

Date: December 28, 2018

To: All Local Health Departments & Other Indiana Food Regulatory Agencies

From: George Jones, Interim Director *GS by wah*
Food Protection Program

Subject: Local Health Department Hospital Inspections

Purpose

This guidance document is provided to answer questions and promote consistency among regulators at local health departments (LHDs) and other Indiana food regulatory agencies regarding the transition of hospital inspections by LHDs resulting from House Enrolled Act (HEA) 1260, passed during the 2018 Indiana legislative session with a compliance date of January 1, 2019.

Background

Prior to the passage of HEA 1260 (2018), acute care hospital foodservice operations were inspected by the Indiana State Department of Health (ISDH), with the exception of some hospitals leasing space to other food businesses. As of January 1, 2019, the ISDH, Division of Acute Care will cease conducting hospital surveys for hospitals that have received and hold accreditation status from an accrediting organization approved by the Centers for Medicare and Medicaid Services. Most hospitals, except for the list below, will no longer receive food inspections from the ISDH, Division of Acute Care.

The following hospitals will continue to be inspected by the ISDH, Division of Acute Care:

Rush Memorial Hospital, 1300 N. Main St, Rushville	(Rush County)
St Vincent Neighborhood Hospital, 9613 East US Hwy 36, Avon	(Hendricks County)
St Vincent Neighborhood Hospital 6460 E. 146 th St, Noblesville	(Hamilton County)
St Vincent Neighborhood Hospital, 8602 N. Allisonville Rd, Castleton	(Marion County)
St Vincent Neighborhood Hospital, 2412 E. Main St, Plainfield	(Hendricks County)
Cameron Memorial Community Hospital, 416 E. Maumee St, Angola	(Steuben County)
Community Hospital of Bremen, 1020 High Rd, Bremen	(Marshall County)
Dekalb Health, 1316 E. Seventh St, Auburn	(Dekalb County)
Franciscan Health Rensselaer, 1104 E. Grace St, Rensselaer	(Jasper County)
Indiana Spine Hospital, 13219 N. Meridian St, Carmel	(Hamilton County)

Local Health Department (LHD) Inspections

Because they are retail food establishments, hospital foodservice operations are subject to the requirements of the Sanitary Standards for the Operation of Retail Food Establishments rule, 410 IAC 7-24, and the ordinances of the LHD where the facility is located. The inspection of all hospital food businesses, whether owned and operated by the hospital or not, will fall under the jurisdiction of the LHD for all facilities not listed above. Any county fees required for a retail food establishment permit will apply and help offset the cost incurred by the county in the performance of these inspections. Each department will need to determine if there is more than one retail food establishment operating on a hospital premises.

If it has not already been done, it is recommended that contact be made with the hospital Chief Executive Officer or Administrator's office prior to or as soon as possible after January 1, 2019 to discuss inspection expectations, registration and payment of fees.

This guidance document is not intended to waive or enhance any LHD inspection requirements stated in a local ordinance. When a LHD food ordinance allows inspection frequency to be flexible based on risk, it is recommended there should not be more than one or two inspections annually. Any additional inspections required by an ordinance may be conducted as Hazard Analysis Critical Control Point (HACCP) oriented inspections, looking at only specific aspects of foodservice activities, such as cooling of food or next-day reheating of food.

Also, **extreme caution** must be taken when using LHD enforcement policies that, in other establishments, might involve withdrawal of a permit or closure of a facility, since hospital patients are uniquely dependent on the ability of the hospital to produce food.

The hospital may own or operate other retail food establishments on the same or other premises. Some hospitals provide bulk food to other sites, prepare food for not-for-profit groups, such as Meals on Wheels, and may lease space to other food businesses within the hospital building(s). These should be inspected and permitted accordingly. Vehicles used for delivery of food prepared for not-for-profit entities are not a retail food establishment.

Hospitals are considered to be "Menu Type 4" facilities, and are exempt under the "Certification of Food Handlers" rule, 410 IAC 7-22-15(i), from having a certified food handler.

