Submitted to Senator Simitian 1/14/11

SB 486 Consumer Report Card, 2010

Submitted to California Senator Joe Simitian on behalf of the Senate Bill 486 Evaluation Team

Introduction

This report summarizes a "Consumer Report Card" prepared by the Senate Bill 486 Evaluation Team, supporters of Senate Bill 486 (Simitian). The 2009 enactment of Senate Bill 486 made California the first state in the nation to require drug manufacturers to submit plans that provide for the safe collection and disposal of home-generated sharps waste.

The SB 486 Evaluation Team is comprised of nine (9) representatives from the National MS Society-Northern California Chapter, the Diabetes Coalition of California, the California Conference of Environmental Health Directors, Local Public Health Departments, the California Sharps Coalition and other consumer health organizations that worked together to help pass Senate Bill 486. The group is divided between patient advocates, pharmacists and public health/environmental health agency representatives.

The SB 486 Evaluation Team's Consumer Report Card was developed to assist Californians who self-inject medicine at home. It is based on criteria crafted by the team and announced by the groups and Senator Simitian at a March 2010 press conference, held in the State Capitol. (See Attachment 1: SB 486 Safe Needle Disposal Plans: Evaluation Criteria).

The Consumer Report Card

SB 486 requires pharmaceutical manufacturers to provide information on their websites about the home-generated sharps collection and disposal programs they offer, if any. In addition, they must also submit those plans to the state for display on a state website. One goal of the bill is to make information readily available to consumers who are seeking safe needle disposal options.

However, the mere posting of information from multiple companies is not in and of itself helpful to consumers who may be seeking the best waste management options for safe and legal disposal of used needles.

The purpose of the Consumer Report Card is to allow consumers and the public to see what other home injectors and consumer advocates say about particular drug manufacturers' plans, and to see how the plans compare in key performance areas. The Consumer Report Card scores indicate whether groups representing patients that use home-injected medication have concluded that a plan is providing good or poor home-generated sharps collection and disposal options for their end user.

THE EVALUATION PROCESS

The SB 486 Evaluation Team used the criteria unveiled at the March 2010 press conference to review and grade all plans submitted to the State of California's Department of Resource Recycling and Recovery (CalRecycle). Each plan was rated on a scale ranging from 0 to 100 points, with a corresponding letter grade ranging from "A" to "F." Total possible points were allocated among four weighted categories as follows:

Provision of an Effective Safe Needle Collection and Disposal Method	80 points
Patient Education	10 points
Coordination With Other Entities	5 points
Consumer/Community Involvement	5 points
Total possible points	100 points

As demonstrated by the above scale, the Evaluation Team assigned considerable weight to a manufacturer's actual provision of safe needle collection and disposal services. High marks in this category could earn a manufacturer a solid overall "B" grade, reflecting above-average responsiveness to consumer and environmental health concerns. Attention to the remaining three categories would be necessary for a manufacturer to receive a higher grade, which would reflect excellent responsiveness to consumer and environmental health concerns.

Report Card Findings

The Consumer Report Card consists of grades for all 22 submittals by drug manufacturers received by the State of California as of July 7, 2010. There were:

- Two " A" grade plans;
- Three "C" grade plans;
- Two "D" grade plans;
- Fifteen "F" grade plans.
- One "Honorable Mention" (for Waste Management's plan in recognition that this plan meets the SB 486 Evaluation Team criteria, even though the bill does not require the company to submit a plan).

Manufacturers that submitted a plan after the July 1, 2010, deadline received an "incomplete" grade and the Evaluation Team did not grade those plans. Manufacturers that submitted no plans received an "Out of Compliance" grade.

The complete report card, showing scores for individual drug manufacturers, is provided in Attachment 2: The Consumer Report Card.

