Compounded Sterile Preparations Pharmacy (BCSCP)

2020 Role Delineation Study Revalidation

Executive Summary

Introduction

In Spring 2020, the Board of Pharmacy Specialties (BPS) initiated a role delineation revalidation study (RDS) for the Compounded Sterile Preparations (CSP) Pharmacy certification (BCSCP). The primary purpose of the study was to review and to revalidate the existing tasks and knowledge defining the role of the pharmacist practicing in CSP Pharmacy. The original role delineation was conducted in 2016. Per BPS policy and guidance from accrediting bodies, role delineations and the related knowledge, skills, and abilities should be periodically evaluated to ensure that the scope of certification remains current with practice. However, due to the recent launch of the BCSCP program (Fall 2019), comprehensive reconfiguration of the content scope is not advantageous this time. Thus, the current re-validation project focused on confirming that the knowledge, skills, and abilities on the current content framework remain relevant to practice.

Since the RDS also provides a basis on which content is validated, certification examinations are developed from its outcome, and the RDS process is in alignment with recognized standards established by the testing industry. The re-validation of the Compounded Sterile Preparations Pharmacy content framework was undertaken primarily through conduct of a survey to empirically validate the description of specialty practice and development of the current examination content outline.

Methodology

The current content outline was converted into an online questionnaire format in web-based delivery platform (Qualtrics) in order to collect validity ratings.

All Board-certified pharmacists in Compounded Sterile Preparations Pharmacy (holding the BCSCP credential) were invited to review and validate the work of the RDS Panel by completing the online survey. To increase the response rate, the survey was also disseminated through the following affiliate organizations:

- American Society of Health-System Pharmacists (ASHP)
- American Society of Consultant Pharmacists (ASCP)
- National Home Infusion Association (NHIA)
- Alliance for Pharmacy Compounding (APC)
- APhA Special Interest Group on Sterile Compounding

A qualified and representative sample of pharmacists specializing in Compounded Sterile Preparations Pharmacy provided data. Of those practitioners invited, 210 were actively engaged in sterile
compounding and provided qualified, useful responses, completing at least a substantial proportion of the survey. The survey was open and available from June 24 – August 3, 2020.

Respondents were asked to evaluate each task and knowledge element in the content outline, rating them using 4-point scale for Point of Acquisition and a 5-point scale for Frequency (how often the task is performed, or knowledge invoked in practice). Point of Acquisition was conceptualized as a question: at what point in relation to entering the specialty is the task performed or knowledge required? Frequency was defined as how often the pharmacist performs duties that require proficiency in each of the knowledge elements.

- **Point of Acquisition:**
  - 1 = Not at all
  - 2 = Within the first year of entering the specialty
  - 3 = Between 1-4 years of entering the specialty
  - 4 = Only beyond 4 years of entering the specialty

- **Frequency:**
  - 1 = Never / Not at all
  - 2 = Yearly
  - 3 = Monthly
  - 4 = Weekly
  - 5 = Daily

**Results**

The primary domains exhibited very high endorsement on both of the rating scales. While space in this executive summary does not permit reporting these indices for every element of the outline, similar summaries of survey ratings were evaluated by the BPS psychometricians for every task and knowledge statement on the survey. The conclusions are as follows:

- The respondent sample was representative of population of pharmacists specializing in Compounded Sterile Preparations Pharmacy.
- All of the tasks delineated in the 5 domains exhibited moderate to high levels of endorsement, and all were consequently retained.
- All of the knowledge elements in 5 domains of the content outline exhibited moderate-to-high levels of endorsement from the respondents and are recommended for retention on the outline.
- Open ended comments reflecting suggestions for additional tasks and knowledge elements were reviewed and considered by the BPS for inclusion. It was found that most of these fit into one or more domains and existing task and knowledge statements.
Test specifications

A statistical analysis and subsequent review of the survey ratings of the respondent sample also formed the basis for a test blueprint for the Compounded Sterile Preparations Pharmacy specialty examination. The test blueprint indicates relative emphasis that each domain will receive on the examination and translates into the number of questions an examinee will receive from each core domain.

The table below the proposed domain weights calculated by several methods from the survey data, the average of these methods, as well as the recommendation for domain weights to the Council.

