The information contained in the Initial Statement of Reasons at the time of Public Notice remains unchanged. As authorized by Government Code Section 11346.9(d), the California Department of Public Health (Department) incorporates by reference the Initial Statement of Reasons prepared for this rulemaking.

The regulation text was made available for public comment for at least 45 days, from February 19, 2021 through May 6, 2021. A Public Hearing was held on April 14, 2021. A summary of public comments is below.

**Statements of Determinations**

**Local Mandate Determination:**
The Department has determined that the regulation would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by part 7 (commencing with Section 17500) of division 4 of the Government Code, nor are there any other nondiscretionary costs imposed. The change clarifies the authority of local governments and the state in authorization of a syringe exchange program (SEP). It does not create new mandates. All authority was established in 2011 through passage of Assembly Bill (AB) 604 (Skinner, Statutes of 2011) and defined in Health and Safety Code 121349(b) and 121349(c).

**Economic Impact Assessment:**
These proposed regulations do not eliminate jobs but may create new job opportunities as they may provide additional opportunities for new SEPs to form. These proposed regulations may allow existing SEPs doing business within the State of California to increase the size or scope of their operations or expand into new geographic areas to respond to public health need.

**Anticipated Benefits to Public Health, Worker Safety and the Environment:**
These proposed regulations will not affect worker safety. They may improve the health and welfare of California residents by affording the creation of new SEPs, which have been found to reduce the transmission of HIV, HCV and other bloodborne pathogens.

Scientific studies have found that the presence of SEPs increases the likelihood that used syringes will be safely disposed of, and thus reduce litter in the environment. SEPs also reduce the odds that used syringes in circulation contain viral or bacterial pathogens, and thus protect public health by reducing the potential infectiousness of injection equipment that may be reused or shared by people who inject drugs.

**Consideration of Reasonable Alternatives:**
The Department must determine that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the
Department would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulatory action or would be more cost-effective to affected private persons. Because this proposal makes technical, non-substantive, or clarifying changes to current regulations, the Department made an initial determination that no reasonable alternative existed.

The Department considered two types of suggestions from commentators on elements of the proposed rulemaking, including:
1. To leave the regulations unchanged.
2. To leave the length of the public comment period at 90 days.

The Department rejected these alternative proposals, in part because the length of public comment period was changed in Health and Safety Code 121349(e) and must be changed in the regulations to match. No other suggestions for changes to the proposed regulations were submitted by the public.

Consequently, in accordance with Government Code Section 11346.9(a)(4), the Department has determined that no alternative would be more effective in carrying out the purpose for which the regulation is proposed; or would be as effective and less burdensome to affected private persons than the proposed regulation; or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Authority Cited and References

Two code sections have changed since DPH-11-021, Syringe Exchange Program Certification was finalized in 2013. AB 1743 (Ting, Chapter 331, Statutes of 2014) deleted BCP 4145, and AB 2077 (Ting, Chapter 274, Statutes of 2020) deleted HSC 121285. References to these code sections are now deleted from the Authority Cited and References sections in CCR Title 17, Sections 7000, 7002, and Section 7014. These are non-substantial changes.

Public Comment Period and Public Hearing

Of the 289 written comments received during the public comment period, 167 were in support of the proposed regulations, 122 were in opposition.

The public hearing was held virtually due to COVID-19 protocols on April 14, 2021. Eighty-four people logged on to the hearing and 24 commented. Thirteen were in support of the proposed regulations, 11 were in opposition.

Nineteen municipalities or local elected officials also commented either in writing or at the public hearing, or both.

Summary of Written and Oral Comments and Department Responses
The summary of written and oral comments is organized by theme.

The list of all commenters can be found in Appendix One. Individual commenters are indicated in the summary below with the number corresponding to their name in the appendix. Those individuals who made oral comment during the public hearing are indicated PH plus the corresponding number. Municipalities or local elected officials are indicated by Muni plus the corresponding number.

