

Legal Preparedness Toolkit Project

Revision Plan – Group 3
July 24, 2019

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Refresher: Current Document Types

- **Executive Overviews**
One-page snapshots of key concepts and issues
- **Fact Sheets**
One-page documents addressing fundamental issues or legal authorities
- **Issue Briefs**
In-depth information and analyses of fundamental issues
- **State Analysis Guides**
Aids to assist states in identifying / analyzing their statutes, regulations, and policies
- **Current Issues and Updates**
Periodic updates on new and evolving issues
- **Resource Materials**
Bibliographies and links to key agencies, organization, laws, and other documents

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Revisions Across All Toolkits

- Overall goals of revision
 - Update contents
 - Streamline the various types of documents in the toolkits
 - Eliminate redundancies among and within documents
 - Create documents that can be used in more than one toolkit
 - Reorganize the way toolkit documents are presented
- Create framework for addition of future documents/toolkits

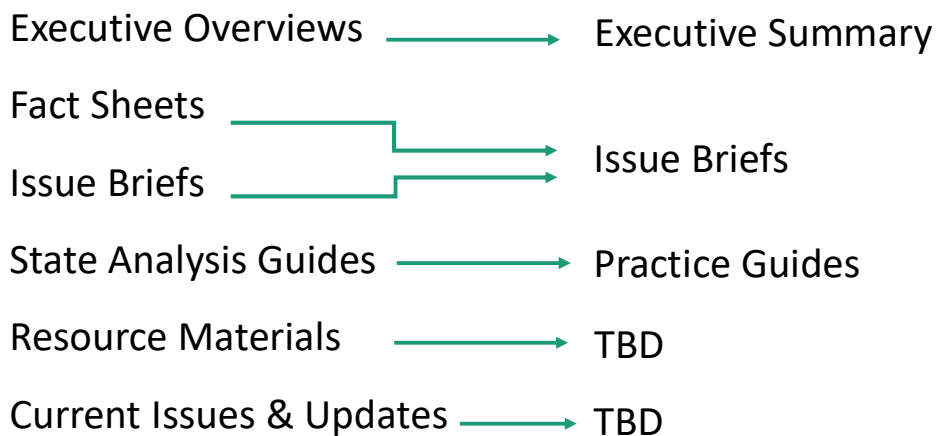
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Streamlined Document Types

Current Toolkits

Revised Toolkits



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Revised Document Types

- **Executive Summary**
 - 2 to 3-page summary of all issues in toolkit; 1 Executive Summary per toolkit
- **Issue Briefs**
 - 4 to 10-page documents; multiple issue briefs; may be used in more than one toolkit
- **Practice Guides**
 - 3 to 6-page documents; combines prior SAGs with practice notes in documents
- **Resource Materials**
 - Will be included; still reviewing options
- **Current Issues & Updates**
 - Will be reserved for future use - TBD

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Eliminate Redundancies

- **Goal:** To the extent possible, eliminate/reduce redundancies among and within toolkit documents while explaining how an issue applies to the toolkit topic
- **Proposed Solution:** Provide fuller explanation of key issues in expanded fact sheets (issue briefs), while streamlining prior issue briefs and eliminating prior fact sheets that are repetitive of issue brief contents
- **Example:** Description of HIPAA Privacy Rule in multiple documents within (and across toolkits)

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Create Documents for Use in Multiple Toolkits

- **Goal:** Create a single document on an issue that can be used in multiple toolkits
- **Proposed Solution:** Create more comprehensive documents about specific topics that apply across multiple toolkits to reduce redundancies and make future updates easier
- **Example:** Create a more comprehensive document about HIPAA Privacy Rule than current 2-page fact sheet in Schools toolkit; use this new document in Information Sharing toolkit and in Schools toolkit

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Reorganize How Toolkit Documents are Presented

- **Currently:** By document type within the toolkit table of contents/ landing page
- **Proposed Solution:** Organize by sub-issues within toolkits
- **Example:** From the PH & Information Sharing toolkit:

PH & Information Collection, Use, Sharing, and Protection

- IB - PH Legal Authorities to Collect, Use, Share, and Protect Information
- IB - FERPA
- IB - HIPPA Privacy Rule
- Practice Guide – PH & Information Collection, Use, Sharing, and Protection

PH Collection and Use of Information as an Employer

- IB - PH Collection and Use of Information as an Employer
- IB – ADA
- Practice Guide - PH and Employee Information

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Questions ?