CONCLUSIONS

SB 486 requires pharmaceutical manufacturers to provide information on their websites about the home-generated sharps collection and disposal programs they offer, if any. In addition, they must also submit those plans to the state for display on a state website. The goal of the bill is to make information readily available to consumers who are seeking safe needle disposal options.

However, the mere posting of information from multiple companies is not in and of itself helpful to consumers who may be seeking the best waste management options for safe and legal disposal of used needles.

Manufacturer Compliance with SB 486 Requirements did not Work Well

Despite the explicit requirements of SB 486, some pharmaceutical manufacturers did not submit a plan. Others submitted their plans after the July 1, 2010 deadline. And many of the manufacturers who submitted plans failed to post them on their web sites as required by SB 486. While some of these lapses may be attributable to start-up issues, the resistance to the passage of SB 486 presented by pharmaceutical manufacturers appears to be continuing. We believe that many manufacturers deliberately thwarted the legislative intent of SB 486.

The Majority of Plans Submitted Failed to Address the SB 486 Evaluation Criteria

As reflected in the grades, most submitted plans restated, in varying degrees of completeness and clarity, the status quo of home-generated sharps collection and disposal programs and information without regard to SB 486 Evaluation Criteria. Also, none of the pharmaceutical manufacturers acted on the Evaluation Team's offer of assistance.

The Current SB 486 Requirements to submit a plan do not appear to have affected pharmaceutical policies or Procedures regarding the safe collection & disposal of Home Generated Sharps Waste

During the debates on SB 486, drug company representatives argued that granting companies maximum flexibility in their responses to the sharps waste problem would be generate greater cooperation and more creative approaches than mandating a specific set of responses. A review of the plans submitted by the companies, however, reveals that few are accepting the challenge of offering their consumers access to free, easy-to-use sharps disposal solutions. Neither SB 486 nor public consumer review and peer pressure have been effective in achieving company new policies or practices.

As all of the injectibles regulated by SB 486 are prescribed, there is little opportunity for consumers to shop pharmaceutical manufacturers. And the absence of penalties for non-compliance gives pharmaceutical manufacturers no incentive to comply with SB 486. In addition, at present, almost all successful home generated sharps collection and disposal programs are local efforts that have no pharmaceutical manufacturer involvement. In fact CalRecycle has identified 11 cities and 19 counties that have in-place or planned home generated sharps waste collection and disposal programs, none of which are underwritten or supported by drug manufactures.

RECOMMENDATIONS

Require Drug Manufacturers to submit Future Annual SB 486 Plans in an Electronic Format Prescribed By CalRecycle

While trying to evaluate the drug manufacturer's plans there were a few hurdles. While drug manufacturers were required by law to submit plans to CalRecycle by July 1, 2010, many did so in an antiquated paper format. This lead to a delay of posting of the plans since CalRecycle's web and information technology department had to hand-scan many of the documents to put them in a format that was web-ready. While most of the reports were "in-hand" they were not made available to Californians seeking them on the CalRecycle website for upwards of four weeks. Because of this delay, the SB 486 Evaluation Team recommends that in the future, **drug manufacturers be required to submit their SB 486 plans in an electronic format prescribed by CalRecycle.**

Require Drug Manufacturers to Place a Prominent Link to their SB 486 Plans on the Home Page of their Websites

Since most plans weren't published on the CalRecycle website until July 27, 2010 or later it was impossible to know which manufacturers had complied with the legislatively mandated deadline of July 1st and which had not. Simply looking at manufacturer's websites wasn't a surefire way to see if they had written a plan since many of the manufacturers buried their report deep in their websites. This made it virtually inaccessible to even the most web savvy consumer searching for it. Therefore, we also **recommend that a date stamp be applied by CalRecycle when posting the plan submissions and a new requirement be made of the manufacturers that their plans (or a headline link) be posted on their "home page" of their internet web site or in a sufficiently prominent location that a consumer who is not familiar with the site could easily find the report. The report should also be easily accessible through the manufacturer's website search function.**

Establish an Administrative Fee For Submitting SB 486 Plans

CalRecycle received no funding for administering SB 486, and that presented numerous logistical problems during the evaluation process. In the 2010 Legislative Session Assembly Bills 1343 and 2398 which mandate product stewardship for paint and carpet respectively, have provisions for collecting administrative fees.