1) **Comment**: Commenters expressed their support for the proposed regulations through a web-generated form letter. The letter detailed support for changing existing regulations to provide consistency with the Health and Safety Code and to remove ambiguity and clearly define the authority of the Department to authorize SEPs. Commenters stated their belief that the proposed changes are critical to protect state-authorized SEPs from bans by local ordinances.

**Commenters**: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 124, 125, 126, 127, 128, 129, 132, 172, 175, 194, 195, 196, 208, 209, 212, 244, 245, 246, 247, 248, 249, 250, 251, 253, 254, 256, 257, 260, 261, 263, 264, 265, 266, 267, 268, 269, 270, 271, 277, 278, 279, 282

2) **Comment**: Commenters stated the need for regulation changes to address the challenge of starting and operating SEPs in communities with elected officers who do not view SEPs as a viable public health strategy. Commenters also supported the need to establish SEPs in communities with increased vulnerability for infectious disease and fatal opioid overdoses.

**Commenters**: 210, 225, 252, 275, 289

3) **Comment**: Commenters expressed that the operation of SEPs should not be stymied by local politicians making decisions based on politics instead of public health best practices.

**Commenters**: 289, PH11, PH14, PH15, PH16, PH18, PH20, PH21, PH22, PH24

4) **Comment**: Commenters expressed that having local authorities, such as counties and cities, oversee SEPs causes confusion as it contradicts state law. Concern was raised that “infectious diseases do not recognize county borders.”

**Commenters**: 289, PH11, PH14, PH15, PH16, PH17, PH18, PH19, PH20, PH22, PH24, PH26.

**Response to #1 - #4**: The Department appreciates the indication of support for adoption of the proposed regulations.
5) **Comment:** Commenters expressed that local authorities, such as counties and cities, should have the right to ban syringe services and stated the proposed regulations are an overreach by the state and bad public policy. Commenters stated that the state is attempting to remove power from local authorities and that the state is not aware of needs and desires of people at the local level. 

**Commenters:** 110, 122, 130, 131, 133, 134, 135, 136, 138, 139, 140, 141, 142, 143, 144, 145, 147, 148, 152, 153, 154, 155, 157, 158, 159, 160, 161, 162, 164, 165, 166, 167, 169, 173, 176, 177, 178, 180, 181, 182, 183, 184, 185, 186, 188, 189, 191, 192, 193, 197, 198, 199, 200, 205, 206, 207, 211, 213, 214, 215, 216, 217, 218, 221, 222, 223, 224, 227, 230, 234, 237, 238, 239, 240, 242, 243, 255, 258, 262, 272, 273, 274, 276, 280, 281, 283, 284, 286, 287, 288, 290, PH2, PH3, PH5, PH6, PH8, PH9, PH10, Muni1, Muni2, Muni3, Muni4, Muni5, Muni6, Muni7, Muni8, Muni9, Muni10, Muni11, Muni12, Muni13, Muni14, Muni15, Muni16, Muni17, Muni18, Muni19

6) **Comment:** Commenters stated that the Department does not understand the intent of AB 604 or the Health and Safety Code and that that making these changes to the regulations is beyond the legal authority of the Department. Commenters stated that the Department’s interpretation of Health and Safety Code 121349(c) as preempting all local ordinances and land use decisions related to SEP operations is unreasonable and inconsistent with state law. Commenters stated that if the proposed regulations were to be approved, they would be challenged in court and overturned.

**Commenters:** 143, 239, 242, PH1, PH3, PH5, PH7, PH12, Muni1, Muni2, Muni3, Muni7, Muni8, Muni11, Muni13, Muni15, Muni17, Muni18

7) **Comment:** Commenter stated that by reducing the public comment period from 90-days to 45-days, the Department is needlessly reducing the opportunity for public comment.

