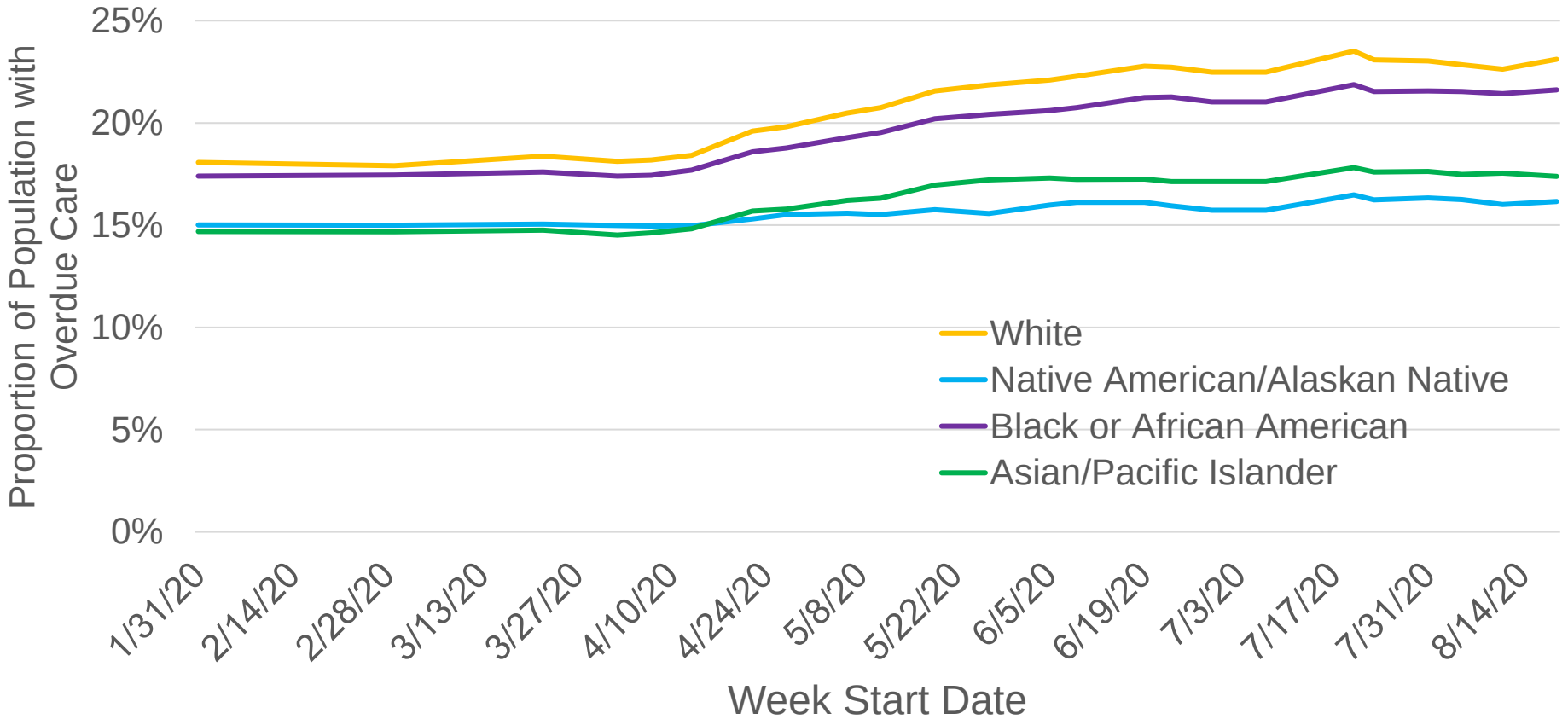
Proportion of Population[1] with Overdue Well Child Visits 3-6 by Race



