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DQA Memo 08-020

To:	Adult Day Care Centers	ADC 03
	Adult Family Homes	AFH 09
	Community Based Residential Facilities	CBRF 09
	Facilities for the Developmentally Disabled (FDD)	FDD 09
	Home Health Agencies	HHA 07
	Hospices	HSPC 09
	Hospitals	HOSP 11
	Nurse Aide Training Programs	NATP 04
	Nursing Homes	NH 14
	Residential Care Apartment Complexes	RCAC 08
	Rural Health Clinics	RHC 04
	Certified Mental Health and AODA	CMHA 04
	Ambulatory Surgery Centers	ASC 05
	End Stage Renal Dialysis Units	ESRD 04
	Outpatient Rehabilitation Facilities	OPT/SP 03

From: Otis Woods, Administrator
Division of Quality Assurance

Recent FDA Medication Recalls and Compliance

The Centers for Medicare and Medicaid Services (CMS) has become aware, during facility surveys nationally, of instances where facilities have not been in compliance with various Food and Drug Administration (FDA) recalls.

Recent recalls have included heparin products and Digitex ®. These recalls were due to adverse effects occurring in patients, including deaths. Therefore, facility removal of the recalled products is imperative for patient safety. The FDA information on recalled products and lot numbers may be accessed at the FDA Web site located at <http://www.fda.gov/opacom/7alerts.HTML>.

Pharmacy providers and distributors and health care providers should be monitoring their supplies, including, for example, crash carts and storage cabinets, and removing recalled products in order to assure that recalled products are not available for patient/resident use.

In response to the recent finding nationally, CMS has asked the state survey agencies to do the following:

- Distribute a list of recalled heparin drugs to surveyors;
- Include a check of the possible presence of these recalled drugs during the course of surveys;
- Request a copy of any facility-written procedures for implementing drug recalls; and
- Request a description of staff notification and education efforts used to ensure that recalled heparin is not used for patient care.

For further information, please contact Doug Englebert at (608) 266-5388.