**Commenters:** Muni18

**Response to #5 - #7:** The Department is moving forward with the proposed regulations to remove ambiguity and clearly define the authority of the Department to authorize and oversee state-authorized SEPs notwithstanding any other law. The proposed changes will also bring the regulations into compliance with the change to the length of the public comment period for SEP authorization made by Assembly Bill (AB) 1810 (Committee on Budget, Chapter 34, Statutes of 2018).

AB 604 (Skinner, Chapter 744, Statutes of 2011) gave authority to the Department to authorize, as specified, certain entities to provide syringe exchange services in any location where the Department determines that the conditions exist for the rapid spread of HIV, viral hepatitis, or any other potentially deadly or disabling infection spread through the sharing of used hypodermic needles and syringes. The Department’s Office
of AIDS, Office of Viral Hepatitis Prevention and the Centers for Disease Control and Prevention (CDC) have determined that all counties in California are at such risk.

Prior to the passage of AB 604, only local governments had the authority to authorize SEPs. HSC 121349(b) defines local authority and HSC 121349(c) defines the state authority. HSC 121349(b) and 121349(c) delineate separate processes for SEP authorization.

CCR, Title 17, Section 7002(a)(13)(A) defines one of the steps for state-authorized applicants. It states that SEP applicants must provide a signed statement attesting to “compliance with state laws, regulations and local ordinances.” Section 7014 states “the program and its staff shall operate and furnish services in compliance with all applicable state laws, regulations and local ordinances.” CCR, Title 17, Section 7002(a)(13)(A) and Section 7014 should not have included “local ordinances” as part of the regulations, as HSC 121349(c) does not contain this requirement.

This change will amend CCR, Title 17, Section 7002(a)(13)(A) and 7014 by removing the words “local ordinances.” It will not prevent local governments from authorizing applicants to provide syringe services in their jurisdictions, nor will it impose additional requirements on local governments or locally-authorized SEPs. This change also will not impermissibly expand the Department’s authority beyond what is already authorized by statute. Rather, it will allow the Department to approve applicants based on compliance with the requirements set forth in HSC 121349 and on state priorities for public health and communicable disease control.

8) **Comment**: Commenters stated that the change will mislead SEPs into believing that local laws will not apply to their programs and will waste resources in establishing programs that may later be shut down by local ordinances.

   **Commenters**: Muni2, Muni11 (copied from Muni 2)

   **Response to #8**: The Department has received no indication that SEPs will be confused by the proposed regulations, and no SEP expressed this concern. In contrast, SEPs have expressed strong support for this regulatory change. The consensus among SEPs is that the removal of reference to unspecified local ordinances will clarify current law. The Department believes the proposed regulations meet the “clarity” standard of the Administrative Procedure Act as they are consistent with the authorizing statute, which is silent on local ordinances.

9) **Comment**: The commenters oppose the proposed regulations and stated that if the Department wants to allow SEPs, then the Department should operate the SEPs, not local entities.

   **Commenters**: 136, 235
10) **Comment:** Commenters stated that SEPs and/or harm reduction services are not useful public health interventions. Commenters stated SEPs increase drug use in their communities and enable people who use drugs.

**Commenters:** 110, 122, 123, 130, 134, 135, 136, 138, 143, 145, 146, 147, 148, 149, 150, 151, 152, 156, 157, 161, 163, 167, 170, 171, 174, 178, 179, 180, 181, 184, 185, 186, 189, 191, 197, 199, 201, 202, 204, 205, 206, 213, 214, 217, 218, 219, 221, 222, 223, 224, 226, 227, 229, 231, 232, 233, 234, 236, 237, 243, 259, 262, 272, 276, 281, 283, 284, 288, PH2, Muni7, Muni13, Muni16

11) **Comment:** Commenters stated that SEPs and/or harm reduction services are critical public health interventions that support people who use drugs with dignity and respect. Commentors also stated SEPs are excellent at assisting people who use drugs in accessing needed services including treatment for substance use disorder.

