Guidance for Developing a Mandatory Influenza Vaccination Program

This document is intended to provide guidance and information for developing a mandatory influenza vaccination program within individual hospitals. This document does not provide an exhaustive list of all elements that should be considered when adopting a mandatory influenza vaccination program however it does provide a framework for major areas that should be considered.

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Background

The Centers for Disease Control and Prevention (CDC) recommends that healthcare personnel and persons in training for healthcare professions should be vaccinated annually against influenza. Despite this recommendation, vaccination of healthcare personnel remains inconsistent. Data collected from Colorado hospitals in March 2011 indicates that vaccination rates range from 60-90%.

In recent years, there has been a significant effort to increase vaccination among healthcare personnel. Various national accrediting and professional organizations, including the Infectious Disease Society of America (IDSA) and Association for Professionals in Infection Control and Epidemiology (APIC), support mandatory vaccination policies. In addition, Colorado now mandates reporting of influenza immunization data by acute care hospitals.

Colorado Hospital Association recognizes that Colorado hospitals and health systems are committed to patient safety. Vaccination of healthcare workers against influenza not only protects patients and their families, but also protects our valuable workforce against illness. Therefore, CHA put before its Board of Trustees a resolution in support of requiring annual influenza vaccinations for all healthcare personnel.

“All CHA member hospital and health systems should adopt a mandatory influenza policy and provide influenza vaccination to all healthcare personnel such that all healthcare personnel are required to provide: 1) annual documentation of influenza immunization; OR 2) documentation from a licensed physician indicating evidence-based medical contraindication against influenza vaccination AND be required to wear a surgical mask at all times while on the premises of the health care facility.

Documentation is required to be part of the healthcare personnel record and evaluated annually for applicability. In the event that healthcare personnel do not receive an influenza vaccination annually due to evidence-based medical contraindication, the healthcare personnel should be required to wear a surgical mask.”

This resolution was unanimously approved by CHA Board of Trustees on May 20, 2011. Similarly, American Hospital Association recently endorsed their support of mandatory vaccination of healthcare workers and encouraged hospitals to consider implementing this important policy within their institutions.
Colorado Hospital Association Resolution in Support of Requiring Annual Influenza Vaccinations for all Healthcare Personnel

WHEREAS, Influenza is a contagious respiratory illness caused by influenza viruses that can cause mild to severe illness and at times can lead to death;

WHEREAS, Healthy persons infected with the influenza can transmit it to people at higher risk for complications;

WHEREAS, Complications of the influenza include bacterial pneumonia, ear infections, sinus infections, dehydration and worsening of chronic medical conditions, such as congestive heart failure, asthma or diabetes;

WHEREAS, Healthcare providers with medical conditions who are not vaccinated against the influenza put patients and other healthcare workers at a higher risk of severe complications from influenza;

WHEREAS, Healthcare personnel are defined as all persons whose occupation involves contact with patients or contaminated material in a healthcare, home healthcare, or clinical laboratory setting. Healthcare personnel are engaged in a range of occupations, many of which include patient contact even though they do not involve direct provision of patient care, such as dietary and housekeeping services. The term healthcare personnel includes not only employees of the organization or agency, but also contractors, clinicians, volunteers, students, trainees, clergy, and others who may be in contact with patients.

WHEREAS, The Centers for Disease Control and Prevention (CDC) recommends that healthcare personnel and persons in training for healthcare professions should be vaccinated annually against influenza. These include physicians, nurses and other workers in both hospital and outpatient-care settings, including medical emergency-response workers (paramedics and emergency medical technicians) employees of nursing homes and long-term care facilities who have contact with patients or residents;

WHEREAS, Efforts to increase vaccination coverage among healthcare providers using mandatory vaccination policies are supported by various national accrediting and professional organizations, including the Infectious Diseases Society of America;
WHEREAS, the Colorado Hospital Association is committed to patient safety and quality healthcare for all Coloradans:

Be it therefore resolved that the Colorado Hospital Association recommends the following:

All CHA member hospitals and health systems should adopt a mandatory influenza policy and provide influenza vaccination to all healthcare personnel such that all healthcare personnel are required to provide: 1) annual documentation of influenza immunization; OR 2) documentation from a licensed physician indicating evidence-based medical contraindication against influenza vaccination AND be required to wear a surgical mask at all times while on the premises of the health care premises.

