



## The Struggle toward Compliance

Just as we are becoming more aware of the growing dangers from improperly disposed medications leaching into our drinking water supply, so are the many regulatory bodies that oversee pharmacy. The resulting regulatory pressure is driving many changes in approaches to pharmaceutical waste management. In a bid to better understand where pharmacy practice stands today, *Pharmacy Purchasing & Products* conducted the second annual Going Green survey of health-system pharmacy waste processes.

### Survey Design

In the fourth quarter of 2009, *PP&P* polled a random, nationwide sampling of health system directors of pharmacy. We asked about their pharmaceutical waste management practices, expenditures, regulatory compliance, and staff training methods. Responses were solicited via e-mail, and we received a total of 260, yielding a confidence interval of 5.94 (95% +/-5.94) based on the total population of DoPs nationwide.

We intentionally surveyed a random sampling of DoPs, not just readers of *PP&P* to ensure our data reflects trends across the whole of hospital pharmacy practice. We were pleased to learn that 61% of DoPs nationwide use *PP&P* as a resource for information on pharmaceutical waste management.

Significant growth in spending in 2009 and an expectation that spending and the commitment to compliant waste management will continue to increase over the next few years. In fact, 66% of DoPs would consider purchasing off-contract or even higher priced products to meet their institution's environmental objectives.

Investing in developing compliant practices became more imperative this year as EPA and state inspectors have demonstrated increased comfort with the regulations and issued significantly more recommendations and citations to hospitals. Forty-five percent of inspected facilities have received a recommendation or been cited. Given that RCRA violations can result in fines of up to \$37,500 per violation, per day, developing the expertise necessary to manage pharmaceutical waste is crucial not only to ensuring a facility's environmental responsibility but also its financial health. Nonetheless, 43% of hospitals have no plan to establish a budget for managing pharmaceutical waste. Without a solid financial commitment from pharmacy and administration, attaining compliant practices will be a daunting assignment.

### Challenges for Pharmacy

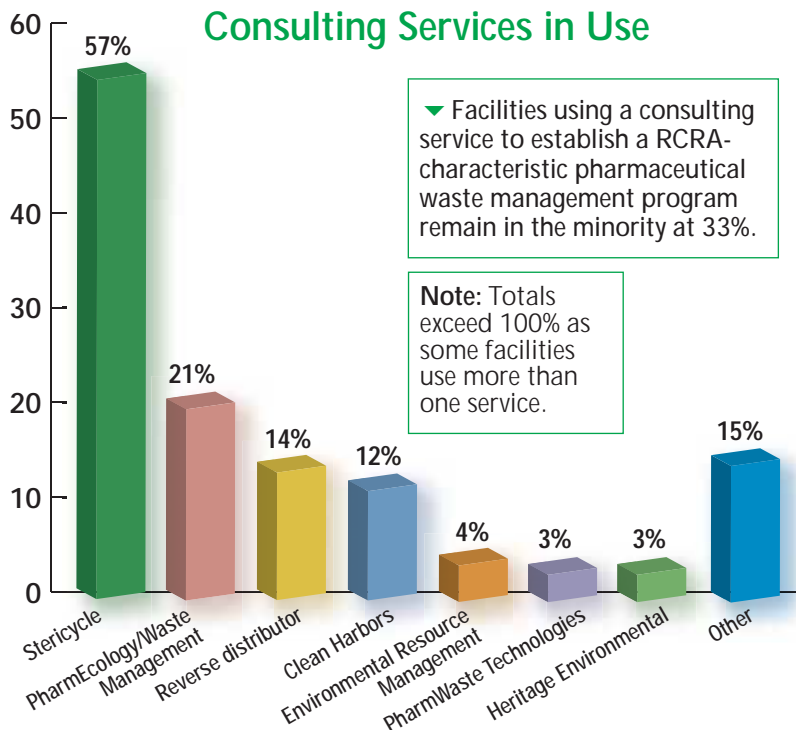
Pharmacy is well aware of the challenges they face in achieving compliance given the complexity of the regulations and a lack of in-house expertise. Most facilities report that their RCRA-regulated and non-hazardous waste practices are not in compliance, although hazardous chemotherapy and controlled substance waste management compliance rates fared somewhat better.

DoPs demonstrated increased awareness of proper waste stream disposal for many hazardous drugs this year. Fewer facilities are disposing of warfarin >0.3 mg in the regular trash and red sharps bins, for example. However, those properly using RCRA-hazardous containers for disposal of this P-listed product and other hazardous drugs are still in the minority.