**Commenters:** 285, 289, PH17, PH18, PH20, PH21, PH22, PH23, PH24, PH25, PH26

12) **Comment:** Commenters stated their concerns regarding public safety, stating that SEPs cause increased crime in their communities, bring unhoused people from neighboring communities, and place people at risk for accidental needle-stick injuries in public spaces.

**Commenters:** 122, 123, 130, 132, 134, 135, 136, 138, 141, 143, 144, 145, 148, 149, 154, 156, 163, 166, 167, 171, 178, 182, 184, 189, 205, 206, 213, 214, 217, 219, 221, 222, 223, 224, 232, 233, 236, 237, 259, 262, 272, 276, 281, 283, 284, PH2, PH3, PH4, Muni4, Muni6, Muni8, Muni10, Muni12, Muni13, Muni16

13) **Comment:** Commenters stated that SEPs are a public nuisance, have a negative impact on the environment and are the cause for syringe litter in their communities, primarily around encampments of unhoused people located in public parks and near waterways.

**Commenters:** 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 144, 146, 148, 218, 234, 238, 255, 276, 281, 283, 284, 286, 287, 288, PH3, PH4, PH5, PH6, PH13, Muni4, Muni8, Muni9, Muni10, Muni12, Muni13, Muni16, Muni17

14) **Comment:** Commenters stated that their community has no public health issues regarding infectious diseases (HIV, viral hepatitis) and/or opioid overdoses. They expressed their desire to have public health focus on COVID vaccinations and reopening of schools.

**Commenters:** 142, 145, 147, 148, 156, 174, 235, 243

15) **Comment:** Commenter does not want an SEP in their community and/or is generally opposed to DPH-18-015.

**Commenters:** 168, 187, 190, 203, 220, 228
16) **Comment:** Commenters expressed opposition to a pending assembly bill, AB 1344 (Arambula).

**Commenters:** 132, 135, 142, 144, 145, 148, 183, 236, 284, 286, PH1

**Response to items #9-16:** While many commenters raised other issues related to SEPs, these comments do not relate to the contents of this rulemaking and are not in scope. The proposed regulations do not provide new authority for SEPs or for the Department. Rather, they resolve an inconsistency between the Department’s regulations and the authorizing statute, which sets out the two separate processes for SEP authorization.

HSC 121349(c) provides a clear process for state authorization of an SEP without any requirements related to local law. The law provides:

“In order to reduce the spread of HIV infection, viral hepatitis, and other potentially deadly bloodborne infections, the State Department of Public Health may, **notwithstanding any other law**, authorize entities that provide services set forth in paragraph (1) of subdivision (d), and that have sufficient staff and capacity to provide the services described in Section 121349.1, as determined by the department, to apply for authorization under this chapter to provide hypodermic needle and syringe exchange services consistent with state standards in any location where the department determines that the conditions exist for the rapid spread of HIV, viral hepatitis, or any other potentially deadly or disabling infections that are spread through the sharing of used hypodermic needles and syringes [emphasis added].”

The inclusion of reference to local ordinances in CCR Title 17, Section 7002(a)(13)(A) and Section 7014 in the 2014 regulations has created a direct conflict with HSC 121349(c) and had the effect of subverting the Legislature’s stated intent of enabling the state to authorize SEPs meeting the requirements of the statute. The purpose and scope of this regulation package is to address that regulatory inconsistency.

17) **Comment:** Commenters stated concerns via the chat feature during the hearing regarding the public hearing: time for speakers was too short, speakers were cut off when time expired, could not see “the committee hearing officers.”

**Commenters:** PH1, PH5

**Response to items #17:** The Department acted within the rules set forth for a public hearing. Due to the number of attendees, the Department announced at the beginning of the hearing that each speaker would have three minutes to speak and could submit additional comments through the Department’s Office of Regulations. The public was made aware that lines would be muted at the end of three minutes. No participants or Department staff had video enabled during the hearing.
18) **Comment:** Commenters alerted the Department that the date for the close of public comment in the California Regulatory Notice Register 2021, No. 8-Z, p. 192 was May 6, 2021 and was listed in the announcement posted on the Department’s website as April 5, 2021.