- [1]Sub-population denominators are for ages 1-5 whereas well visit data are for 3-6
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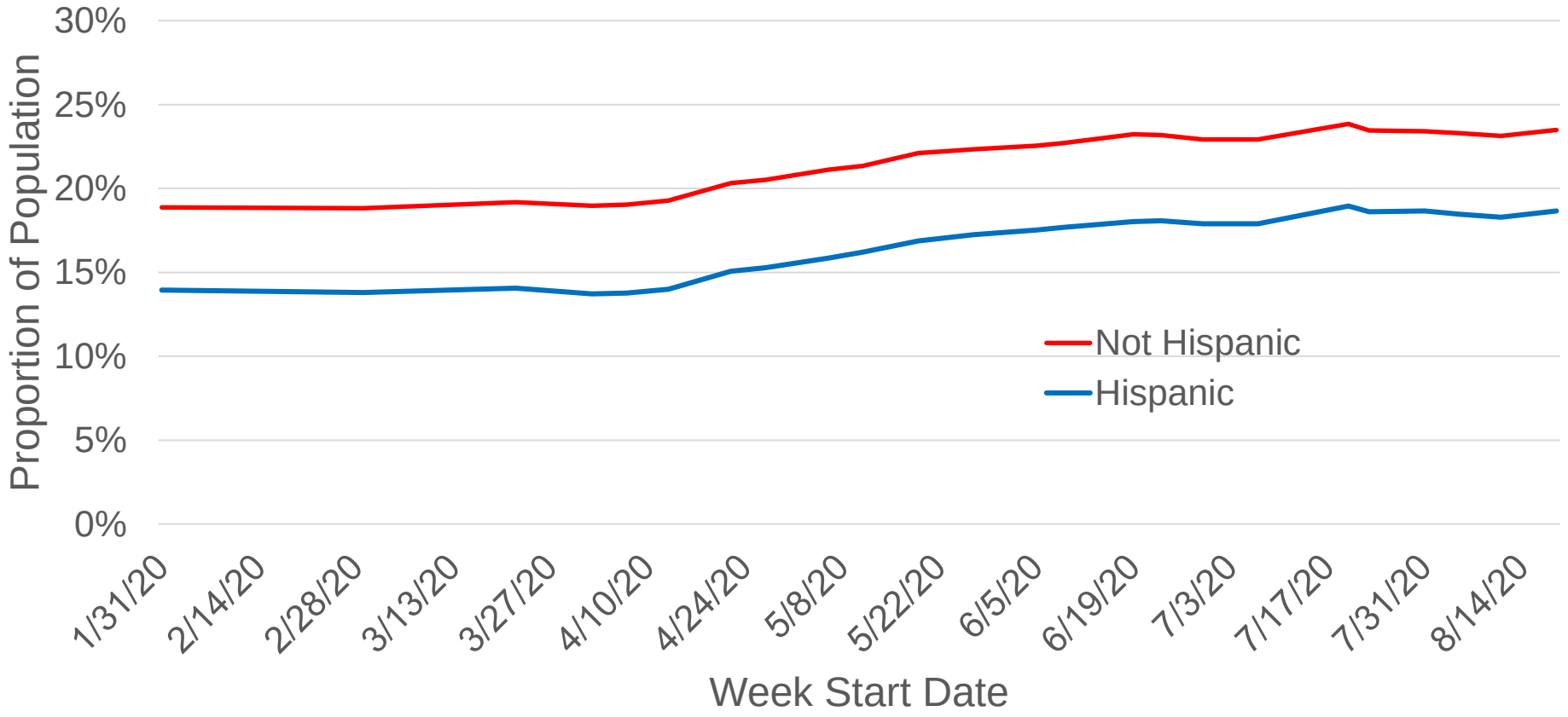
Proportion of Population[1] with Overdue Well Child Visits 3-6 by Ethnicity