A major impediment to establishing compliant practices is the dearth of expertise among pharmacy staff. Most DoPs report that their staff is not sufficiently knowledgeable about hazardous pharmaceutical waste practices. This is not surprising given that only 27% of facilities provide formal education on pharmaceutical waste management. Those pharmacy leaders who do provide training have recognized the value of comprehensive education and provided this training to staff much more regularly this year. Of note, the small number of facilities that require risk managers and administrators to receive waste training along with the clinical staff report much higher rates of compliance for RCRA-regulated waste.

### Conclusion

In addition to the potential cost of fines, the potential cost to employees' health and our environment from improper waste stream disposal should be deemed completely unacceptable by pharmacy and the hospital administration. Just as pharmacy is responsible for ensuring patients receive safe and effective medication, pharmacy must also lead the drive for ensuring safe and proper drug disposal.



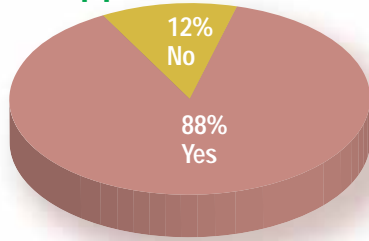
### Investing in Compliance

Despite an overall tightening of hospital budgets, the commitment to environmental protection in general and to compliant pharmaceutical waste management in particular increased this year. This was backed up by signif-

# Commitment to Compliant Waste Management

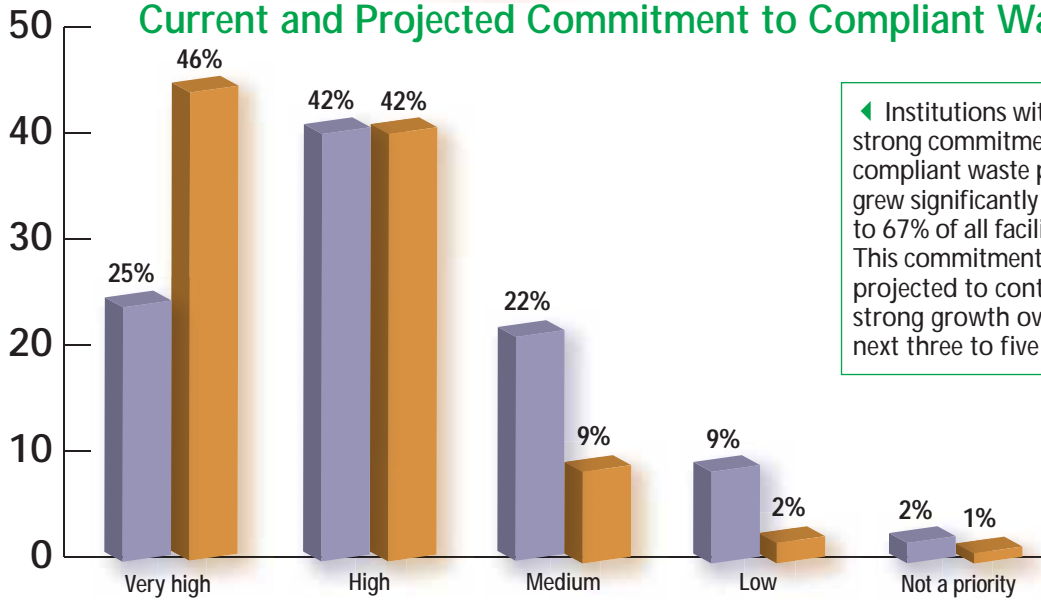
## Administration Support

Administration support is evident in 88% of all facilities.



A **commitment** to compliant pharmaceutical waste management is firmly ensconced in most hospitals. In addition, a majority of facilities have written policies and procedures in place and a committee to address hazardous waste management (68% and 63%, respectively).

