Pharmacy Technician Oversight:  
New York’s Journey to the 20th Century and Where We Go From Here

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Knowledge Assessment Question #1

In May 2019, how many pharmacy technicians were employed in New York State?

A. 71,260  
B. 42,400  
C. 20,360  
D. 0  

*Hint: It may be a trick question!*
Employment of pharmacy technicians, by state, May 2019

National - ~422,300
Hospitals - 66,300 (15.7%)
NYS - 20,360

US Bureau of Labor Statistics
https://www.bls.gov/oes/current/oes292052.htm#st
Annual mean wage of pharmacy technicians, by area, May 2019

US Bureau of Labor Statistics

https://www.bls.gov/oes/current/oes292052.htm#st
National Technician Scorecard
Emily Jerry Foundation

https://emilyjerryfoundation.org/
Actually, scoring is quite generous for April 2021!

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>SCORE</th>
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<tbody>
<tr>
<td>Education &amp; Training</td>
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<tr>
<td>Certification</td>
<td>6 of 10</td>
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<tr>
<td>Registration/Licensure</td>
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<tr>
<td>Continuing Education</td>
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<td>Total Score</td>
<td>11 of 35</td>
</tr>
<tr>
<td>Percentage</td>
<td>31%</td>
</tr>
</tbody>
</table>

Please see Appendix 1 for full text of statutes and regulations, on which this scorecard is based.
Statute (Legislature) vs. Regulation (Agencies)

• Statutes dictate the goals and means of legislative intent
  • Statute: “All pharmacists must dispense a peanut butter and jelly sandwich with each prescription”

• Regulations provide the details that allow statutes to work
  • NYS Education Department would write regulations:
    • Pharmacist should assess patient for peanut allergies
    • The peanut butter must be crunchy
    • The bread must be whole wheat
September 12, 2018
“Enforcement Day”

Board of Regents section 29.7 A21IIIB4
The facts underlying this proceeding are not in dispute but the litigants sharply contest the legal consequences based on the facts. Petitioners Genesee Hospital and , the hospital's head pharmacist, were found guilty of misconduct in practicing pharmacy under two specifications: they permitted persons without pharmacy licenses (in this case nurses) to dispense and mix drugs and ingredients, and delegated to them the responsibility of measuring, weighing, compounding and mixing ingredients in preparation of hyperalimentation, peripheral intravenous solutions and intravenous solutions, an activity reserved to a trained pharmacist. The hospital was censured and reprimanded and **351 fined $1,000 under each specification. , was censured and reprimanded and fined $250 under each specification. Petitioners and , nurses who worked for the hospital, were charged with two specifications of unprofessional conduct in the practice of nursing by practicing nursing beyond its scope in that they measured, weighed, compounded and mixed ingredients in preparation of intravenous solutions and prescriptions. They were censured and reprimanded and placed on probation for 18 months to insure their completion of a course of instruction in the legal aspects of nursing. Petitioners then commenced this proceeding challenging the determinations.
But Larry said.....(in 1994)

However, our regulatory structure makes a distinction between compounding and dispensing and the repackaging or manufacturing of medications. This distinction is analogous to federal over-sight of the manufacturing processes that routinely use unlicensed personnel under strict supervision to prepare drugs in bulk quantities. The particular rule to be referenced in this regard is 8NYCRR29.7(a)(15). This rule allows, for example, the repackaging of a bottle of 1000 tablets into containers of 40 tablets each. An unlicensed person, under the supervision of a registered pharmacist can perform this repackaging. The rule requires specific record keeping when this form of repackaging is done, including:

We are often asked if there is a minimum number of units that must be prepared or repackaged (batched). In fact, the rule does not indicate either an upper or lower limit for the repackaging of medications. Therefore, pharmacists must decide, based upon the anticipated needs of the pharmacy how best to utilize limited resources. It is imperative that, regardless of whether 1 or 1,000 units are being prepared for subsequent dispensing, a pharmacist consistently adheres to the standards for record keeping. It is imperative to note that the manufacturing or bulk compounding of products is a procedure expressly allowed for each pharmacy. A registered pharmacy may not sell or transfer such products to another pharmacy despite common ownership of more than one pharmacy.