Comments

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Emergency Use Authorization Toolkit

Summary of Revisions

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Refresher: Current EUA Toolkit Documents

Executive Overviews	• Key Emergency Use Authorization and Medical Countermeasures Laws and Programs (2 p)
Fact Sheets	• Emergency Use Authorization: §564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (4 p) • Comparing Emergency Use Authorization to Investigational New Drug & Investigational Device Exemption Protocols (2 p) • Federal Shelf Life Extension Program (SLEP) (4 p) • Project BioShield Act (2 p) • Public Readiness and Emergency Preparedness Act (PREP Act) (2 p) • Strategic National Stockpile (SNS) (2 p)
Issue Briefs	
State Analysis Guides	• State Pharmaceutical and Dispensing Authorities (5 p)
Current Issues & Updates	• Current Issues and Updates—Winter 2012—Pandemic and All-Hazards Preparedness Act Reauthorization (2 p) • Current Issues and Updates—Fall 2011—FDA Doxycycline Mass Dispensing EUA (1 p) • Current Issues and Updates—Summer 2011—Evolving Policy Issues (2 p)
Supplemental Materials	(7 p)
<i>Total Documents</i>	11 (12)

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EUA Toolkit Revisions – Overview of Changes

- Change name of toolkit to “Medical Countermeasures and Distribution”
- Focus on the three facets of issue: (1) Medical countermeasures and distribution; (2) State and federal medical products issues; (3) Key federal laws
- Eliminate/combine existing executive overviews into a new Executive Summary document
- Streamline/combine fact sheets on EUA, SLEP and SNS into new Issue Brief(s)
- Create Issue Brief on state vs. federal medical products issues from existing fact sheets and state analysis guide
- Expand fact sheets on key federal laws to create Issue Briefs
- Create new Practice Guides from existing state analysis guide and “practice notes” sections in current fact sheets and issue briefs

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Revised Documents – Executive Summary

Current

Executive Overviews

- Key Emergency Use Authorization and Medical Countermeasures Laws and Programs

Revised

Executive Summary

- Medical Countermeasures and Distribution
 - Will cover three areas:
 - Medical countermeasures and distribution
 - State and federal medical products issues
 - Key federal laws

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Revised Documents – Medical Countermeasures & Distribution

Current

Fact Sheets

- Emergency Use Authorization: §564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act)
- Comparing Emergency Use Authorization to Investigational New Drug & Investigational Device Exemption Protocols
- Federal Shelf Life Extension Program (SLEP)
- Strategic National Stockpile (SNS)

Revised

Issue Briefs

- Medical Countermeasures and Distribution

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Revised Documents – State and Federal Medical Products Issues

Current

Fact Sheets

- Federal Shelf Life Extension Program (SLEP)
- Strategic National Stockpile (SNS)

State Analysis Guides

- State Pharmaceutical and Dispensing Authorities

Revised

Issue Brief

- State and Federal Medical Products Issues

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Revised Documents – Key Federal Laws

Current

Fact Sheets

- Project BioShield Act
- Public Readiness and Emergency Preparedness Act (PREP Act)

Revised

Issue Briefs

- Pandemic and All-Hazards Preparedness and Advancing Innovation Act
 - Project BioShield Act
- Public Readiness and Emergency Preparedness Act (PREP Act)

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Revised Documents – Practice Guides