- The first method is an analytical approach which involves using the average of the Frequency ratings for the knowledge statements and summing those averages within each domain. The percentage for each domain is calculated by dividing the sum of frequency means for the knowledge elements within a given domain, by the sum of frequency means for all domains.
- The second method is based on a holistic approach, in which the percentage for each domain is calculated by simply taking the average of domain weight allocations indicated by respondents on the survey.

The recommendation is to increase the percentage of questions in Domain 3 from 25% to 30%, and to reduce the percentage of questions in Domain 1 from 20% to 15%. The implementation of this revised blueprint would be Fall 2021.

<table>
<thead>
<tr>
<th>Domain (%) from 2016 RDS</th>
<th>Knowledge Statement Frequency</th>
<th>Respondents</th>
<th>Average</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Standards, Regulations, and Best Practices (20%)</td>
<td>6%</td>
<td>23%</td>
<td>15%</td>
<td>15%</td>
</tr>
<tr>
<td>II. Facilities, Equipment, and Environmental Control (20%)</td>
<td>17%</td>
<td>20%</td>
<td>18%</td>
<td>20%</td>
</tr>
<tr>
<td>III. Compounded Sterile Preparations (25%)</td>
<td>35%</td>
<td>29%</td>
<td>32%</td>
<td>30%</td>
</tr>
<tr>
<td>IV. Patient Care (15%)</td>
<td>20%</td>
<td>14%</td>
<td>17%</td>
<td>15%</td>
</tr>
<tr>
<td>V. Quality Management (20%)</td>
<td>22%</td>
<td>16%</td>
<td>19%</td>
<td>20%</td>
</tr>
</tbody>
</table>

Conclusion

BPS conducted this role delineation survey in order to revalidate a framework for content development of the Compounded Sterile Preparations Pharmacy specialty certification, to verify and maintain a linkage between the certification examination specifications and actual role requirements of the pharmacists in this specialty area, and to allow the community of practitioners of Compounded Sterile Preparations Pharmacy to provide input into the design of the examination.
Tasks and knowledge elements of the content outline were revalidated using scales indicating Point of Acquisition and Frequency. These data supplied support for decision-making about what elements should be retained or deleted from the content outline and how primary domains should be weighted.

Respondents’ data provided strong evidence of validity for the five domains of the content outline, as well as for all tasks and knowledge statements included in the content outline. Slight adjustments were recommended to the domain weights (%) to align to survey evidence and item writing efforts. After revisiting the current outline, it is determined to keep the current outline that was developed in 2016 and launched in Fall 2019, with minor adjustments to the domain percentages in Domains 1 and 3. Barring any urgent need to introduce revisions, this content framework and test blueprint will remain in effect until the next scheduled RDS in 2025.
Compounded Sterile Preparations Pharmacy (BCSCP) Role Delineation Study (RDS)

The purpose of the BPS Board Certified Compounded Sterile Preparations Pharmacy (BCSCP) program is to validate a pharmacist’s advanced knowledge and experience to:

- Ensure quality patient care;
- Improve therapeutic outcomes;
- Assure safety; and
- Supervise, train, and ensure competency of all personnel involved in sterile compounding.

2020 Finalized Compounded Sterile Preparations Pharmacy Outline

Domain 1: Standards, Regulations, and Best Practices (15%)

Task 1: Comply with state and federal regulations

Knowledge of:

a. Federal regulations related to sterile preparation (e.g., Drug Quality and Security Act, Food and Drug Administration guidance documents, Center for Medicare and Medicaid Services)
b. Federal regulations related to workplace and patient safety (e.g., Occupational Safety and Health Administration, National Institute for Occupational Safety and Health, Environmental Protection Agency)
c. Relationship between federal and state requirements

Task 2: Use standards and best practices to develop and implement standard operating procedures for patient safety

Knowledge of:

a. Standards related to sterile preparation (e.g., United State Pharmacopeia, National Institute for Occupational Safety and Health)
b. Best practices (e.g., Institute for Safe Medication Practices, Centers for Disease Control and Prevention, ASPEN, ASHP, Oncology Nursing Society, Infusion Nurses Society, accrediting bodies)

Task 3: Respond to inspection and survey reports with corrective and preventive actions

Knowledge of:
  a. Regulatory requirements for responding to inspection and survey reports (e.g., Food and Drug Administration, Drug Enforcement Administration, Occupational Safety and Health Administration, state regulatory agencies, accrediting bodies)
  b. Corrective and preventive action plans

Domain 2: Facilities, Equipment, and Environmental Control (20%)