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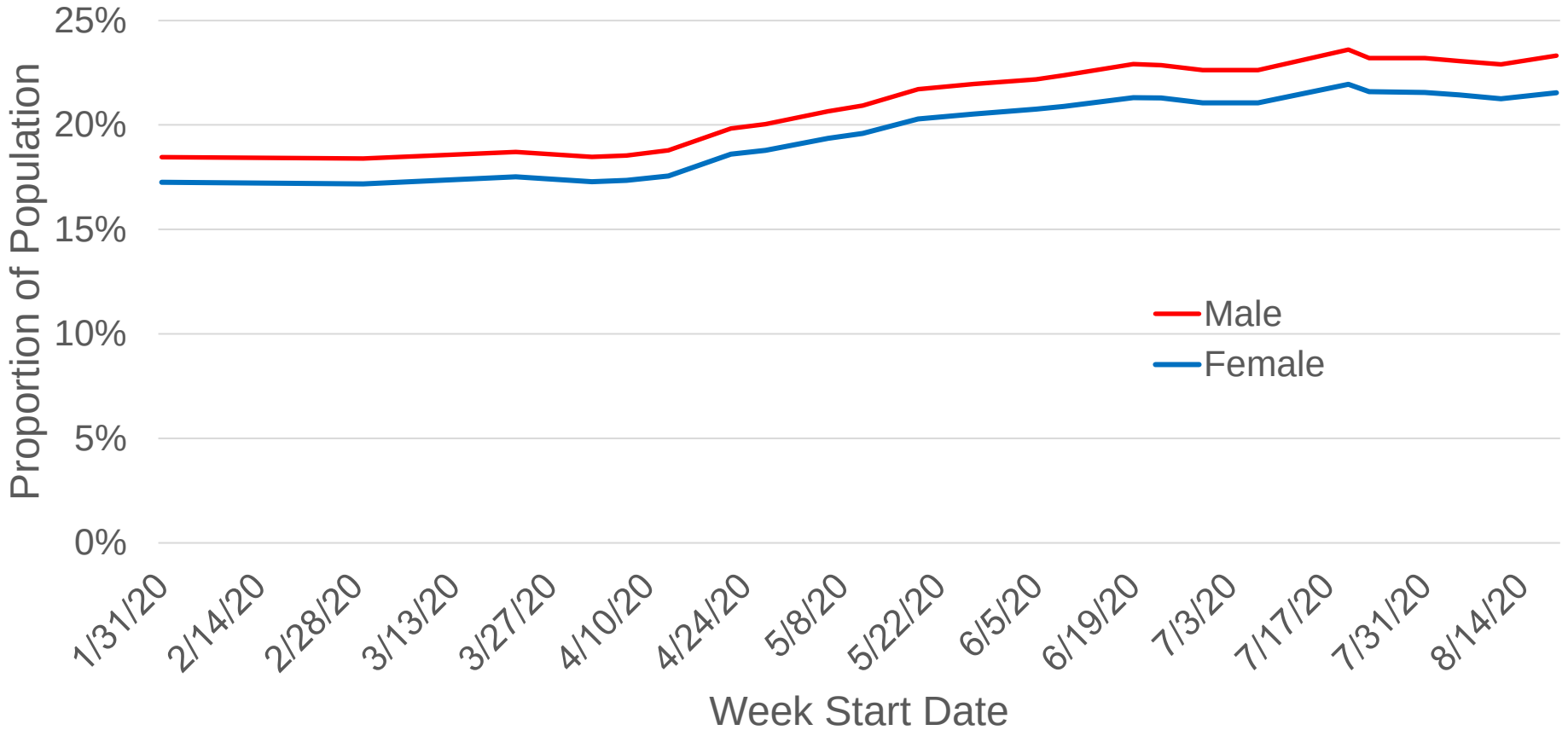
Proportion of Population[1] with Overdue Well Child Visits 3-6 by Gender