Documentation is required to be part of the healthcare personnel record and evaluated annually for applicability. In the event that healthcare personnel do not receive an influenza vaccination annually due to evidence-based medical contraindication, the healthcare personnel should be required to wear a surgical mask from the point of entry into the hospital and throughout the duration of their shift without exception.

Approved by the CHA Board of Trustees on May 20, 2011
Getting Started

The purpose of this tool kit is to provide some examples and resources for your organization to consider when implementing a mandatory vaccination program.

One of the keys to successful implementation is having executive leadership sanction a mandatory vaccination program. Leadership involvement is essential to ensuring that any policy is supported and enforced at an organizational level. In addition, it is important to engage key stakeholders within the organization when initiating the policy development process. The composition of these stakeholders will widely vary depending on your unique facility, however some examples of individuals to consider may include:

- Chief Executive Officer
- Chief Medical Officer
- Chief Nursing Officer / Director of Nursing
- Chief Quality Officer / Quality Director
- Infection Prevention Department (Chief Infectious Disease Physician, Infection Preventionist)
- Human Resources / Employee Health
- Compliance Officer
- Legal Council

Drafting a Policy

A policy requiring mandatory influenza vaccination for all health care workers should be drafted following your organizational format. The following should be considered for inclusion in the policy including:

- **Justification for the policy**: Background on why the policy is important to your organization and why the policy is being implemented.

- **Definitions**: The policy should outline what mandatory vaccination means and to whom within the organization it applies.

- **Procedures**: This explains how mandatory vaccination will be implemented within the hospital. Details might include vaccination timeframes, procedures for getting vaccination and/or the process for providing influenza documentation.
**Exemptions**: The policy should clearly outline the types of exemptions that the facility will allow and the process of requesting an exemption.

**Communication / education**: Resources should be available for staff to learn more about influenza vaccines and the organizational policy specific to mandatory influenza vaccination.

**Enforcement and consequences**: This section outlines the consequences for health care worker non-compliance. Interim and/or absolute deadlines should be established and clearly outlined.

**Contingency plans**: This section explains how the policy will be affected by vaccination shortages or delays. This should also include the identification of the professional staff that has the authority to amend the policy when necessary.

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**Sample Policy**

A sample policy is available to provide guidance on how to develop your organization’s policy related to mandatory influenza vaccination of healthcare personnel. See below to view a copy of the sample policy, and go to this [link](#) to access a copy of the policy to adapt to your facility.
PURPOSE
To help protect staff, providers, patients, residents and visitors of (INSERT FACILITY NAME) from acquiring seasonal influenza disease and to help prevent the unnecessary spread of the influenza virus. Vaccine programs are an essential part of infection prevention and control for slowing or stopping the transmission of seasonal influenza viruses from adversely affecting those individuals who are most susceptible. This is accomplished through the requirement that all healthcare workers receive annual influenza vaccination, unless the individual has a valid exemption. (Note: Refer to Colorado Department of Public Health and Environment regulations (6 C.C.R. 1011-1, Ch.02, Part 10 (the “Rules”)).

DEFINITIONS

Common Areas – those areas that are commonly-used by patients and visitors, including but not limited to patient rooms, hallways of nursing units, waiting areas, and areas where patients receive treatment, such as imaging and therapy areas.

Employee – any person who performs a service for wages or other remuneration for a licensed healthcare entity.

Healthcare Worker (or Healthcare Personnel) - any person working in a healthcare entity who has the potential to expose patients, residents, or consumers of the healthcare entity to the influenza virus. The following are considered healthcare workers and are required to obtain the influenza vaccination each influenza season:

- all full-time, part-time or PRN persons employed by (INSERT FACILITY NAME), whether or not they have direct contact with patients or visitors;
- all licensed independent practitioners (MDs, DOs, physician assistants and advance practice nurses) with medical staff privileges who are practicing at this facility;
- all individuals who are performing work at this facility and who have a contract directly with this facility;
• all students 18 years or older who train at this facility for 1 day or more from October 1 through December 31 of the current flu season;
• all persons who serve as volunteers at the facility.

