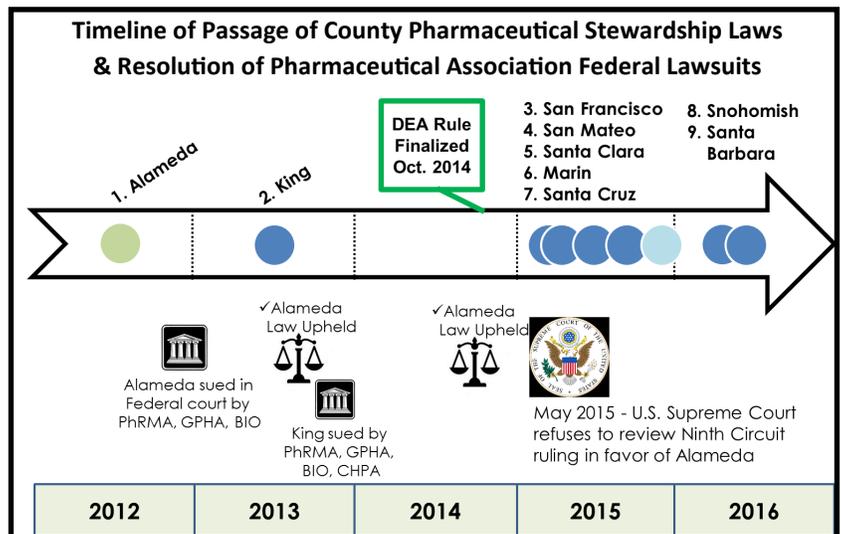




Secure medicine take-back programs are part of a comprehensive approach to preventing medicine abuse and unintentional poisonings, and preventing waste residential medicines from contributing to pharmaceutical pollution. Medicine take-back options are often not available in all communities and existing programs lack sufficient resources. In pharmaceutical stewardship policies, also called extended producer responsibility policies, the companies that produce the medicines finance and coordinate a convenient system for secure collection and environmentally sound disposal of leftover medicines.

Passage of Local Pharmaceutical Stewardship Ordinances for Secure Medicine Take-back: The nation’s first product stewardship law for prescription medicines was passed by the Board of Supervisors of Alameda County, CA in July 2012. The Board of Health of King County, WA passed the second law in July 2013 for secure return of prescription and over-the-counter medicines. King County’s law was more specific on the performance standards for the stewardship program, including requiring that producers meet a minimum convenience standard for providing secure drop boxes at pharmacies and police stations throughout the county. In 2015, five more CA counties passed laws modeled on King County’s regulations, with some modifications. Alameda County amended their ordinance in February 2016, making it more similar to the other ordinances.

Thus far in 2016, pharmaceutical stewardship laws have been enacted in Snohomish County, WA and Santa Barbara, CA, as well as in the cities of Capitola and Santa Cruz in Santa Cruz County, CA.



Unsuccessful Industry Lawsuits: Alameda County and King County were each sued in federal court, unsuccessfully, by pharmaceutical industry associations. Both counties voluntarily extended their deadlines for stewardship plan submission as the Alameda case worked the courts. The [Northern California District Court](#) and the [Ninth U.S. Circuit Court of Appeals](#) each upheld Alameda County’s ordinance, dismissing the industry’s claim of a violation of the dormant Commerce Clause. After the Ninth Circuit ruling in September 2014, both counties resumed implementation deadlines. A petition from the pharmaceutical associations to the U.S. Supreme Court to review the Ninth Circuit ruling was denied in May 2015.

Counties Assisting Pharmaceutical Industry in Stewardship Learning Curve: Medicine producers finance and operate medicine take-back programs in other countries, but these stewardship laws were new to the U.S. offices of these companies. Additionally, in October 2014, the DEA finalized regulations governing protocols for secure take-back of controlled substances by pharmacies, hospitals, and other authorized collectors. Alameda County and King County have conducted extensive outreach to pharmaceutical companies to explain the laws and assist the industry in developing successful stewardship plans.