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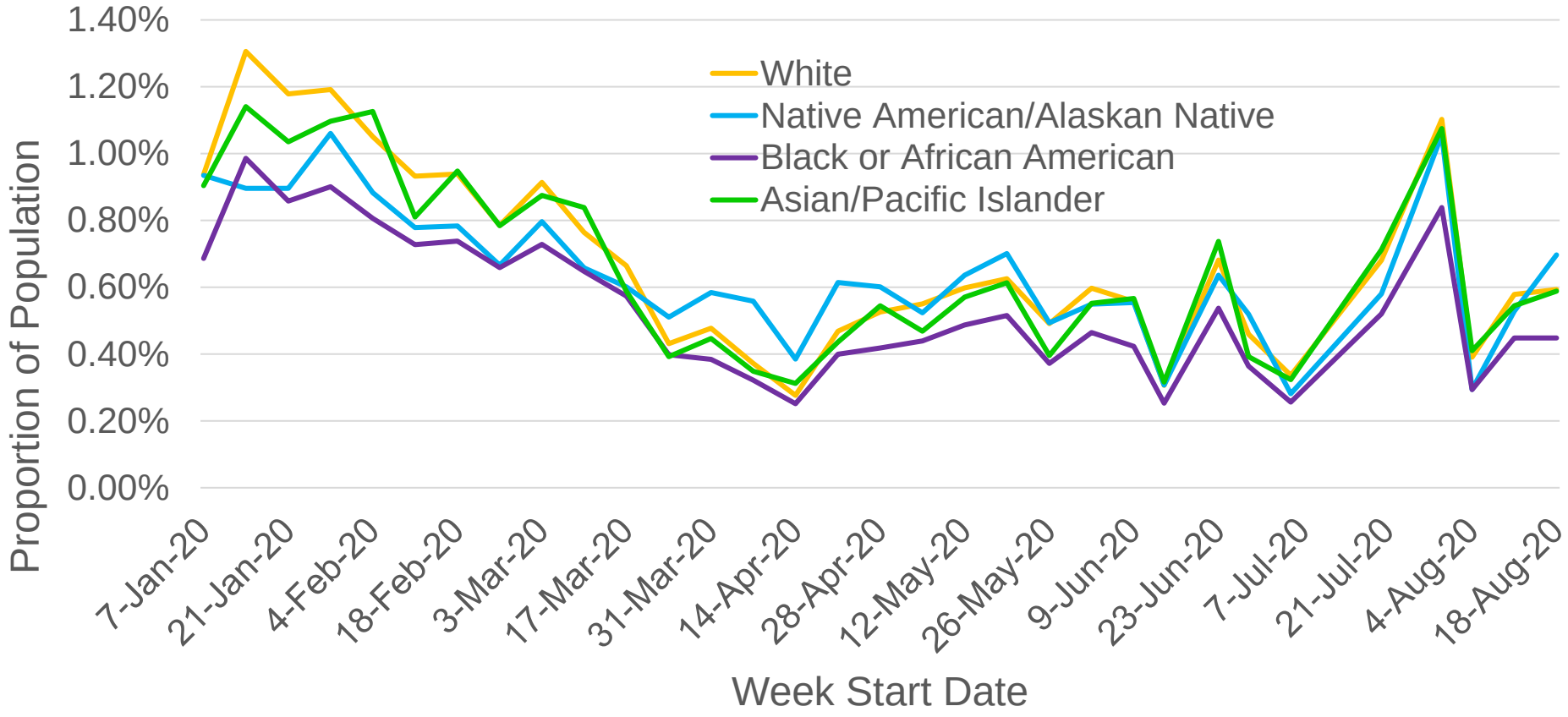
Weekly Proportion of Population[1] Receiving Childhood Immunizations[2] by Race