An inspection should review all aspects of the food service operation, including on-site/off-site food storage. Hospital purchased food stored in various locations in medical and personnel areas of a hospital, sometimes known as "floor pantries," are storage sites for small quantities of usually prepackaged food convenient to patients and/or employees. Potentially hazardous food items may be stored there as well. These areas may be inspected on a random or very infrequent basis due to a relative low level of risk. Infant formula dates can be evaluated during these random or infrequent floor inspections, or within the main hospital storage area that is directed by their food service manager.

It is unnecessary to follow patient trays all the way to the patient, although any complaints should be investigated. A food delivery system utilizing heated trays is a function of food quality and accreditation standards. It is not a public health hazard when food is delivered from the point of preparation to the consumer within four hours. A hospital food service system using time control under 410 IAC 7-24-193 must request LHD approval and cannot use time control for raw eggs.

Review of Rule Sections

There may be some sections of the Sanitary Standards for the Operation of Retail Food Establishments rule, 410 IAC 7-24, that are not as commonly used by LHD inspectors. Hospitals serve patients who constitute a “highly susceptible population,” as that term is defined in 410 IAC 7-24-46. It is recommended that these rule sections be reviewed prior to inspection. The rule sections are:

410 IAC 7-24-46 “Highly susceptible population” defined:

Sec. 46. “Highly susceptible population” means a group of persons who are more likely than other populations to experience foodborne disease because they are:

- (1) immunocompromised or adults who are at least sixty-five (65) years of age and in a hospital;
- (2) preschool age children in a facility that provides custodial care, such as a child care center; or
- (3) children nine (9) years of age or younger in a school or custodial child care facility that are served juice.

410 IAC 7-24-121, involving food employee exclusions and restrictions.

410 IAC 7-24-122, involving removal of food employee exclusions and restrictions.

410 IAC 7-24-153, involving the use of pasteurized food and prohibited food (includes criteria for juice and pasteurized eggs, and specifies not allowing raw or partially cooked animal foods and raw seed sprouts).

410 IAC 7-24-193, involving the use of time as a public health control (in a retail food establishment that serves a highly susceptible population, time alone shall not be used as the public health control for raw eggs).

Conclusion

Historically, the ISDH, Division of Acute Care, conducted retail food inspections for food services provided within a hospital and under a hospital’s license as part of the hospital survey process. In addition, the LHD retained jurisdiction for inspections of retail food operators who leased space within a hospital facility and for which the hospital did not own or operate the service.

As a result of HEA 1260 (2018), effective January 1, 2019, the ISDH, Division of Acute Care, will cease conducting hospital surveys for hospitals that have received and hold accreditation status from an accrediting organization approved by the Centers for Medicare and Medicaid Services. Therefore, hospitals will no longer receive food inspections from the ISDH, Division of Acute Care. Subsequently, the inspection of all hospital food services, whether owned and operated by the hospital or not, will fall under the jurisdiction of the LHD for all accredited facilities. Any county/local fees required for a retail food establishment permit will apply and help offset the cost incurred by the county in the performance of these inspections.

Questions related to this document or topic may be directed to your ISDH Food Protection Program (FPP) field staff, to dmiller@isdh.in.gov, or to the ISDH FPP Office at 317-234-8569. Below is a copy of a “Frequently Asked Questions” (FAQ) document related to LHD hospital inspections that was released a few weeks ago and recently revised by ISDH FPP.

FREQUENTLY ASKED QUESTIONS

Regarding transition of Hospital/Acute Care facility food establishment inspections from ISDH to LHDs

*Compiled August 2018 (Version 1)
Updated by ISDH November 21, 2018
ISDH FPP revised December 28, 2018*

This compilation is being sent to all Indiana Local Health Departments to answer the many circulating questions about the upcoming transition of food establishment inspections in hospitals/acute care facilities from ISDH oversight to Local Health Department oversight. It is simply a document pulling together questions being posed by various local health departments and answers being provided by the Indiana State Department of Health, Acute Care Division Director. All answers and this document as a whole are subject to change as new information becomes available.

Q: What precipitated the change of food establishment inspections in hospitals/acute care facilities from ISDH to local health departments?