Current

Fact Sheets

- “Practice Notes” sections

Issue Briefs

- “Practice Notes” sections

State Analysis Guides

- State Pharmaceutical and Dispensing Authorities

Revised

Practice Guides

- Medical Countermeasures and Distribution
- State and Federal Medical Products Issues

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Summary of Revised Documents – MCMs & Distribution

Executive Summary	• Medical Countermeasures and Distribution
Issue Briefs	• Medical Countermeasures and Distribution • State and Federal Medical Products Issues • Pandemic and All-Hazards Preparedness and Advancing Innovation Act • Public Readiness and Emergency Preparedness Act (PREP Act)
Practice Guides	• Medical Countermeasures and Distribution • State and Federal Medical Products Issues
Current Issues & Updates	<i>[Reserved]</i>
Supplemental Materials	<i>[TBD]</i>
<i>Total Documents</i>	<i>7 (8)</i>

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Questions ?



Comments

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Scope of Practice Toolkit

Summary of Revisions

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Refresher: Current Scope of Practice Documents

Executive Overviews	• Scope of Practice Key Issues and Concepts (1 p)
Fact Sheets	• Modified Scope of Practice Used by States in the 2009 H1N1 Influenza Pandemic (2 p) • Scope of Practice Issues in Public Health Emergencies (4 p) • Understanding Licensing, Credentialing, Certification, and Privileging (1 p)
Issue Briefs	
State Analysis Guides	• Scope of Practice Issues (5 p)
Current Issues & Updates	
Supplemental Materials	(7 p)
<i>Total Documents</i>	5 (6)

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Scope of Practice Toolkit Revisions – Overview of Changes

- Focus toolkit into two areas: (1) scope of practice issues; and (2) PH interactions with state licensing boards/agencies
- Eliminate/combine existing executive overview and one fact sheet into a new Executive Summary document
- Eliminate/combine fact sheets on scope of practice, etc. into a new Issue Brief
- Create a new Issue Brief about relationship of PH to state licensing boards/agencies in scope of practice issue
- Create two new Practice Guides based on focus areas; conduct new research and repurpose information in existing state analysis guide and “practice notes” sections in current fact sheets and issue briefs

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Revised Documents – Executive Summary

Current

Executive Overview

- Scope of Practice Key Issues and Concepts

Fact Sheet

- Understanding Licensing, Credentialing, Certification, and Privileging

Revised

Executive Summary

- Scope of Practice
 - Will cover two areas:
 - Scope of practice issues
 - PH interactions with state licensing boards/agencies

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Revised Documents – Scope of Practice

Current

Fact Sheets

- Modified Scope of Practice Used by States in the 2009 H1N1 Influenza Pandemic
- Scope of Practice Issues in Public Health Emergencies
- Understanding Licensing, Credentialing, Certification, and Privileging

Revised

Issue Briefs

- Scope of Practice Issues in Public Health Emergencies

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Revised Documents – Interactions with Licensing Boards

Current

Fact Sheets

- Scope of Practice Issues in Public Health Emergencies
- Understanding Licensing, Credentialing, Certification, and Privileging

State Analysis Guides

- Scope of Practice Issues

Revised

Issue Brief

- PH Interactions with State Licensing Boards and Agencies

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Revised Documents – Practice Guides

Current

Fact Sheets

- “Practice Notes” sections

Issue Briefs

- “Practice Notes” sections

State Analysis Guides

- Scope of Practice Issues

Revised

Practice Guides

- Scope of Practice Issues
- PH Interactions with State Licensing Boards and Agencies

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Summary of Revised Documents - SOP

Executive Summary	• Scope of Practice
Issue Briefs	• Scope of Practice Issues in Public Health Emergencies • PH Interactions with State Licensing Boards and Agencies
Practice Guides	• Scope of Practice Issues • PH Interactions with State Licensing Boards and Agencies
Current Issues & Updates	<i>[Reserved]</i>
Supplemental Materials	<i>[TBD]</i>
<i>Total Documents</i>	<i>5 (6)</i>

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Questions ?



Comments

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