- [1]Sub-population denominators are for ages 1-5
- [2]A higher value is favorable
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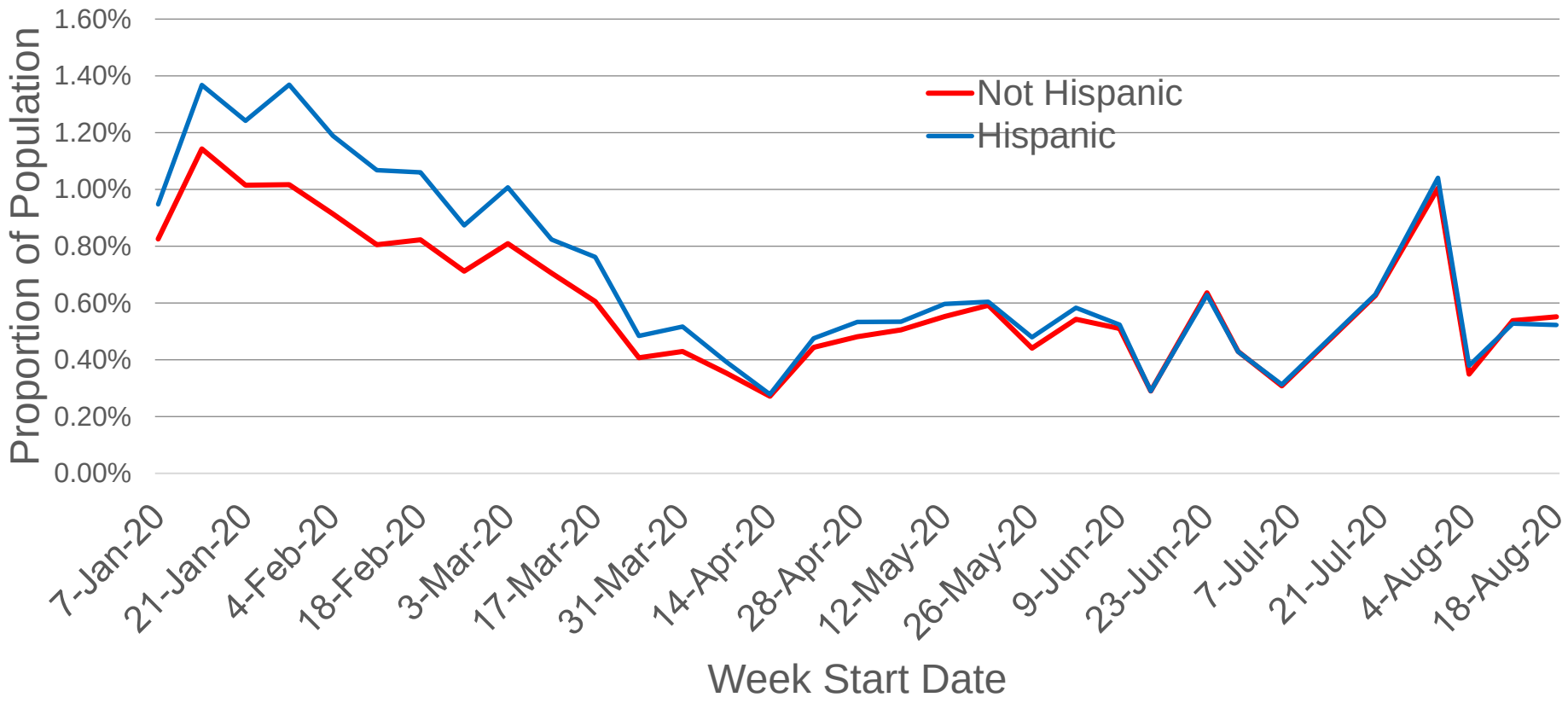
Weekly Proportion of Population[1] Receiving Childhood Immunizations[2] by Ethnicity