Task 1: Assess the facility’s needs, size, and engineering controls to optimize patient care and ensure initial and ongoing compliance with regulations and standards

Knowledge of:
  a. Fundamentals of primary and secondary engineering controls (e.g., airflow patterns, Biological Safety Cabinet, ISO Class 5 work bench, robotic devices, restricted access barrier system, isolators, buffer room, ante area, certification requirements)
  b. Principles of viable and non-viable particle generation and control
  c. Specification of equipment and materials within compounding environments
  d. Principles of design and construction of secondary engineering control; storage, and compounding environments (e.g., ISO air quality specifications; sink placement; flooring; ceiling tiles; pressure gradients; wall joints; airflow patterns; air returns; Heating, Ventilation, and Air Conditioning; air changes per hour; temperature; humidity)

Task 2: Use appropriate processes to clean, disinfect, and decontaminate engineering controls, equipment, materials, and compounding environments

Knowledge of:
  a. Supplies and agents for cleaning and disinfecting (e.g., germicidal, disinfectants, sporicidals, wipes)
  b. Techniques and frequency for cleaning and disinfecting (e.g., dwell time, contact time)
  c. Cleaning, disinfecting, deactivating, and decontaminating hazardous compounding environments and equipment

Task 3: Perform personal hygiene and garbing procedures to minimize particles and bioburden
domain 3: compounded sterile preparations (30%)

task 1: specify requirements for equipment, supplies, active pharmaceutical ingredients (api), and other ingredients

knowledge of:

a. requirements for the quality of source materials from fda-registered facilities (e.g., united states pharmacopeia, national formulary, or a component of an approved drug product)

b. requirements pertaining to the verification of source materials (e.g., certificate of analysis, safety data sheet, visual inspection)

c. storage of source materials (e.g., temperature, humidity, light)

d. equipment and supplies that are suitable and compatible for use (e.g., propriety bags and vial systems, pharmacy bulk packages)

e. containers and closures (e.g. sterile, depyrogenated, certificates of analysis)

f. record keeping required upon receipt of items (e.g., date received, dating of stored materials, lot, expiration)

g. disposal procedures for equipment, supplies, active pharmaceutical ingredients (api), and other ingredients

h. beyond use dating of final compounded sterile preparations

task 2: verify components using specifications to determine suitability

knowledge of:
a. Requirements for the quality of source materials from Food and Drug Administration-registered facilities (e.g., United States Pharmacopeia, National Formulary, or a component of an approved drug product or on the Food and Drug Administration approved list)

b. Acceptance criteria, certificate of analysis
c. Inspection for integrity
d. Proper handling, storage, and use
e. Equipment that is suitable for use (e.g., automated compounding device in the proper volume range, compatibility of active pharmaceutical ingredients with devices, calibration)

Task 3: Compound sterile preparations in accordance with regulations, standards, and best practices

Knowledge of:

a. Work flow processes consistent with best practices
b. Development of master formulation records and use of compounding logs
c. Equipment and supplies (e.g., pediatric considerations, considerations for hazardous or biologic preparations, chemically interactive compounded sterile preparations, filters, heating apparatus)
d. Calculations
e. Proper personal protective equipment for hazardous and non-hazardous compounding (e.g., garbing and hand hygiene)
f. Methods of sterilization (e.g., steam, filtration, dry heat)
g. Aseptic technique and appropriate manipulations for hazardous and non-hazardous preparations
h. Visual inspection and other tests for final release of hazardous and non-hazardous preparations
i. Pre-release storage requirements
j. Requirements related to batching versus single-patient use

Task 4: Evaluate conditions that may compromise compounded sterile preparations

Knowledge of:

a. Detection of quality issues using compounding documentation and batch yields (e.g., theoretical vs. actual yields, master formulation record and compounding logs)
b. Physicochemical characteristics (e.g., compatibility, tonicity, osmolarity, solubility, leaching)
c. Issues related to cleaning and maintenance (e.g. incorrect or lack thereof)
d. Issues related to the environment (e.g. temperature, humidity, lighting, air quality)
e. Issues related to storage, handling, and transporting
f. Issues related to equipment (e.g., calibration, malfunction)
g. Issues related to personnel (e.g., non-compliance, improper training, lapse in competence, inadequate supervision, infection control)
h. Issues related to supplies (e.g., improper selection, incompatibility)
i. Issues related to components (e.g., improper storage, deterioration, expiration)
j. Issues related to cross-contamination of preparations