(Note: CDPHE does not recognize volunteers as healthcare workers; however, they are included as a category of healthcare workers for reporting to Centers for Medicare and Medicaid Services via NHSN, and Centers for Disease Control recommends immunization of volunteers.)

The following are considered healthcare workers for whom annual immunization is highly recommended but not required:

• individuals who are not employees of this facility but who are employed by agencies to perform work in the facility, including those from staffing agencies.

(Note: A facility may elect to include these individuals in the requirement for annual influenza immunization.)

**Proof of Immunization** - a written statement from a healthcare provider who has administered an influenza vaccine to a healthcare worker, specifying the vaccine administered and the date it was administered. For CDPHE purposes, proof may also be demonstrated via an electronic entry in the Colorado Immunization Information System (CIIS). See, 6 C.C.R. 1011-1, Ch.02, Part 10.5(K).

**Influenza Season** - that period of time from October 1 through March 31 of the following year.

(Note: CDPHE may change the beginning date of the influenza season in any given year as the CDPHE flu surveillance team determines to be appropriate---See 6 C.C.R. 1011-1, Ch.02, Part 10.5(H).)

**Influenza Vaccine** - a currently licensed FDA approved vaccine product.

**Medical Exemption** – An exemption to the influenza vaccine based on medical contraindication as verified in writing from a physician, physician's assistant, advanced practice nurse or nurse midwife licensed in the State of Colorado.

**Religious Exemption** – An exemption based on sincere religious beliefs that are contrary to receipt of the influenza vaccine. **(Note: Medical exemption is not recognized by CDPHE or by CMS or CDC. Refer to religious exemption section below under “POLICY”).**

**Volunteer** - a person who provides services without wages or other remuneration.

**POLICY**

I. All healthcare workers as defined above must receive the season influenza vaccine or submit proof of an approved exemption by December 31 of each year.
II. When sufficient vaccine supplies are available the influenza vaccine will be offered at no charge by \textit{(INSERT FACILITY NAME)} to healthcare workers employed by the facility and to licensed independent practitioners who are credentialed by the facility and working at the facility.  
\textit{(Note: Language may be added here regarding the facility’s policy if the facility elects to reimburse a healthcare worker for influenza vaccination received from another source.)}

III. Any healthcare worker who receives the influenza vaccine from a source other than this facility must submit written proof of vaccination including the name of the person receiving the vaccine, the date it was received, and the name of the provider where the vaccine was administered.  
\textit{(Note: Insert how and where the written proof is to be submitted.)}

IV. Individuals who are performing work at this facility and who have a contract directly with this facility will be required to show proof of immunization.  
\textit{(Note: Indicate how and to whom the proof must be submitted.)}

V. Employees whose date of hire is during influenza season will be required to present proof of immunization or will be given the influenza vaccine at health screening if hire date is between October 1 (or earlier if influenza season begins earlier as determined by CDPHE) and March 31. Licensed independent practitioners who are newly-credentialed will be required to present proof of immunization or will be given the influenza vaccine if the start date is between October 1 (or earlier if influenza season begins earlier as determined by CDPHE) and March 31.

VI. Each healthcare worker who does not have proof of immunization will be required to wear a surgical or procedural mask during influenza season when in direct contact with patients and when in common areas of the facility. A list of those healthcare workers who are required to wear a mask will be provided to the respective manager/supervisor, who will be responsible for monitoring and compliance.  
\textit{(Note: The facility may indicate here how it will easily identify who do or do not need to wear a mask during influenza season. An example is a colored sticker placed on the name badge of those healthcare workers who received the vaccine.)}

VII. By December 31 of each year, for any healthcare worker who has not received the influenza vaccine and does not have an approved exemption, one of the following will occur, as appropriate.  
\begin{enumerate}
\item The healthcare worker who is an employee of the facility will be subject to disciplinary action, up to and including termination. 
\item An individual performing work under a direct contract with this facility will not be allowed to perform the work.
\end{enumerate}
c. A licensed independent practitioner will be placed on automatic administrative suspension from the medical staff.
d. A student will not be allowed to continue training in the facility.