**Commenters:** 241, 216

**Response to item #18:** The Department corrected the date for the close of public comment in all announcements and on all platforms.

19) **Comment:** Commenter submitted a list of questions for the Department outside the scope of the public comment for this regulations package.

**Commenter:** 216

**Response to Item #19:** The Department provided the commenter with the link to the Department’s Public Records Request (PRA) Portal. The commenter submitted PRA# P012233-031821 on March 18, 2021. The PRA was responded to and closed on 4/2/2021.

**APPENDIX ONE**

List of commenters who submitted written comment via email, electronic form, or postal mail.

1. Carl Baker
2. David Jay
3. Libby Guthrie
4. Tara Stamos-Buesig
5. Anita Ramirez
6. Jenna Haywood
7. Savannah O'Neill
8. Tia Paneet
9. Timothy Zembek
10. Ryan Clary
11. Lorie Violette
12. Miriam Thompson
13. Terri Reynolds
14. Lasara Allen
15. Liane Bruckstein
16. Stacey Dee
17. Raphaela O'Meara
18. Mahan Naeim
19. Petra Reyes
20. Sarah Whipple
21. Lynell Clancy
22. Lo Petty
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<td>Dr Phillip Summers</td>
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Madelyn Frank
Katherine Rosecrance
Nicole Carbonel
Micheal Banacky
Susan Wilson
Catriona Lewis
Denise Lopez
Libby Guthrie
Lauren Kennedy
Rob S.
Dallas Augustine
Laura Pineda
Alan Shu
Joubin Khazaie
Cyrus Oloumi
Brianna Patti
Irene Masini
Harwant Khehra
Clare D.
Yolanda Chavez
Lauren Coomber
Natasha Rastegari
Serena Tally
Siana Sonoquie
Yamini Patibandla
Hilary Crosby
Anvesh Macherla
Jean Plaza
Michael LoBasso
Faisal Omar
Michelle Au
Madeleine Hart
Lesa Jara
Neeki Amirjavadi
Leila Yousefi
Evelyn Zermeno
Mahan Naeim
Natasha Vanderhoof
Luis Reyes Romo
Ryan Wythe
Travis Frampton
Joyce Adams
Kate Copeseelely
Cyrus Kiani
Natassia Dunn
113 Kyle Johnson
114 Neema Tabarani
115 David Borjon
116 Molly Greenberg
117 Cyndi Blackman
118 Gianni Caponera
119 Paulina Torres
120 Sofia Laguna
121 Ashley Doherty
122 Jeff Oster
123 Penny Poole
124 Erin Cantrell
125 Rupert Reyneke
126 Cassie Jewell
127 Joshua Wilson
128 Gabriella Alvarado
129 Ashley Rollerson
130 Amy Wheeler
131 Melanie Whelche
132 Steve Hicklin
133 Effie Hale
134 Michelle Reutlinger
135 Kathi Whiteley
136 Peggy Hicks RN
137 Nancy Doherty
138 Jeff Oster
139 Judy Sousa
140 Ray Dwyer
141 Lanita Fedorchuk
142 Lanita Fedorchuk
143 Robert Berry
144 Robert Berry
145 Larry Coleman
146 Laura Morris
147 Jessica Montgomery
148 Nichole Nava (Louis)
149 Sandra Lee
150 Joni Hendrickson
151 Lara Longo
152 Scott Evans
153 Ron Ostarello
154 Beth Reimers
155 Chris Crutchfield
156 Jenn Spring
157 Cheryl Ballantyne
158 Linda Anderson
159 Michelle Anchordoguy
160 Heidi Lecair
161 M Hall
162 Genzoli
163 Delilah Ackley
164 Suzanne Wasilchen
165 Les Heringer
166 Christopher Price
167 Robert Sheridan
168 Joan Gillette
169 Gina Bax
170 JR Gonzal
171 Brooke Baker
172 Timothy Zembek
173 Sherry Smith
174 Ted Bryson
175 Lydia Bransten
176 Jackie Uttecht
177 Susan Lance
178 Laura Willman
179 Stephanie Contreras
180 John S. Wichman
181 Patty Grace McKee
182 Brad Hall
183 Darryl Brock
184 Marci Pittman
185 Laurie Wandtke
186 Greg Foutz
187 Jackie Roberts
188 Steve Kramer
189 Carolyn DeHart
190 Roxane Atkinson
191 Karyn Glasgow
192 Mark W. Smith
193 Jennifer Davis
194 Candace Winstead
195 Sandi Clement
196 Katie Taylor
197 Jean Stevenson
198 Leslie Carbah
199 D. Lunsford
200 Suzanne Campbell
201 Gloria Lees
202 Chris Fogleman
Public Hearing – April 14, 2021