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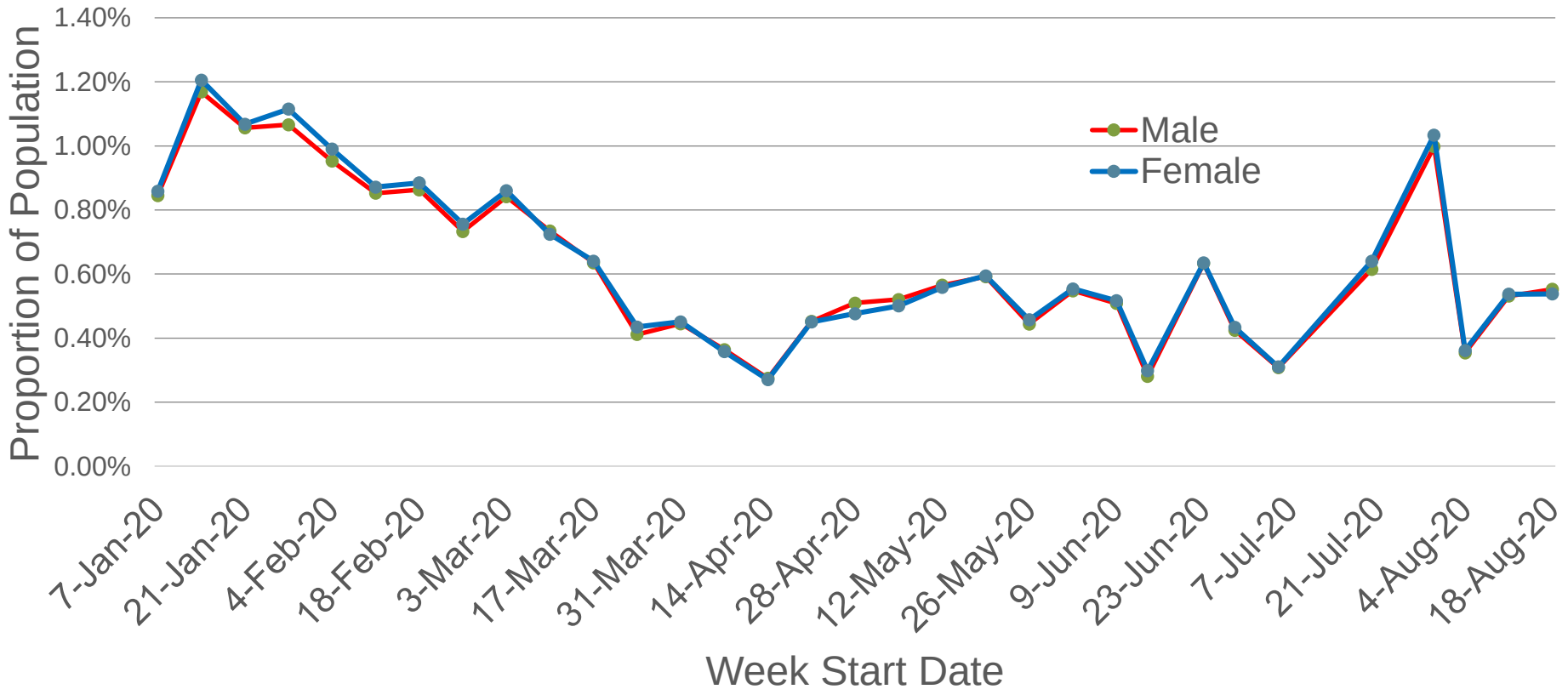
Weekly Proportion of Population[1] Receiving Childhood Immunizations[2] by Gender



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Targeted Practices

All practices that provide primary care to children:

- **Pediatrics**
- **Family Medicine**
- **School-based clinics**
- **Local Health Departments**
- **FQHCS and RHCs**