Not on letterhead, not signed and not on SED website
But this is the guy that signed my license in 1982.....
NYSCHP Position on Technicians Compounding

• “The New York State Council of Health-system Pharmacists supports certified and registered pharmacy technicians, under the supervision of a registered pharmacist, to prepare patient-specific medications in New York State.”

NYSCHP Position Statement 07-16
What was happening in Fall 2018?

- Pharmacy Orgs working with legislature on Tech bill
  - Conversations between legislature and NYSED
- Council heard of OPD changes (Enforcement Day)
  - Changes in interpretation?
  - Talks of $1,000 fines
  - Techs and Pharmacists being re-assigned
- Council brought issue to Pharmacy Conference
  - Attended by BOP and other Pharmacy organizations
  - Discussion of what “batching” means
    - Including “mated” items
  - Members informed
The Council attended the quarterly NYS Pharmacy Conference in Albany, NY on Friday, December 14th. This conference is attended by a wide range of stakeholders in the profession and a full write up will be available in a future newsbrief. One item we’d like to share is a discussion with the Board of Pharmacy and other Conference attendees regarding the role of unlicensed persons (including pharmacy technicians).

Long-standing NYS regulations state that unlicensed persons may not “measure, weigh, compound or mix ingredients”. Traditionally guidance has meant that unlicensed persons (e.g. technicians) may not prepare patient-specific compounds, but with proper oversight by a pharmacist, may create a non-patient-specific “batch” — can draw up fifty 3mL oral syringes, can make twenty IV bags of penicillin, etc. This has also been interpreted to allow the preparation by unlicensed persons of “mated items” — such as antibiotic vials attached to diluents through binary connectors (like addEASE, Vial-Mate, Mini-Bag Plus, etc).

It appears as though the Board is interpreting the above regulations more strictly, implying that unlicensed persons (e.g. technicians) would not be permitted to prepare these batches, as they involve “measuring” or “mixing”. The Board cited the fact that technicians remain unlicensed/unregistered/unregulated in NYS.

The Council has communicated with our Pharmacy Coalition partners – PSSNY, Chain Pharmacy Association, GYNHA Ventures, 1199 trade union — and are currently acting on a strategy of engaging the Governor and the NY Legislature on this issue rapidly, with the hopes of clarifying technician job functions in statute/regulation.

While we are not aware of any enforcement actions reported by members’ hospitals at this time, we understand the members may be concerned about what they are hearing. Our recommendations are to review compounding and “batching” processes in your facilities, ensure good practices and your policies are being followed, and report any concerns to the NYSCHP Board of Directors.

Thank you!

Andrew Kaplan, Pharm.D., BCPS, BCgp
Vice President of Public Policy
BOP Communique 2/25/19

Good Afternoon,

There is no further need for interpretation of Rules of Board of Regents Part 29.7(a)(21)(ii)(b)(4) 29.7(a)(21)(ii)(b)(4). Batching is mixing and therefore not allowed to be performed by an unlicensed staff member.

Regards!

New York State Board of Pharmacy
09 Washington Ave., 2nd Floor West
Albany, NY 12234
Phone: 518-474-3817 ext. 130
Fax: 518-473-6995
Email: phambo@nysed.gov
Web: www.op.nysed.gov/prof/pharm

“Please understand that the Education Department does not answer hypothetical questions, issue advisory opinions or offer detailed legal advice. Such requests should be directed to your attorney. While we can share with you commonly accepted interpretations of applicable laws and regulations, it should be noted that the applicability of statutes and regulations depend ultimately on the distinctive nature of a particular case, which will change given a different set of circumstances.”

