

Harter Secrest & Emery LLP

ATTORNEYS AND COUNSELORS

# New York State Legislative Update



# Who am I

- A Partner at Harter Secrest & Emery
- I am a Government Affairs Attorney
- I've been working with NYSCLA for over 20 years now
- What I do for the Association



# Presentation Overview

- Provide overview of Albany and the legislative process
- Discuss major legislative and regulatory efforts



# Albany Overview



- Two main players:
  - The Legislature
  - The Governor

# Albany Overview



- The Legislature:
- The Assembly
  - The Senate

# Albany Overview

## ■ New York State Assembly



### — 150 Members

- 101 Democrats (with 1 Independent), 48 Republicans (1 Conservative) and 1 vacancy
  - Speaker of the Assembly is head of the house
- Assemblymember Carl Heastie is the Speaker
  - Speaker appoints the Majority Leader
  - Assemblymember Crystal Peoples-Stokes is the Majority Leader



# Albany Overview

## ■ New York State Senate



- 63 Members
  - 42 Democrats, 21 Republicans
- The Senate Majority Leader is the leader of the Senate
  - Senator Andrea Stewart-Cousins is the Senate Majority Leader
- Majority Leader picks the Deputy Majority Leader
  - Senator Michael Gianaris is the Senate Deputy Majority Leader

# Albany Overview

## ■ Veto Proof

- Both the Assembly and Senate are veto proof
- This means that if the Governor were to veto a bill that was passed by both houses, then there are enough votes to override the veto
- Has not yet been used





# Albany Overview

## ■ Governor Kathy Hochul

- Serving as the 57<sup>th</sup> Governor of New York
- Elected to her first four year term in November 2022
- First female Governor in New York history
- First Governor from Western New York since the early 20<sup>th</sup> century



# Albany Overview

- The 2023 legislative session was fully in person again
- Budget deadline was April 1, but final budget was not passed until May 3
- Last schedule day of session was June 8
  - Senate finished June 10
  - Assembly left June 10 and returned June 20 for a two day session to wrap up unfinished business



# NYSED vs. NYSDOH

- Two agencies that oversee issues related to laboratories in New York State
- NYSED
  - Oversees the licensed laboratory professionals
  - Charged with overseeing and regulating the education and licensing of the provider
- NYSDOH
  - Oversees the licensed laboratory facilities
  - Charged with overseeing and regulating the running and operation of the facility itself



## **Reviewing the Implementation of the Clinical Laboratory Clean Up Bill**

- For a number of years, the main legislative priority for NYSCLA has been to address the staffing issues in the industry and try to make changes to New York's licensing laws
- There were ongoing conversations about the need for more flexibility in New York's current rules and regulations

## **Reviewing the Implementation of the Clinical Laboratory Clean Up Bill**

- For the duration of the pandemic, there was an executive order in place waiving many of the licensing requirements
- We knew that once the EO expired, there would be exacerbated problems on the staffing front
- We were in touch with SED and with the legislature and Governor's office to talk about impacts and changes that were needed

## **Reviewing the Implementation of the Clinical Laboratory Clean Up Bill**

- Last year, the Clinical Laboratory Clean Up Bill was signed into law on July 21, 2022 as Chapter 446
- Once signed, we began working with SED on the draft regulations that would be needed to implement the law

## Laboratory Cleanup Bill Recap:

- Created the title of Histotechnologist
- Changed the title of Histological Technician to Histotechnician
- Allows for national or state licensing and certification to fulfill the education requirements for all Clinical Laboratory titles in New York
- Creates a pathway for Clinical Laboratory Technicians to become Clinical Laboratory Technologists
- Corrects the fee that is paid for a Provisional Permit (technical issue) and changes the duration of the permit from 1 year to 2 years

## Reviewing the Implementation of the Clinical Laboratory Clean Up Bill

- Effective dates:
  - Most of the provisions of took effect at the end of last year, December 28, 2022, as an emergency regulation with the final regulations adopted on May 11, 2023
  - The provisions related to the creation of the Histotechnologist position will take effect in December 2023, and we've been talking with SED about these regulations





## Reviewing the Implementation of the Clinical Laboratory Clean Up Bill

- As we reviewing the implementation of the clean up bill, we learned that EO 4, the EO that had waived many of the license restrictions, was going to be allowed to expire
- EO 4 had been in place since September 2021 and had been renewed every 30 days since then
- When we learned of EO 4's expiration, we sent out word to the industry that it was ending and asked once again if there were any outstanding issues that the clean up bill had not addressed
- Upon making this call, we learned there was an issue with the Restricted License categories



## Reviewing the Implementation of the Clinical Laboratory Clean Up Bill

- Per the EO, the limitations of the restricted licenses were expanded and molecular testing in all areas, including infectious diseases, were allowed
- With the pending expiration of the EO, this expanded use would be gone and those holding a restricted license would only be able to test in the area of molecular diagnosis for genetics and oncology
- After reviewing all of the information, we drafted legislation that would remove the genetics and oncology limitations on the restricted license

