

SB 486 Safe Needle Disposal Plans: Evaluation Criteria

The plan evaluation criteria are intended to help both manufacturers and their customers determine when a manufacturer has succeeded **in providing** a convenient, end-of-life management system for the self-injection devices.

I. PROVIDE FOR EFFECTIVE SAFE NEEDLE COLLECTION AND DISPOSAL (up to 80 points possible)

- Does the plan outline how the manufacturer, either individually or through a stewardship organization, is **providing** a free and convenient statewide safe needle disposal program?
- Examples could include a mail-back program approved by the California Department of Public Health, a pharmacy take-back program or any other program as outlined as a safe needle disposal method by the U.S. Environmental Protection Agency.

Points may be deducted if the program:

- Charges consumer fees.
- Limited scope -- Is not statewide or does not cover all injectible products.
- Is not reasonably convenient for most consumers.
- Does not provide approved sharps containers* for transport to drop-off facilities.
- Does not protect confidentiality.

**"Sharps container" means a FDA-approved sharps container that is a rigid, leak-proof, puncture resistant box, available in various sizes, made of hard plastic with a lid that can be securely sealed to keep contents from falling out and clearly marked with the biohazard symbol.*

II. PATIENT EDUCATION (up to 10 points possible)

- Does the manufacturer educate and inform their end users about safe needle/sharps disposal methods? For example, is the home injectible sold with literature about the sharps disposal ban in California? Is the material easy to read? Is it prominent?

III. COORDINATION (up to 5 points possible)

- Does the plan describe the manufacturer's efforts to coordinate their sharps program with local, regional, or state-level sharps management efforts?
- Has the manufacturer made efforts to assist in the development of local or community-based safe needle/sharps disposal efforts?

IV. CONSUMER/COMMUNITY INVOLVEMENT (up to 5 points possible)

- Does the manufacturer have a community or consumer advisory body to aid in the development of a consumer- and community-friendly sharps disposal program?
- Has the manufacturer surveyed their consumers about their needle or sharps disposal needs, and whether it is easy to use their disposal product or program?
- Has the manufacturer incorporated consumers' ideas in their safe needle or sharps disposal efforts?
- Has the manufacturer assisted with community awareness programs to educate consumers about proper sharps disposal laws and sharps disposal methods?

SB 486 Plan "Report Card" Criteria

GRADE	POINTS	EXAMPLE
A- to A Excellent	90-100	Drug manufacturer is providing a free and convenient safe needle disposal method, and some of or all the following: <ul style="list-style-type: none"> • Patient education materials about the sharps ban • Coordinating with community safe sharps disposal programs • Consumer and/or community involvement.
B- to B+ Good to Very Good	80-89	Drug manufacturer is providing a safe needle disposal method (80 possible points). Possible increased points for patient education, community coordination and/or consumer/community involvement. Possible deductions for failure to: <ul style="list-style-type: none"> • Run a statewide program • Offer free program • Protect patient confidentiality • Provide reasonably convenient program for the consumer • Include consumer involvement • Coordinate with local, regional or state-level sharps management efforts • Provide sufficient patient education materials.
C- to C+ Average, Satisfactory	70-79	Drug manufacturer is providing or planning a safe needle disposal method. Possible downgrades for failure to: <ul style="list-style-type: none"> • Offer a statewide program • Provide program for free • Protect patient confidentiality • Offer a safe needle disposal method that is reasonably convenient for the consumer • Include consumer involvement • Coordinate with local, regional or state-level sharps management efforts • Provide sufficient patient education materials.
D Marginal	60-69	Plans fail to include some or all of the following criteria: <ul style="list-style-type: none"> • Offer a free, safe and convenient safe needle disposal program • Offer a statewide program • Protect patient confidentiality • Offer a safe needle disposal method that is reasonably convenient for the consumer • Consumer involvement • Coordinate with local, regional or state-level sharps management efforts • Provide sufficient patient education materials.
F Fail	0-59	Plans fail to include a free statewide disposal program, as well as other high priority criteria referenced above.
Incomplete	No points given; to be evaluated again at a later date.	Applicable to plans that are submitted after the July 1, 2010 legal deadline or are missing plan components and require individual follow up.