As a result of House Enrolled Act No. 1260 (2018), effective January 1, 2019, the Division of Acute Care will cease conducting hospital surveys for hospitals that have received and hold accreditation status from an accrediting organization approved by the Centers for Medicare and Medicaid Services. Therefore, hospitals will no longer receive food inspections from the Indiana State Department of Health, Division of Acute Care. Subsequently, the inspection of all hospital food services, whether owned and operated by the hospital or not, will fall under the jurisdiction of the local health department for all accredited facilities. Any county/local fees required for a retail food establishment permit will apply and help offset the cost incurred by the county in the performance of these inspections.

Q: When will this change take place?

January 1, 2019.

Q: What hospital food establishment facilities will the ISDH, Division of Acute Care, retain inspection of as of 1/1/19?

See list provided by ISDH that was emailed along with the earlier release of this document (entitled: "2018.08.16 Non Accredited Hospitals").

Q: What hospital food establishment facilities will local health departments need to begin permitting, inspecting and generally overseeing as of 1/1/19?

See list provided by ISDH that was emailed along with the earlier release of this document (entitled: "2018.08.20(2) LHD Food Inspections Hospitals by County").

Q: Do some hospitals have more than one hospital license for their hospital "system" that may operate more than one facility?

Under state law, a hospital may have one license for multiple hospitals. Under federal law, hospitals may have provider based hospital outpatient/inpatient departments located within a 35 mile radius of the main hospital. Every hospital has an off-site list that accompanies their license. When local health departments begin to work with hospitals to confirm the amount of facilities within their county with food establishments located in them, they may simply ask the hospitals for this off-site list and have the hospitals indicate which, if any, of the listed buildings has a retail food service. Now that the county has jurisdiction, all retail food services (hospital owned and operated and non-hospital owned and operated but within the licensed buildings) will be inspected by the county.

Q: Can ISDH provide a list of areas within hospitals that were inspected during their last survey?

See list provided by ISDH that was emailed with the earlier document (entitled: "Hospital Food Inspection Reports"). This attachment contains all inspections performed over the past two years, and is in alphabetical order by hospital name. It is possible that a hospital may not have had an inspection during the past two years. Any data older than 2 years would not be useful.

Q: Can ISDH provide prior inspection reports to aid local health departments in knowing prior inspection issues/requirements, etc.?

See list provided by ISDH that was emailed along with the earlier document (entitled: "Hospital Food Inspection Reports"). This attachment contains all inspections performed over the past two years, and is in alphabetical order by hospital name. It is possible that a hospital may not have had an inspection during the past two years. Any data older than 2 years would not be useful.

Q: How often did ISDH inspect hospitals?

Some have not been inspected for several years. Some more often than others. There are a multitude of state and federal processes in play with hospitals. For multiple reasons, ISDH does/did not do annual surveys of each and every one of the 132 hospitals.

Q: How are we to handle hospital food establishment facilities which may be observed to have facility/equipment deficiencies upon initial inspection?

All facilities have been through proper state plan review and should have a copy of ISDH's plan approval letter. This does not likely account for facilities which have made changes

since the last ISDH survey, or sites that may have added new or expanded their food establishment facilities without approval from ISDH. This does not include third party vendors who have a rental or lease agreement with the facility. These third party vendors should have been under county authority for inspection.

Q: How do LHDs handle enforcement issues if they come across facilities which have food establishments/areas that were never inspected by ISDH, or if changes/additions have been made to facilities that were not approved in advance by ISDH, or not observed by ISDH if a survey has not taken place for multiple years?

If counties find locations that are under the hospital's license (owned and operated by the hospital) and the hospital cannot produce an approval letter, then they are subject to the applicable county enforcement action. If a third party vendor is operating within the facility and there is no county permit currently, then the applicable county enforcement would apply. Perhaps counties may wish to withhold enforcement for third parties without permits, get them under a permit, and then hold everyone accountable going forward for any changes/additions.

***Note:** It is probably best for each county to discuss these issues with their county attorney and make the most appropriate decision warranted by the circumstances encountered.*

Q: Does this change apply to Nursing Homes (aka Long Term Care) facilities?

This does not apply to nursing homes. The legislation that led to this change only addresses hospitals.

Q: What areas other than the kitchen area would be required to be inspected?