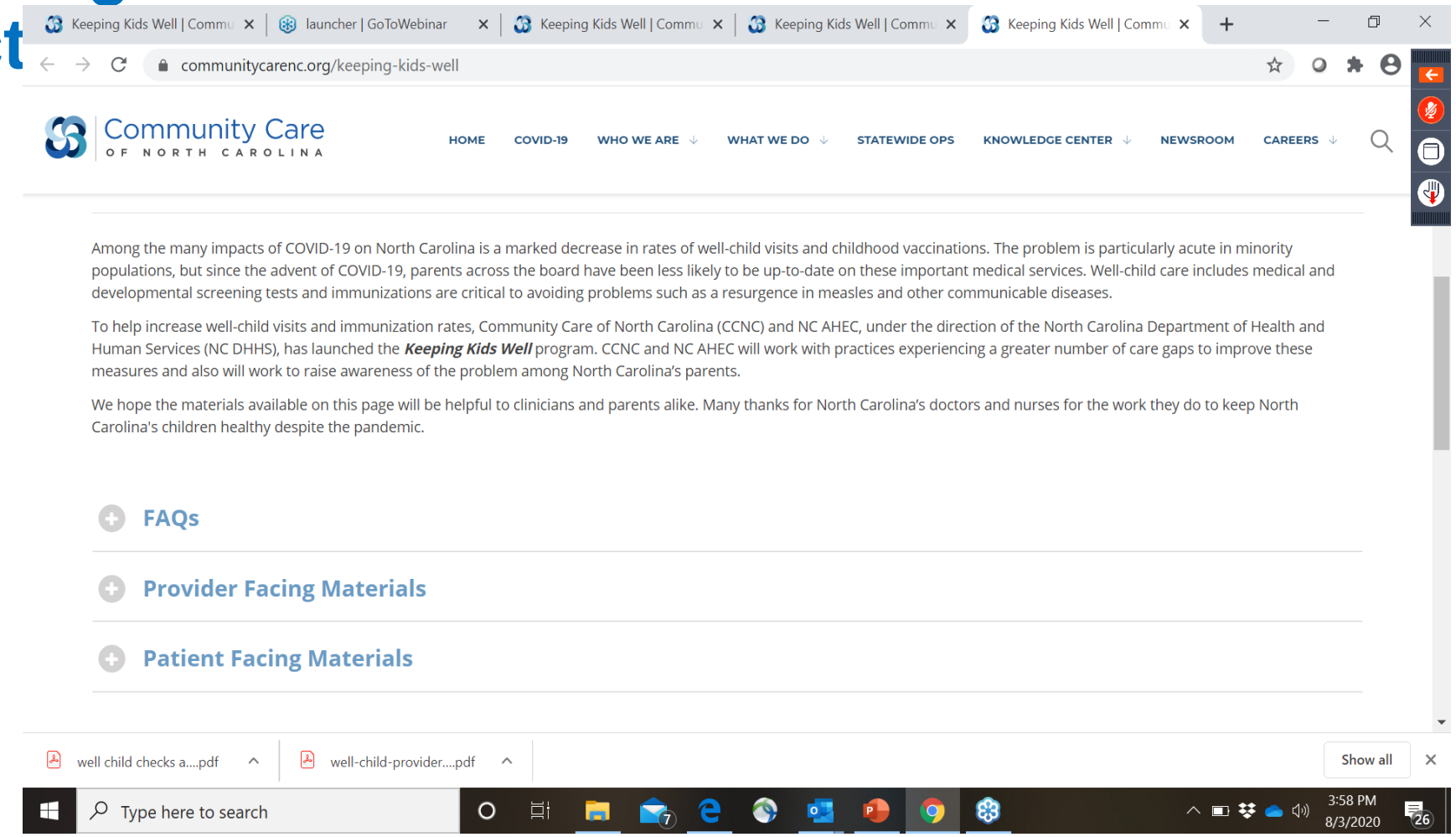
Project Highlights

- **Project started August 3rd and will run through the fall.**
- **Media campaign targeted to patients and the public by DHB with information available in English and Spanish.**
- **CCNC care management programs will reach families with tailored messaging to Latinx and African-American families.**
- **Local Health Departments will deploy care managers to do active outreach to children in care management who are missing immunizations and well visits.**
- **Practices with >500 care alerts for pediatric patients are included in the 1:1 practice support work. This comprises 300 independent and health system practice locations across North Carolina.**
- **Practice support provides 1:1 coaching support comprising recommended best practices or interventions, standardized workflows, clinical workflow redesign, educational tip sheets and toolkits.**
- **NCDHHS is leading an advisory group to gather feedback into outreach and communications, provide mass communications outreach to membership, and partner on delivery of webinar content and speakers.**

Interventions

- ❑ Use the EHR to generate a list of children who are behind on well child care.
- ❑ Utilize the Internet and social media to reach parents and families.
- ❑ Utilize your staff and physical space to promote well child visits & immunizations.
  - ❑ Partner with local school systems to get the message out about well child care and immunizations.
  - ❑ Remind families across your catchment area of the importance of well child care and immunizations via local news outlets.
  - ❑ Run a WCV/Immunization Promotion Month.
  - ❑ Incorporate well child care into your acute care visits.
  - ❑ Develop workflow to document immunizations that were received elsewhere.
  - ❑ Implement group visits for well child care (Post-COVID-19 pandemic).

Keeping Kids Well Website Includes Resources for Pract



Questions & Feedback

NCCHCA Updates

340B Update, Brendan Riley, Director of Policy, NCCHCA

Recap of Manufacturer Actions

Tuesday's Announcement by Eli Lilly

- Effective September 1, 2020, Eli Lilly will no longer permit any 340B-priced drugs to be dispensed to any contract pharmacies (with a possible exception of one contract pharmacy location for health centers with no in-house pharmacies.)
- Eli Lilly will make an exception for penny-priced insulin, allowing these drugs to be shipped to all contract pharmacies. However, health centers who purchase this penny-priced insulin must agree to cover the full costs of dispensing the drug, as well as contracting with, overseeing, and reporting on the compliance of the contract pharmacies – and would be prohibited from billing any third-party payer for the insulin.