Moving Forward—Producers’ Stewardship Plans Accepted in Multiple Counties: To address these regulations, more than 300 medicine producers created a membership association called the Pharmaceutical Product Stewardship Work Group or PPSWG. The PPSWG member companies have formed the MED-Project™ LLC which is acting as their stewardship organization to develop, implement, and operate the required secure medicine take-back programs.

Stewardship plans developed by the MED-Project have been accepted by Alameda, King, San Francisco, and Santa Cruz counties as compliant with their local ordinances. Implementation of these plans by MED-Project is proceeding. The MED-Project has sponsored a number of collection events in Alameda County, and is working on a timeline to have a fully operational collection system throughout King County in January 2017. In San Mateo and Santa Clara counties, review of stewardship plans is ongoing. In other counties, plan submission deadlines are later in 2016 or 2017. Additional information about the implementation status of each county ordinance, and links to further resources, are provided on the following pages.

Alameda County, CA Safe Drug Disposal Ordinance Implementation

Passed July 24, 2012; Effective August 24, 2012.

December 2012 to September 2014 – Unsuccessful pharmaceutical industry lawsuit. PhRMA, GPhA, and BIO sued Alameda County in federal court in Dec. 2012, and the county voluntarily extended the stewardship plan submission deadline. Deadlines resumed after the Ninth Circuit ruled in favor of Alameda in Sept. 2014.

February 2015 – County approved the [Alameda MED-Project stewardship Plan](#) representing about 320 producers. The Plan proposed one collection event per month and a roll-out of services for law enforcement drop boxes during year 1, then expansion to drop boxes in pharmacy and healthcare locations during year 2.

Implementation of the Plan was slower than expected during 2015 as the Plan learned about forming contracts with public and private entities. The county and local agencies have continued to coordinate medicine collection events and operate 30 secure collection sites until the Alameda MED-Project can take over that role.

August 2015 – First take-back event held; > 360 pounds of medicines collected. After this event, MED-Project stopped participating in collection events to consider how to address the over-the-counter medicines returned by residents because the ordinance the only required collection of prescription drugs.

February 2016 – Alameda Board of Supervisors amended the 2012 ordinance to align with similar laws in King County and other CA counties by requiring stewardship of over-the-counter medicines, requiring collection of controlled substances pursuant to DEA's regulation, requiring that any qualified collector is included as a drop-off location, and other adjustments. The [Amendment](#) took effect on March 3, 2016. In March, the Alameda MED-Project Plan amended its agreement with Sheriff's Office, and clarified how controlled substances and over-the-counter medicines would be collected.

Increased Collection Efforts During 2016 – Alameda MED-Project Plan has held more than 20 collection events thus far in 2016, and plans to conduct a total of 24 take-back events around the county during 2016. The Plan is working to provide ongoing drop boxes around the county, and as of early August had formed contracts with 3 law enforcement sites and 9 pharmacies.

King County, WA Secure Medicine Return Regulations Implementation

Passed June 20, 2013; Effective July 20, 2013.

November 2013 to September 2014 – Unsuccessful pharmaceutical industry lawsuit. PhRMA, GPhA, BIO, and CHPA sued King County in Nov. 2013 on same basis as suit against Alameda's ordinance. No hearings were held in King case because the Alameda suit was working through federal courts. King County voluntarily agreed to extend the stewardship plan submission deadline until after the Ninth Circuit decision in the Alameda lawsuit. The Ninth Circuit ruled in favor of Alameda in Sept. 2014.

February 2015 – Two stewardship organizations submitted plans: ReturnMeds ([Call2Recycle](#)) and [King County MED-Project \(PPSWG\)](#). Both plans were rejected on initial review, and producers were required to create revised plans. The ReturnMeds plan was accepted after one round of revision. The King County MED-Project plan was accepted after two rounds of revision.

October 2015 – Revised plan from ReturnMeds was accepted and designated the Standard Plan, representing 12 producers.

March 2016 – Revised plan from King County MED-Project was accepted as an Independent Plan, representing > 370 producers.

April 2016 – The King County MED-Project plan was designated the approved [Standard Plan](#) after ReturnMeds withdrew its participation as an approved stewardship plan due to lack of sufficient participating producers.