PH1 Rob Berry
PH2 Kami Denlay
PH3 James Gallagher
PH4 Judy Sousa
PH5 Andrew Coolidge
PH6 Jeff Stephens
PH7 Walt McNeil
PH8 Karm Bains
PH9 Gary Lewis
PH10 Kim Bergel
PH11 Madeleine Clyde
PH12 Chris Branscum
PH13 Chrissie Breton
PH14 Jasmine Guerra
PH15 Carol Newark
PH16 Jessica Smith
PH17 Wesley Saver
PH18 Laura Thomas
PH19 Robyn Learned
PH20 Charles Hawthorne
PH21 Denise Elerick
PH22 Amy Lieberman
PH23 Tara Stamos-Buesig
PH24 Jenna Haywood
PH25 Amber Sheldon
PH26 Annina Van Voorene

Municipalities and Elected Officials

Muni1 Butte County (Mailed to CDPH)
Muni2 League of California Cities and Rural County Representatives of California
   (Emailed in by ddolfie@cacities.org)
Muni3 City of Anaheim (Faxed to CDPH)
Muni4 City of Oroville (Mailed to CDPH)
Muni5 City of Wheatland – Proclamation (Emailed to Office of Regulations (OOR)
   by kgiurbino@wheatland.ca.gov)
Muni6 County of Yuba – Resolution (Emailed to OOR by
   jcyang@CO.YUBA.CA.US)
Muni7 Oroville City Councilman (Emailed to OOR by dpittman@cityoforoville.org)
Muni8  Assembly Member 3rd District – (Emailed to OOR by
Assemblymember.Gallagher@assmbly.ca.gov)

Muni9  City of Biggs – (Emailed to OOR by Mark@biggs-ca.gov)

Muni10 City of Yuba City – (Emailed to OOR by mboomgaarden@yubacity.net)

Muni11 City of Eureka – (Emailed to OOR by mslattery@ci.eureka.ca.gov)

Muni12 City of Red Bluff – (Emailed to OOR by rcrabtree@cityofredbluff.org)

Muni13 City of Santa Ana – (Emailed to OOR by DSoto@santa-ana.org)

Muni14 Glenn County – (Emailed to OOR by SDeMoss@countyofglenn.net)

Muni15 Town of Paradise – (Mailed to CDPH)

Muni16 City of Marysville – (Emailed to OOR by bbuttacavoli@marysville.ca.us)

Muni17 County of Santa Cruz – (Emailed to OOR by
CaitlinSmith@santacruzcounty.us)

Muni18 City of Costa Mesa– (Emailed to OOR by
ALEXANDER.GONZALEZ@costamesaca.gov)

Muni19 Placer County – (Emailed to OOR by JJoyce@placer.ca.gov)