## Current and Projected Commitment to Compliant Waste Management

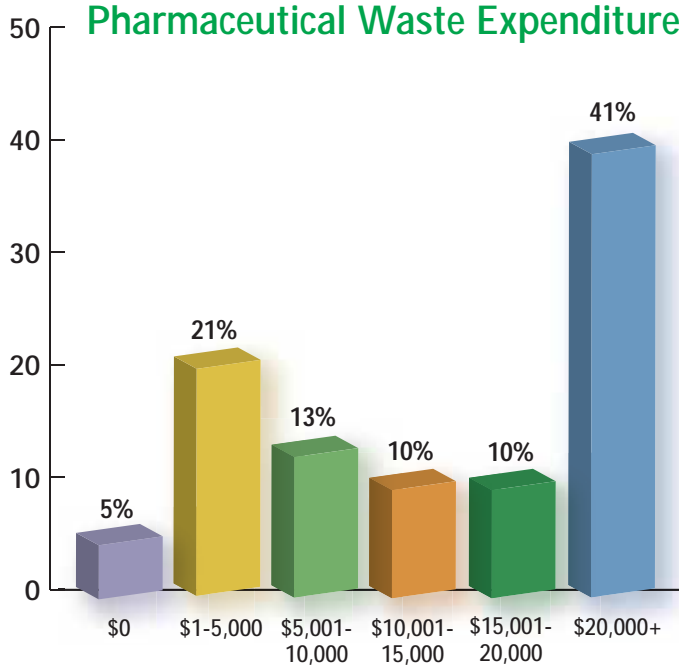


Institutions with a strong commitment to compliant waste practices grew significantly this year to 67% of all facilities. This commitment is projected to continue its strong growth over the next three to five years.

**KEY:** Commitment  
■ Current  
■ Projected

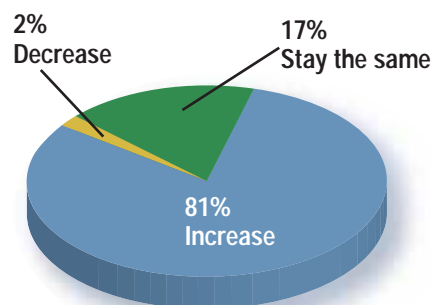
# Pharmaceutical Waste Management Budget

## Pharmaceutical Waste Expenditures



The **financial commitment** to pharmaceutical waste management increased this year as facilities not only spent more to manage their waste, but also predict that expenditures will continue to increase over the next few years. In an improvement over last year, 29% of facilities (up from 21% in 2008) now have a line item in the operating budget for pharmaceutical waste management.

## Projected Expenditure Change



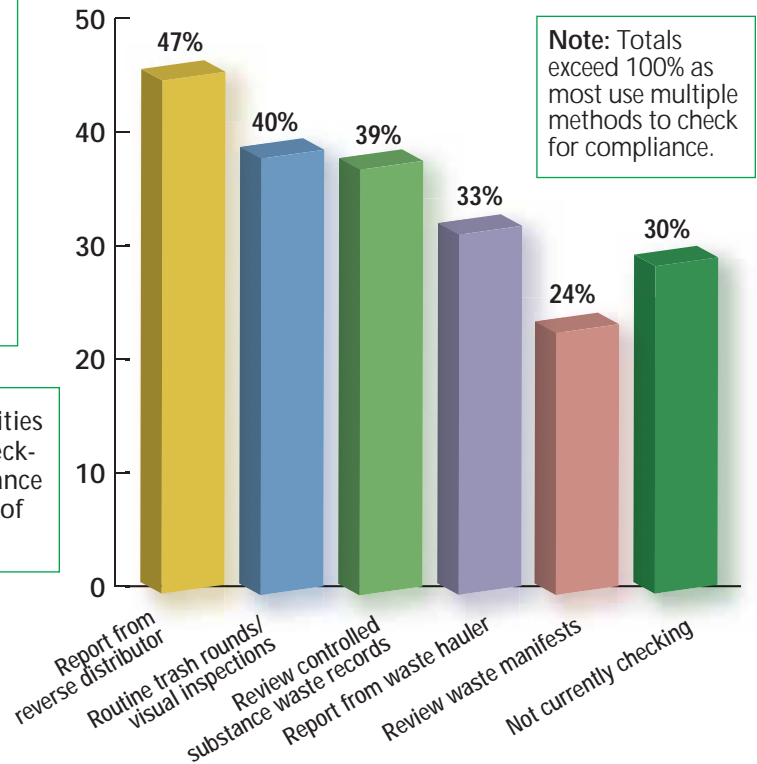
The growth in expenditures is predicted to continue over the next few years.

Annual expenditures grew significantly this year with almost half of all facilities spending more than \$20,000 on pharmaceutical waste management, up from 29% in 2008.