In other words, to make Lilly's penny-priced insulin available to their patients via contract pharmacies, health centers would be forced to incur significant costs while simultaneously giving up the ability to retain any savings to help cover these costs.

Recap of Manufacturer Actions Since July

Actions Thus Far by Eli Lilly, Merck, Sanofi, AstraZeneca, Novartis

- Refusing to ship 340B-priced drugs to contract pharmacies
- Refusing to ship 340B-priced drugs to more than one pharmacy site
- Demanding claims data from 340B covered entities across payors (in order to identify and eliminate rebates paid to PBMs for those drugs, which leads to discriminatory contracting when PBMs cut reimbursements to health centers for 340B drugs)
- Eliminating 340B discounts and replacing them with an after-the-fact rebate [TBD—manufacturers expected to use Kalderos system that launches Sept. 8]

What Can You Do?

Contact your members of Congress!
Every new manufacturer action is good cause for a contact. We have to break through the noise.

Resources to help:

- NACHC Template Letter to Lawmakers from 340B Toolkit
- NCCHCA Messaging Guidance for Phone Call Conversations

Good news: Yesterday, leading Democrats on the House Energy & Commerce Committee sent a letter expressing concerns to HRSA, urging them to protect 340B program.

Updated 9/1/2020

Guidance for Communicating with Members of Congress and Their Staff About 340B Manufacturer Actions

Table of Contents:

Primary Talking Points

These are the key messages you should lead with and cover during your conversation to frame the issue and educate the member of Congress or Congressional staffer.

1. **Community health centers are vital safety net providers of care to North Carolina's underserved communities.**
   a. Like all community health centers, we provide comprehensive primary medical, behavioral health, and other health care services to medically underserved communities in our state -- without regard for insurance status or ability to pay. Through our sliding fee discount program, our patients can afford these vital services.
      i. [*Feel free to share general info about the target population you serve, the communities you serve, your number of sites, and your specific services*]
   b. Over 40% of health center patients in NC are uninsured. As nonprofit safety net providers, we stretch every dollar we receive as far as possible to make our services affordable and accessible to our patients.

DOs and DONTs: Messaging Tips for Communicating about 340B

DON'T	DO
DON'T provide dollar amounts for how much income or savings the 340B provided to your health center.	DO use the term "savings" when talking about income or revenue that 340B program generates for your health center ...and... DO discuss the patient-facing programs and services that 340B savings support at your health center.
DON'T get drawn into a discussion about other 340B covered entities (e.g. hospitals) and how they use the program.	DO emphasize that community health centers, by our mission and requirements, reinvest all savings in health center programs and services for patients.
DON'T talk about the workforce supported by your 340B savings ***without*** talking about how that workforce directly serves or benefits your patients.	DO center the impact on patients, including how important medications are for managing patients' health, how 340B helps make them affordable, and how patients might go without their meds without 340B.
	DO talk about how any 340B contract pharmacies you use promote access in terms of geography, hours, specialty drugs, etc.

Executive Order Developments

- On July 24, President Trump signed Executive Order instructing HRSA to condition 330 grants on whether FQHCs charge low-income patients 340B acquisition cost for insulin and EpiPens.

- The administration is in the process of finalizing an Interim Final Rule to implement the Executive Order. It be published any day – and could go into immediate effect. Next steps TBD.

- *Dear Colleague* letter circulating in House urging the U.S. Department of Health and Human Services to rescind the Executive Order.

NCCHCA Fall Board Meeting

September 10, 10:00am-12:30pm

Upcoming FQHC Task Force Calls

September 18, 10:00-11:30am

October 9, 10:00-11:30am

October 23, 10:00-11:30am

Stay connected!

www.ncchca.org/covid-19/

covid19@ncchca.org