Draft A New Bill with Stronger Language & Penalties

A major point of compromise in the passage of SB 486 was the Legislature's acceding to drug manufacturers' arguments that the bill should allow the manufacturers flexibility in determining how they would develop plans that help their customers properly dispose of sharps wastes. Additionally, while the bill clearly requires the manufacturers to submit plans annually, it provides no penalties if manufacturers fail to comply with this requirement. The SB 486 Evaluation Team strongly believes that the 2010 experience points to the need for immediate steps to be taken to strengthen SB 486. We have the following specific recommendations.

Drug Manufacturers Should Face Penalties if SB 486 Legislative Intent and Requirements are Violated. With the 2010 submittals, a substantial majority of the drug manufacturers subject to SB 486 requirements demonstrated that the Legislature's intent in passing SB 486 is being ignored and even thwarted. Our analysis showed that 15 of the 22 manufacturers subject to SB 486 requirements either failed to comply with the spirit and intent of the law, or simply violated state law by not submitting a plan at all. (see Attachment 3). We believe that this track record demonstrates that the current approach to submissions is not working as the Legislature intended. **Consequently, we support amending state law to establish fines and penalties for manufacturers that fail to submit a plan in accordance with SB 486.**

Plan Contents Should be More Clearly Defined. SB 486 was designed to allow drug manufacturers a substantial degree of flexibility in developing their plans to help consumers manage their sharps wastestream. In this, the Legislature bowed to the arguments of drug manufacturers, who urged flexibility as a means of achieving broad levels of compliance.

However, the Consumer Report Card demonstrates that, from the perspective of what consumers need to comply with state law, most manufacturers receive failing grades. The SB 486 Evaluation Team – representing over 1 million Californians who need the information these plans were intended to provide -- strongly supports new legislation that, at a minimum, would provide more specific guidance to drug manufacturers as to what constitutes an acceptable plan, including implementing Extended Producer Responsibility and Product Stewardship mandates on manufactures of these home injectable drugs.

SB 486 Language Should Be Strengthened

If a new bill is introduced, it could also be an opportunity to fix some of the more permissive faults of SB 486. We could strike language such as, "typically injected at home" as a drug is or is not injected at home. We could also strike the problematic, "if anything" language, meaning that manufacturers would be required to submit a plan outlining what they do (not what if anything they do). Also, we should enable CalRecycle or the Department of Public Health to prohibit a drug manufacturer from

selling or offering for sale a home injectable medication to any person in the State unless that manufacturer is deemed by CalRecycle or DPH as being in compliance with SB 486.

Manufacturers Should be Required to Provide Free, Safe Sharps Disposal Solutions. The criteria adopted and used by the SB 486 Evaluation Team to develop the Consumer Report Card shows clearly that, from a consumer perspective, a free, safe sharps disposal program is the ONLY way a drug manufacturer should be credited with a "B" level (above average) grade. Under current law, drug manufacturers are not required to provide this service. We believe that this situation must change, in order for California to effectively manage its sharps disposal problems, and protect consumers from inadvertently violating state prohibitions on illegally disposing of sharps in municipal garbage. We therefore believe it is time for the Legislature to require manufacturers to provide, at no cost to the consumer, a safe needle disposal product as outlined by the Federal EPA or the California Department of Public Health.

As always, the SB 486 Evaluation Team and the organizations we represent are available to provide our input on future legislative language with Senator Simitian and his staff.

Attachment 1: SB 486 Safe Needle Disposal Plans: Evaluation Criteria

Attachment 2: Consumer Report Card

Attachment 3: Violators of SB 486