Overview of Collection Services to be Provided to Residents: Secure drop boxes must be distributed throughout the county to meet a minimum geographic and population based standard. Producers are also required to partner with any pharmacy or law enforcement site that offers to host a drop box. In any areas lacking drop boxes, periodic collection events or pre-paid return mailers must be provided. Pre-paid return mailers must also be available for home-bound or differentially-abled residents.

Implementation of Standard Plan: MED-Project began implementing its approved plan in March 2016, but did not launch the program by the regulation's 90-day deadline. King County reviewed and approved a revised timeline from MED-Project to have the required collection system fully operational in January 2017.

As of mid-September, MED-Project has formed contracts with 77 collection sites, including 38 retail pharmacies, 22 hospitals, and 17 law enforcement agencies. Secure drop boxes have been ordered and installation is planned. Collection events are also being scheduled. By program launch, more than 90 secure drop boxes are anticipated county-wide.

Status of County Pharmaceutical Stewardship Laws Enacted in 2015 & 2016

City & County of San Francisco, CA.

[Safe Drug Disposal Stewardship Ordinance](#)

Passed March 26, 2015; Effective April 25, 2015.
Stewardship plan deadline: April 2016

MED-Project [stewardship plan](#) accepted conditionally on July 25, 2016.
County adopted a [regulation](#) on producers' outreach activities.

San Mateo County, CA.

[Safe Medicine Disposal Ordinance](#)

Passed April 28, 2015; Effective May 28, 2015.
Stewardship plan deadline: May 28, 2016

County is reviewing MED-Project plan received May 27, 2016.

Santa Clara County, CA.

[Safe Drug Disposal Ordinance](#)

Passed June 23, 2015; Effective June 23, 2015.
Stewardship plan deadline: July 2016

County is reviewing MED-Project plan received July 23, 2016.

Marin County, CA.

[Safe Drug Disposal Ordinance](#)

Passed Aug. 11, 2015; Effective Sept. 11, 2015.
Stewardship plan deadline: September 12, 2016

County is reviewing MED-Project plan received Sept. 12, 2016.

Santa Cruz County, CA.

[Safe Drug and Sharps Disposal Ordinance](#)

Passed Dec. 8, 2015; Effective Jan. 8, 2016.
Stewardship plan deadline: March 1, 2016.

MED-Project plan submitted. County reviewed and rejected the plan several times. A revised MED-Project plan accepted in September 2016, with ongoing discussion on some program details.

Snohomish County, WA

[Secure Medicine Return Regulations](#)

Passed June 14, 2016; Effective July 15, 2016
Stewardship plan deadline: December 2016.

Santa Barbara, CA

[Extended Producer Responsibility Stewardship for the Collection and Disposal of Unwanted Covered Drugs](#)

Passed June 21, 2016; Effective July 21, 2016.
Stewardship plan deadline: July 21, 2017.

The San Francisco ordinance is modeled after the King County law, with some modifications.
Ordinances in the three other counties were modeled after San Francisco's, with some modifications.

Implementation Status:

In progress and being coordinated across the 4 CA counties with similar laws (San Francisco, San Mateo, Santa Clara, Marin).

Each ordinance has compliance deadlines leading up to the 1 year deadline for submission of a stewardship plan.

Similar to King County and subsequent CA county laws, but also includes medical sharps and mandates retailer participation as collectors, as well as other modifications.

If stewardship program not implemented by June 30, 2016, producers must reimburse county for costs of its existing medicine take-back program.

Similar to King County law with some modifications, including refinements to further align with the DEA Rule, an enhanced service convenience goal, shortened implementation timelines, and expanded promotion requirements.

Similar to San Mateo and other CA county laws.

This Policy Update is based on available information from websites referenced, legislative documents, public communications from county officials, and personal communications with county staff. This analysis is intended as an informational update and provides a general description of regulatory requirements, legal proceedings, and compliance actions. Although care has been taken in researching the information presented in this Policy Update, no guarantee is made regarding whether the information is fully up-to-date or complete due to ongoing developments. Analysis presented in this Policy Update does not purport to represent the views of any entities referenced. Community Environmental Health Strategies LLC makes no warranty, express or implied, with respect to such information and disclaims all liability resulting from any use or reliance of this information.