# Regulatory Compliance

**Managing RCRA-regulated waste** continues to pose a significant challenge to pharmacy. DoPs are somewhat more comfortable with managing hazardous chemotherapy waste and controlled substances, reporting compliance levels of 60% and 66%, respectively. The complexity of the regulations and a lack of in-house expertise, budget, and storage space are cited as the top challenges to achieving compliance for all waste streams. The good news is that most facilities are working toward improved compliance and expect to make great strides in their efforts over the coming year.

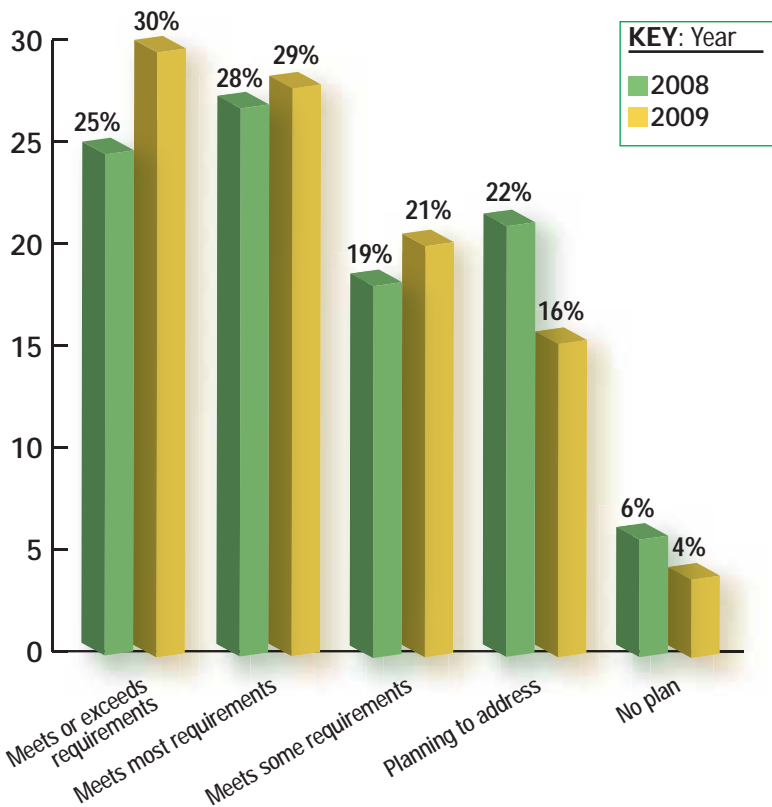
## Approach for Checking Compliance



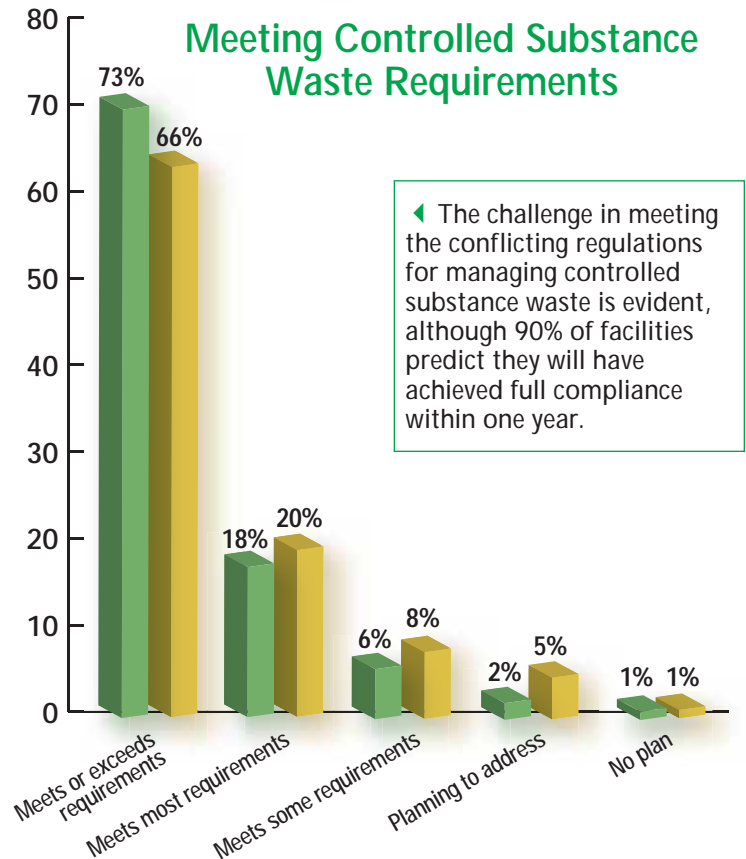
▶ 70% of facilities are actively checking for compliance using a variety of methods.