Q: What about equipment such as ice makers, refrigeration units, etc., that may be located on various floors of hospital facilities?

Any area where food is prepared, handled, held or served to the public. An inspection should review all aspects of the food service operation, including on-site/off-site food storage. Hospital purchased food stored in various locations in medical and personnel areas of a hospital, sometimes known as "floor pantries," are storage sites for small quantities of usually prepackaged food convenient to patients and/or employees. Potentially hazardous food items may be stored there as well. These areas may be inspected on a random or very infrequent basis due to a relative low level of risk. Infant formula dates can be evaluated during these random or infrequent floor inspections, or within the main hospital storage area that is directed by their food service manager.

It is unnecessary to follow patient trays all the way to the patient, although any complaints should be investigated. A food delivery system utilizing heated trays is a function of food quality and accreditation standards. It is not a public health hazard when food is delivered from the point of preparation to the consumer within four hours. A hospital food service system using time control under 410 IAC 7-24-193 must request LHD approval and cannot use time control for raw eggs.

Q: What about the need to inspect other buildings which have food service and or storage such as residence halls, outlying doctor's offices owned and operated by the hospitals?

Yes, any building under the hospital's license that provides a food service to the public (other than pre-packaged foods or vending) will require inspection. We (ISDH) believe these are few.

Q: What about the need to inspect Medicine refrigeration units?

These are excluded from inspections as they should not be part of the retail food service.

Q: If the hospital provides food to a local school or other facility (as some do), would they now be considered separate from the hospital?

In the context of hospitals, the state survey process did not have jurisdiction over non-hospital entities. Food service in an institution other than a hospital would fall to the county. In a scenario where the hospital is providing food away from the preparation site, the hospital food service would be operating as any other caterer within the County.

Q: How many inspections are required for hospitals per year?

There is no set number. Going forward, the number of food inspections will be determined by the county's ordinance requirements for retail food establishments.

Q: HEA 1260 requires the state health commissioner to issue a license upon the application of a hospital that has received accreditation. It says the state department cannot perform routine surveys but may investigate complaints against an accredited hospital. It says the state health department shall conduct random validation surveys when requested by the federal Centers for Medicare and Medicaid Services. It also says the state health department may perform an initial survey of a hospital obtaining a license. Does ISDH's authority preempt local government from permitting and inspecting the facility since it is licensed through and may be inspected/investigated by the state?

It is our understanding that an administrative agreement was made years ago (predating anyone currently at the ISDH). The agreement was that the facility should not be subject to multiple inspections by multiple agencies. Since the ISDH was the licensing entity and to avoid redundancy, the ISDH would do food inspections, using the retail food establishment code, as part of the hospital survey process. The ISDH Food Protection Program trained state survey staff on the performance of the food inspections. Since the county was not performing the inspections (no resources being expended), a permit was not required. The ISDH did not have authority or jurisdiction to inspect food services that were not owned or operated by the hospital. A fairly recent trend by hospitals was to lease space to third parties who provided food for sale. An example of this was a McDonald's located at Riley Hospital (and there are many like this throughout the state). These entities would be under the jurisdiction of the LHD. The ISDH believes that many counties are doing these inspections currently. The new change means that, in addition to these third party vendors,

the LHD will pick up the hospital's food service (kitchen, serveries, preparation and holding areas, extra coffee shops run by the hospital, etc.) at the same time the LHD is inspecting the third party vendors. For those counties that do not have hospitals with third party vendors, this will be a new inspection.

Q: If LHDs and ISDH are both getting complaints on an accredited hospital how will this be handled? Will LHDs take all the food complaints and ISDH will take all the other complaints? What if the complaint involves food and other areas of the facility (i.e. pest complaints, or cleaning issues throughout the building)?

The LHD will only inspect food complaints involving the food service areas. The ISDH does continue to hold authority for the investigation of all complaints. The ISDH would request notification from the LHD if the LHD receives a food complaint. It may be that the ISDH and LHD will do a concurrent inspection since there may be deficiencies in both the retail food establishment code and state/federal deficiencies related to infection control etc. Likewise, when the ISDH receives a food service complaint, the ISDH will notify the LHD and again the possibility of a concurrent inspection may exist.