Task 5: Perform quality checks for the release of compounded sterile preparations
Knowledge of:
   a. Sample size required for quality control testing
   b. Post-compounding testing (e.g., physical appearance, sterility, analytical testing, endotoxin, filter integrity)
   c. Verification of final label
   d. Requirements for transport (e.g., packaging, temperature, mode, radiation shielding)

**Domain 4: Patient Care (15%)**

Task 1: Assess factors related to compounded sterile preparations that affect patient outcomes

Knowledge of:
   a. Patient-specific parameters (e.g., laboratory values, disease state, age, pathophysiology, anatomy, pharmacology, infectious disease)
   b. Preparation-specific parameters (e.g., microbiology, pharmaceutical chemistry, compatibility, chemical stability)
   c. Patient adherence
   d. Applicable regulatory implications
   e. Availability, cost, and timeliness
   f. Routes and methods of administration
   g. Delivery systems
   h. Strategies for communicating with prescribers and other members of the healthcare team

Task 2: Educate patients and healthcare professionals on compounded sterile preparations, and on their administration and use

Knowledge of:
   a. Signs and symptoms of adverse events
   b. Storage, handling, and disposal requirements
   c. Preparation and administration techniques
   d. Duration of therapy
   e. Safety, hazards, and infection control
   f. Adherence
   g. Drug information
   h. Communication systems for problems, concerns, and complaints

Task 3: Evaluate adverse events to prevent future occurrences and to satisfy reporting requirements

Knowledge of:
   a. Nature and incidence of previously reported adverse events (e.g., primary bloodstream infection, phlebitis, extravasation, loss of patency)
   b. Mechanisms and symptomatology associated with adverse events
   c. Methods for treating or alleviating adverse events
d. Adverse event investigation and reporting systems
e. Troubleshooting and identifying the source of adverse events (e.g., root cause analysis)

**Domain 5: Quality Management (20%)**

Task 1: Train staff didactically and experientially on aseptic processes, infection control, equipment, and applicable regulations and standards for hazardous and nonhazardous preparations

Knowledge of:

a. Regulatory requirements, accreditation standards, and standards of practice
b. Aseptic processes and appropriate manipulations
c. Equipment and supplies
d. Principles of adult education
e. Safety culture (e.g., error prevention, hazard communication, medical surveillance)

Task 2: Assess staff competence through direct observation and testing

Knowledge of:

a. Regulatory requirements and standards of practice
b. Aseptic processes and appropriate manipulations
c. Equipment and supplies
d. Requirements for observation and testing

task 3: Remediate deficiencies in staff competence

Knowledge of:

a. Strategies for determining the root cause of deficiencies
b. Principles of adult education
c. Corrective and preventive actions

Task 4: Implement a quality control program

Knowledge of:

a. Measurement and interpretation of environmental monitoring results (e.g., hazardous drug surface contamination, pressure differentials, viable and nonviable particulates)
b. Measurement and interpretation of personnel compliance and competence
c. Measurement and interpretation of aseptic compounding processes and outcomes (e.g., master formulation records, compounding records, reproducibility)
d. Equipment calibration and verification
Task 5: Document all aspects of the compounding process and quality control

Knowledge of:
- a. Master Formulation Records
- b. Compounding records
- c. Error reporting and analysis
- d. Documentation practices (e.g., frequency of review of SOPs, recall management)

Task 6: Provide direction for performance improvement by analyzing and acting on quality control data

Knowledge of:
- a. Quality control processes and continuous quality improvement tools (e.g., Corrective and Preventive Action method)

Task 7: Ensure outsourced products and services comply with established process standards and facility requirements

Knowledge of:
- a. Applicable standards pertaining to compounding equipment certification (e.g., Controlled Environment Testing Association, National Environmental Balancing Bureau, National Institute for Standards and Technology, Institute of Environmental Science and Technology)
- b. Professional organization guidance documents for sterile compounding (e.g., ASHP Guidelines on Compounding Sterile Preparations, ASHP Guidelines on Hazardous Drugs, ASHP Guidelines on Outsourcing Sterile Compounding Services, ASHP Foundation tool on Evaluating Sterile Compounding Services, APhA Radiopharmaceutical Vendor Pharmaceutical Checklist, Institute for Safe Medication Practices)
- c. Effective inspection methods
- d. Development and implementation of environmental sampling plans
- e. Environmental services
- f. Hazardous waste management