▼ While less than one third of all hospitals report that they meet RCRA requirements, there has been steady improvement over last year, and most significantly, 80% of all hospitals expect to have achieved full compliance within two years.

## Meeting RCRA Waste Requirements

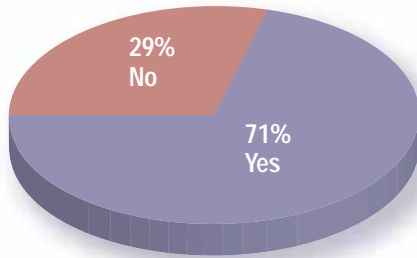


## Meeting Controlled Substance Waste Requirements



# Regulatory Inspections

## EPA and State Boards Inspecting for RCRA Compliance

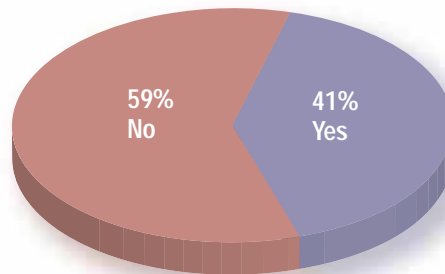


◀ While only 36% of health systems were inspected this year, 71% of the inspections included inquiries about the institution's hazardous drug waste practices and compliance with RCRA.

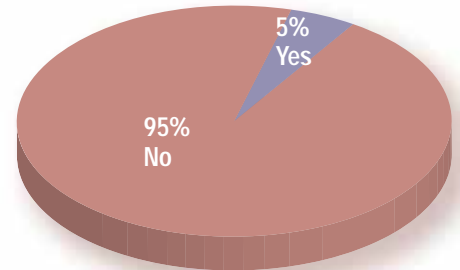
While the frequency of inspections did not increase this year, the expectations of the inspectors did. More facilities were questioned about their hazardous drug waste practices this year and there was a significant uptick in the number of recommendations made and citations issued.

## Recommendations Received

▶ Inspectors' growing expectations for compliant practices were a challenge for many facilities this year. The number of facilities receiving recommendations soared to 41% from 15% last year.



## Pharmacies Cited



▲ Further reflecting the challenges pharmacies face in achieving compliant practices, 5% of facilities were cited in 2009, up from zero in 2008.

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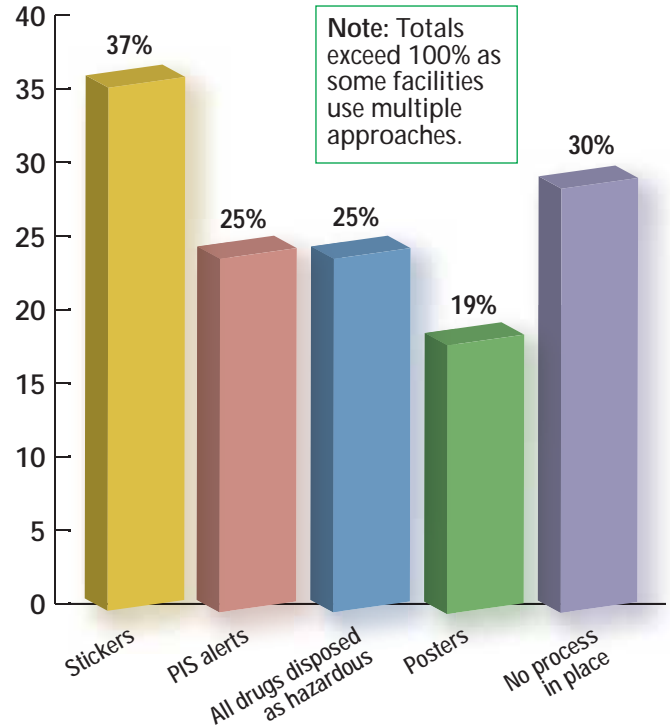
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# Waste Practices

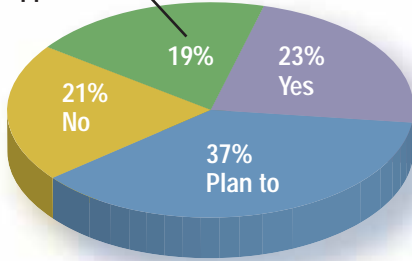
**Pharmacy has demonstrated** an improved awareness of proper disposal methods this year, although facilities with fully compliant processes are still in the minority. Just 43% of health systems have a RCRA-characteristic pharmaceutical waste program in place, and although 52% are using RCRA hazardous containers, only 39% have a designated long-term storage area for this waste.