“Batching is mixing and therefore is not allowed to be performed by an unlicensed staff member”
Petitions Followed – we needed Legislation

Allow New York State CPhTs to Participate in Advanced Institutional Activities

Historical Fate of Technician Legislation in NYS
Building a Coalition

- Pharmacy Profession
  - NYSCHP
  - PTCB
- Hospitals
  - HANYS
  - GNYHA
- Labor
  - SEIU 1199

Having all stakeholders strongly supporting technician legislation was powerful. It really helped when nobody was voicing opposition to this proposal. What was being proposed recognition of existing practice in NYS and elsewhere.
Comparison with other States (in region)

- **Connecticut**
  - Preparation...sterile products....including use of telepharmacy/electronic technology

- **Rhode Island**
  - A Pharmacy Technician II may....provide immunizations, perform sterile, non-sterile compounding

- **Massachusetts**
  - Reconstitute a prescription; Bulk compounding

- **Vermont**
  - “compounding”

- **New Jersey**
  - Counting, weighing, measuring, pouring and compounding of prescription medication or stock legend drugs and controlled substances, including the filling of an automated medication system

- **New Hampshire**
  - Preparing or compounding sterile and non-sterile compounds

[Links to relevant regulations and guidelines]
Comparison - Other States (unlicensed)

- **Pennsylvania**
  - “Assist the pharmacist in preparing and reconstituting parenteral products and other medications”

- **Colorado**
  - “The preparation, mixing, assembling, packaging, labeling, or delivery of a drug or device;”

- **Wisconsin**
  - Compounding sterile preparations….successful…complet[tion] didactic or practical training

- **Hawaii**
  - Process Rx labels, drug packaging, stocking, delivery, record keeping, pricing, documentation of third party reimbursements, and preparing, labeling, compounding, storing, and providing medication;

- **Delaware**
  - Pharmacist may utilize certified pharmacy technician under the direct supervision of a pharmacist if formulation developed by pharmacist before proceeding with the compounding
 Legislative Process

• Legislation initially included in the budget bill
  • Opposition by key legislators (particularly Higher Ed chair) to include in the budget
  • How does the budget process typically work?
• Support in the Senate for stand alone bill
• Usual opposition in the Assembly – Focus on Higher Education Committee
• Advocacy work by all stakeholders and practitioners
  • Focus on Assembly
  • Key meeting with Chair Glick on May 7, 2019
  • Follow-up meetings with SED to draft legislation – June, 2019
  • Legislation passed by Senate and Assembly (S6517/A8319) – June 20, 2019
  • Governor signs legislation – October 25, 2019
  • 18 months to implement – April 25, 2021
Knowledge Assessment Question #2

Which of the following is **NOT** a requirement for licensure and registration as a pharmacy technician in NYS?

A. At least 18 years of age
B. Pharmacy technician board certification
C. Direct supervision by a licensed pharmacist
D. A high school equivalent education
Registered Pharmacy Technician

*Title VIII, Article 137A §6841(1) – Education Law*

A registered pharmacy technician may, under *direct, personal supervision* of a licensed pharmacist:

- Compound, prepare, label, or dispense drugs
  - Pursuant to or in anticipation of a patient order
  - Tasks that do not require professional judgment (limited to pharmacists)

- Only applicable to Article 28 facility, or a pharmacy owned and operated by an Article 28 facility.

Facility is responsible to assure that registered technician receives appropriate training and maintains competency in compounding skills.

2:1 Tech:Pharmacist ratio is applicable for compounding activities.

*Direct personal supervision means supervision of procedures based on instructions given directly by a supervising licensed pharmacist who remains in the immediate area where the procedures are being performed, authorizes the procedures and evaluates the procedures performed by the registered pharmacy technicians.*
# Registered Pharmacy Technician and Compounding

## Technician Licensure Requirements

- Minimum educational standard
- Board certification (PTCB or NHA)
- Age
- Licensing and registration fees

## Hospital Responsibilities

- Training
- Assessment of competence
- On-going training/assessment
- Supervision
Registered Pharmacy Technician

Title VIII, Article 137A §6844 – Education Law

A registered pharmacy technician must meet the following requirements:

• Application – file an application with the department
• Education – must have at least a high school education
• Certification from a nationally accredited technician certification program acceptable to the department
• Age – at time of application must be at least 18 years of age
• Character – must be of good moral character
• Fee – pay the fee determined by the department ($75 initial license, $100 for first triennial registration period)
Pharmacy Technician Implementation

• Take inventory of duties/functions (current state)
  • Assess desired future state
<table>
<thead>
<tr>
<th>JD Element</th>
<th>Hospital 1</th>
<th>Hospital 2</th>
<th>Hospital 3</th>
<th>Hospital 4</th>
<th>Hospital 5</th>
</tr>
</thead>
</table>
| **Inventory Management** | 3. Maintains adequate stock levels in the Pharmacy  
19. Maintains inventory of all needed intravenous supplies  
13. Rotates all antibiotic products to maintain the maximum expiration and properly disposes of all expired products. | 2. Maintain adequate inventory                                                                 | 2. Maintain adequate inventory                                                                 | Assists in Stocking duties when stock clerk unavailable                      | Ensure appropriate inventory on hand at all times and maintains required balances. |
| **Returns**     | 3. Returns reusable medication to stock                                                                 | 3. Returns reusable medication to stock                                                                 |                                                                 |                                                                 | Returns re-useable medications to stock before the end of the shift. |
| **Stocking of non-ADM** | 4. Prepares/ checks Urgent Use Stock orders for patient care areas accurately and does not over-stock. | 4. Fill unit dose cassette performs statistical count | 4. Fill unit dose cassette performs statistical count | Filing and delivering of inpatient medication cassettes to patient units | Restock unit-dose cassettes and performs statistical count of all doses dispensed. |
| **Deliveries, Restocking** | 2. Retrieves and delivers medication in a timely fashion  
21. Delivery of patient IV’s to Nursing Units  
14. Fills orders for satellites not involved with centralized IV program. | 5. Deliveries/rounds | 5. Deliveries/rounds | Filing and delivering of inpatient medication cassettes to patient units  
Assists in floor stock preparation and delivery as needed | Conducts all required deliveries and other patient care area rounds in a timely fashion. |
| **Repackaging** | 6. Repackage medications                                                                 | 6. Repackage medications                                                                 |                                                                 | Prepares unit dose prepackaging of medications | Repackages medications as per departmental policy. |
| **Parenteral** | 10. Reconstitutes antibiotic piggyback bottles with the proper diluents using aseptic technique.  
11. Defrosts frozen antibiotic intravenous mini-bags.  
12. Prepares antibiotic concentrate and aseptically adds to diluents mini-bags. | 7. Prepares parenteral products under direct supervision | 7. Prepares parenteral products under direct supervision | Assisting in the sterile and non-sterile intravenous and extemporaneous products | Prepares parenteral and extemporaneous batch products under the direct supervision of a pharmacist. |
Registered Pharmacy Technician Implementation

• Take inventory of duties/functions (current state)
  • Assess desired future state

• Decide whether one or multiple job descriptions
  • Assess current workflow and workforce certification
  • Bargaining unit, if applicable, can be helpful

• Interface with HR/Labor/Union/DOP’s and set clear expectations
  • Communication key to success
### Align Titles with Job Descriptions

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<td>Pharmacy Technician/Buyer</td>
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</tbody>
</table>
Pharmacy Technician Implementation

• Take inventory of duties/functions (current state)
  • Assess desired future state
• Decide whether one or multiple job descriptions
  • Assess current workflow and workforce certification
  • Bargaining unit, if applicable, can be helpful
• Interface with HR/Labor/Union/DOP’s and set clear expectations
  • Communication key to success
• Effective 4/25/2021, certain duties no longer allowed
  • “They were never allowed to begin with”
• If employ both registered/certified and unlicensed
  • Need clear distribution of duties, training, and strong oversight
NYSCHP Position on Certified Technicians

• “The New York State Council of Health-system Pharmacists supports Directors of Pharmacy, as hiring managers establish a condition of employment for pharmacy technicians at their institution. Such a condition of employment would include the recruitment and hiring of technicians who are certified by ASHP/PTCB.”
Adequate Training and Assessment of Competence

How do you meet this standard?

