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MEMO

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TO: Selected Chief Executives Officers
Governmental Relations Executives
Pharmacy Directors
Infection Control Directors

FROM: Sarah Willson
Vice President of Clinical and Regulatory Affairs

SUBJECT: Contrast Shortage

The Missouri Hospital Association, on behalf of several hospital systems, recently requested assistance from the Department of Health and Senior Services and the Board of Pharmacy to implement flexibilities to help hospitals experiencing a shortage of injection contrast media. Nationally, the shortage of contrast media stems from the temporary shutdown of a General Electric production facility in China. While production at the GE facility is anticipated to increase throughout June, it is not anticipated they will return to normal production levels soon. In addition, distribution from other manufacturers has been impacted and availability remains dependent on the continued presence and spread of COVID-19, access at ports of entry into the United States, iodine shortages and other variables.

Across the state, hospitals have implemented conservation strategies like raising awareness, postponing elective procedures, utilizing alternative imaging techniques, utilizing less contrast per procedure, creating priority matrix within emergent and critical cases, and seeking alternative vendors. While hospitals should continue to exercise conservation strategies as appropriate, actions taken by the state agencies offer additional flexibility with repackaging and distribution of contrast media.

REPACKAGING FOR INTERNAL USE

Hospitals with a cleanroom meeting the United States Pharmacopeia Chapter <797> Sterile Compounding standards, who plan to use repackaged contrast media within their licensed

facility, may repackage into smaller vials to maximize the number of uses per original vial. Hospitals should develop procedures for repackaging the sterile contrast media. They may consider guidance like [ASHP Considerations for Imaging Contrast Shortage Management and Conservation](#) in the development of such procedures.

REPACKAGING FOR DISPENSING OUTSIDE LICENSED HOSPITAL, LICENSED PHARMACY, FACILITY, CLINIC

The Board of Pharmacy took action to allow the distribution of imaging contrast to be exempt from drug distributor licensing requirements under 20 CSR 2220-5.020(1)(B)1 during the national shortage duration. Additionally, they submitted an [emergency rule](#) exempting 20 CSR 2220-2.400(12) to allow a pharmacy to repackage imaging contrast and distribute it to other health care entities without a patient-specific prescription/order. A pharmacy (including hospital pharmacy) licensed as a Class H pharmacy with the Board of Pharmacy may repackage injection contrast and distribute to other health care entities for use in patients where it is clinically indicated without a patient specific order. This is outlined in recent [guidance](#) issued by the Board of Pharmacy. This would allow a pharmacy with a Class H license to provide repackaged contrast without a patient-specific prescription order. The Board will expedite requests for a Class H license and defer survey until the next regularly scheduled survey which likely would be six months to a year.

The actions by the board also will make it easier for distributors outside of Missouri to get product to Missouri facilities without having to have a distributor license. It also will make it easier to supply contrast without a prescription to commonly owned hospitals and health care facilities. Hospitals with a Class H pharmacy within an infusion center could repackage the contrast and supply to the hospital without the need for further licensing.

Please reach out to me at swillson@mhanet.com with questions or suggestions for additional flexibilities.

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