## Hazardous Drug Identification Process



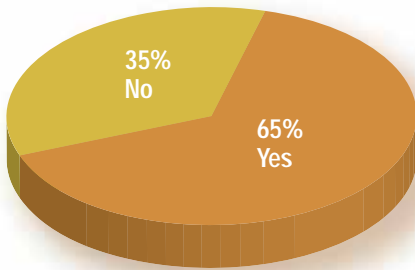
What is a cradle-to-grave approach?

## Cradle-to-Grave Approach



◀ A majority of facilities (60%) are moving toward or currently take a cradle-to-grave approach. Simultaneously, those not familiar with this concept dropped from 32% in 2008 to 19% this year.

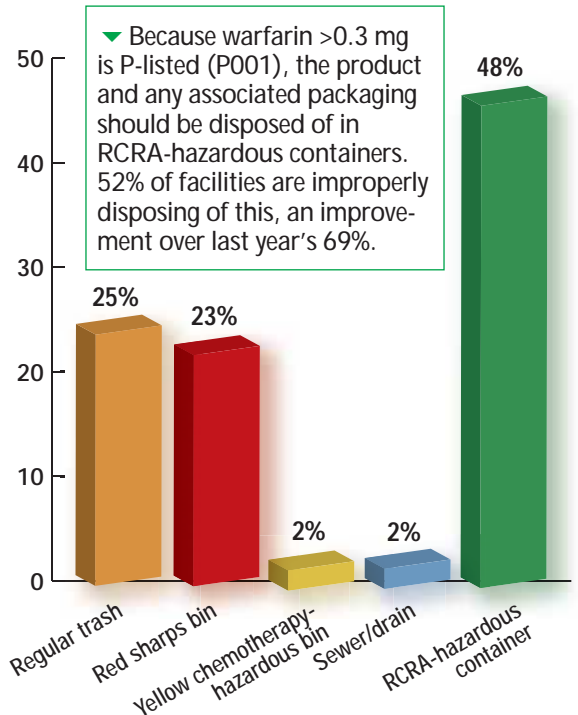
## Compiled List of All Hazardous Drugs



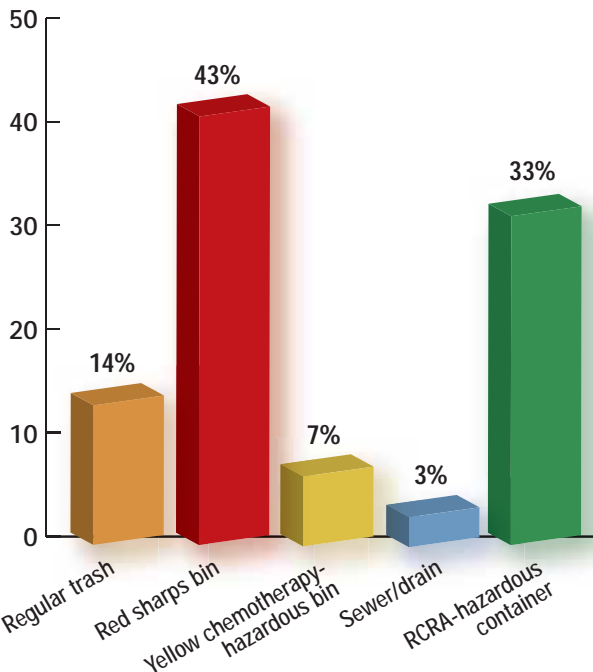
◀ A majority of hospitals have created a list of the hazardous drugs in their facilities, but only 65% of these included off-formulary drugs in use, and just 64% included drugs from all departments in their review.

▲ 70% have a process in place to identify hazardous drugs using a variety of approaches. Those disposing all drugs as hazardous waste report being most satisfied with their approach, followed by those using alerts in the PIS.

## Warfarin >0.3 mg Disposal Methods



## Flu Vaccine with Preservative Disposal Methods



◀ When a flu vaccine contains D-listed thimerosal (D009), any partial or expired doses should be disposed of in RCRA-hazardous containers. Only one third of facilities are doing so, yet this is still an improvement over last year's 22%.