• Recommend the following:
  • Detailed Policies and SOPs in existence
  • Documentation that all registered technicians have been trained on policy and SOPs – Training checklist
  • Formal assessment and documentation of competencies for SOPs – direct observation and assessment
  • USP-mandated finger tip and media fill testing completed and documented
  • At least annual re-assessment of competency
  • Large institutions – consider having a trainer position with responsibility of maintaining all records and assuring training and competencies are completed

• Some very good software available – e.g. Critical Point

• “See one, do one, teach one” is not going to cut it.
This document is 12 pages in total.

It defines all aspects of training, policy to be reviewed and documentation of completion.

Critical Point software used for documentation and on-going assessment.
Knowledge Assessment Question #3

What is the single largest impact of the new technician legislation in NYS?

A. Technicians can continue to participate in compounding
B. Increased technician:pharmacist ratio for other activities
C. Legal recognition of pharmacy technicians
D. That cool certificate you can frame and hang!
“The Future is Now”

• PTCB Certifications
  • Certified Pharmacy Technician (CPhT)
  • Certified Compounded Sterile Preparation Technician (CSPT)
  • Advanced Certified Pharmacy Technician (CPhT-Adv)
  • Billing and Reimbursement Certificate
  • Controlled Substances Diversion Prevention Certificate
  • Hazardous Drug Management Certificate
  • Immunization Administration Certificate
  • Medication History Certificate
  • Technician Product Verification Certificate

• Immunization Authority

• Tech Check Tech
Pharmacy Technician Immunization

• Several states allowed (Idaho, Rhode Island, Utah) as of June 2020

https://tinyurl.com/htvzkpx4
PHARMACY TECHNICIAN IMMUNIZATION TRAINING

https://pharmacy.wsu.edu/pharmacy-technician-immunization-training/
Pharmacy Technician Immunization

• Several states allowed (Idaho, Rhode Island, Utah) as of June 2020
• HHS issued guidance 10/20/2020 under PREP Act
  • Allowing all “Qualified Pharmacy Technicians” to administer COVID-19 vaccine
• Governor Cuomo signed EO 202.90 1/12/2021
  • Temporary licensure of technicians to administer COVID-19 vaccine
  • Under direct personal supervision by a pharmacist
• To vaccinate, pharmacy technician must:
  • Be certified (PTCB or NHA)
  • Complete immunization training approved by the ACPE (include APhA program)
  • Hold CPR certificate
  • Complete NYSDOH Training for Vaccinators
  • Complete 2 hours of ACPE approved CE on immunization within six months

https://tinyurl.com/htvzkpx4
Nebraska Governor Signs Tech-Check-Tech Legislation

On March 12, Governor Pete Ricketts (R) approved Nebraska Legislative Bill 74. The bill allows certified pharmacy technicians to engage in tech-check-tech programs within a hospital setting. Nebraska is the 13th state to approve tech-check-tech for pharmacy technicians. The new law will go into effect on September 6, 2019.
Legal Recognition of Pharmacy Technicians

• The door is open for the first time….pharmacy technicians legally exist in NYS as of April 25, 2021!

• Greater opportunity to promote pharmacy technician careers

• Board certification will indirectly drive minimum education and training standards

• Opportunity to create differentiation in career development of pharmacy technicians

• Is sure to lead to continued growth of the roles of the registered pharmacy technician

• Ultimately will translate into greater compensation
Summary

• Pharmacy technicians finally have legal standing in NYS
• This is only the start of a long road to modernization of the regulatory framework of pharmacy practice in NYS
• Recognition is going to lead to greater career opportunities for the technician workforce
• Recognition, licensure, and career paths are going to lead to greater compensation.
• Much work remains to be done to advance both technician roles and the practice of pharmacy in NYS