## **Reviewing the Implementation of the Clinical Laboratory Clean Up Bill**

- S7527 (Chu)/A7724 (Clark) was introduced in the final days of the legislative session and with a very small window, we were able to pass the bill through both houses
- We were literally the last bill to be passed by the New York State Assembly
- The Governor signed the bill into law on June 30, 2023 as Chapter 186 of the Laws of 2023
- The legislation took effect immediately

## **Reviewing the Implementation of the Clinical Laboratory Clean Up Bill**

- SED is working on regulations now to implement the law changes for the existing and future restricted license holders
- The regulatory process takes some time, so even though the effective date was immediate, there is some needed implementation time

## **Reviewing the Implementation of the Clinical Laboratory Clean Up Bill**

- Once again, this was a coalition effort
- Shout out to our partners:
  - SEIU 1199
  - HANYS
  - GNYHA
  - NYC Health + Hospitals

# Other Issues

- EO's
- DOH Regulations

# Executive Orders

- As a reminder, in 2020, there were a series of executive orders that waived certain New York laws and regulations
- Many of these orders waived professional practice requirements to allow for more healthcare providers to practice in New York
- This included practice waivers and changes for clinical laboratories and clinical laboratory practitioners
- Key components waived – New York licensing requirements and supervisor regulations



# Executive Orders

- These EO's expired in June 2021, without notice, when then Gov Cuomo declared an end to the Covid State of Emergency
- At the end of September 2021, Governor Hochul issued EO 4, which was a state of emergency declared due to the shortage of healthcare workers in New York based on various conversations and challenges that faced a broad cross section of those covered by the previous EO that ended so abruptly
- This EO included many of the same waivers that were included in the original EO
- As noted, the EO was extended every 30 days until June





# Executive Orders

- EO 4 expired on June 22, 2023
- All of the waived laws and regulations are now in effect again
- As we learned that the EO was going to expire, in addition to focusing on the licensing issue, we also focused on the laboratory supervisor issue
- This was another area of regulation that was waived by EO 4



# Supervisor Regulations

- While the EO was in place, we had been continuing to work with the Governor's office and DOH to get a final, updated version of the supervisor regulations in place
- On March 23, 2022, the new updated regulations were published for a 60-day public review and comment period
- However, after the comment period was closed, no final adoption of the regulations was ever done, so the old regulations were still in place if the EO expired
- On March 22, 2023, DOH issued another round of proposed regulations related to the supervisor regulations



# Supervisor Regulations

- After the comment period concluded, these final regulations were adopted on May 6, 2023
- These final regulations were in place before the expiration of EO 4, so there was no concern or worry over a lap in coverage
- With the adoption of the supervisor regulations, DOH noted that there were a few more technical changes that were needed, but in order to avoid any potential gap in coverage between the regulations and the EO, they would address these changes in another round of proposed regulatory changes
- We will continue working with DOH on this and get the final small changes that are needed



# Other Legislative Issues of Note

- S1159 (Senator Skoufis) Requires written notice on the occurrence of false-positive results for any condition included in a prenatal test
- We issued a memo of opposition on the legislation and have had several meetings with the Senator on this bill
- While NYSCLA has no objection to the intent of the bill - providing prospective parents with as much information as possible - the language of the bill is problematic
- The bill is vague and does not distinguish between screening and diagnostic tests
- The bill puts the onus of providing the information to the patients on the labs that perform the testing rather than on the healthcare provider recommending the test
- The Senator seems open to amendments to address our concerns, so we will continue to work with him and his office



# Other Legislative Issues of Note

## ■ Limited Lab Issues

- There have been a variety of proposals to allow additional providers and/or entities to run limited labs (e.g., pharmacists)
- We are carefully monitoring all of these various proposals and responding accordingly based on the details of each specific proposal
- Overall, we would not support something that would allow other entities to function as a Clinical Laboratory without having to meet the same regulatory oversight



# Looking Ahead

- 2024 is going to be a very busy year
- All 213 members of the Senate and Assembly are up for reelection
- All 26 Congressional seats are up for election as is the seat of Senator Kirsten Gillibrand
- The four statewide offices are not up for election, but it is a Presidential Election year as well

# Looking Ahead

- The legislative session will start on January 3, 2024 with the Governor's State of the State address
- Her budget will be due in mid-January
- We are anticipating a tough budget year
- There is a projected deficit - \$9 - \$15 billion
- This gap will not be filled solely with revenue raisers
- Will be looking out for cuts and fees



# 2023 Elections

- There are elections in New York this year
- They are mainly local elections – Election Day is Tuesday, November 7
- Even if you don't have any local elections, there will be two constitutional amendments on the ballot related to school districts and how they raise money
- Go vote!!





??????'s



# Harter Secrest & Emery LLP

ATTORNEYS AND COUNSELORS

ROCHESTER • BUFFALO • ALBANY • CORNING • NEW YORK CITY