(Note: Section VII is not a requirement according to CDPHE regulations. A facility may or may not choose to adopt this requirement. Consult with the Human Resources Department, Medical Staff Office and legal counsel before determining a course of action. If a facility chooses to not adopt this policy statement, the facility should insert here what action will be taken for healthcare workers who do not receive the vaccine and do not have an approved exemption.)

VIII. By December 31 of each year any healthcare worker who has not received the influenza vaccine due to an approved exemption and who does not wear a surgical or procedural mask when in contact with patients and when in common areas of the hospital will be considered not in compliance with this policy and is subject to the same action as noted above (VII).

PROCEDURES

I. COMMUNICATION AND EDUCATION

a. Prior to the annual onset of Influenza Season, (INSERT FACILITY NAME) will inform healthcare workers of the requirement for vaccination, the dates when influenza vaccine(s) are available, and the fact that vaccines will be provided at no cost to employed healthcare workers and licensed independent practitioners. Communication will be through normal information distribution. Education on the influenza virus and the vaccine will be completed throughout (INSERT FACILITY NAME) on an ongoing basis. (Note: The education may also advise healthcare workers of the vaccination procedures, approved exemptions for the vaccine and the consequences of refusing vaccination without an approved exemption or failing or refusing to wear a surgical mask if granted an exemption.)

b. (INSERT FACILITY NAME) will inform other healthcare workers who provide services at the facility that (a) the facility has a policy regarding annual influenza immunization of all healthcare workers, (b) each healthcare worker who has not been immunized is required to wear a mask during influenza season when in direct contact with patients or in common areas, and (c) masks are available for healthcare workers who are not immunized.

II. MEDICAL EXEMPTION

a. A medical exemption from influenza vaccination is allowed if the influenza vaccination is medically contraindicated for the healthcare worker.
b. The healthcare worker must complete a medical exemption form. The medical exemption must be signed by a physician, physician assistant, advanced practice nurse, or nurse midwife and must certify that the influenza vaccination for the healthcare worker is medically contraindicated as described in the product labeling approved by the United States Food and Drug Administration.

(Note: A list of current contraindications to the different types of vaccines can be found at this site: http://www.cdc.gov/flu/professionals/acip/2013-summary-recommendations.htm.)

c. If the healthcare worker with a medical exemption is a licensed independent practitioner, the medical exemption form must be signed by licensed independent practitioner other than that individual.

III. RELIGIOUS EXEMPTION

(Note: CDPHE, CDC, CMS and OSHA do not recognize a religious exemption to the vaccination requirement under the Rule. The Equal Employment Opportunity Commission (EEOC) has acknowledged religious exemptions from vaccination requirements through informal guidance. See this website: www.eeoc.gov/foia/letters/2012/religious_accommodation.html. Each facility is advised to consult with its legal counsel and human resources expert to determine the best approach to an objection on religious grounds under EEOC.)

a. If a healthcare worker has an objection to receiving the influenza vaccine based on a sincerely-held religious belief for which there is documented evidence of opposition to vaccinations, the healthcare worker will contact the facility's Human Resources Department for direction regarding requesting a religious exemption.

b. The healthcare worker must complete a religious exemption form.

(Note: CHA has not created a sample religious exemption form. The facility will need to develop the form if it elects to adopt this exemption.)

c. The Human Resources Department will evaluate all requests for religious exemption on a case-by-case basis.

IV. CONTINGENCY PLAN FOR VACCINE SHORTAGE

a. If there is a shortage of influenza vaccine supply that affects the ability of the facility to immunize all healthcare workers, the facility will develop a contingency plan. This plan will include vaccine prioritization and distribution based on the influenza vaccine supply shortage faced and recommendations from the CDC and the Colorado Department of Public Health and Environment.

b. Communication about the contingency plan and surgical mask use will be provided to healthcare workers.
V. DOCUMENTATION AND REPORTING

a. The facility will annually monitor vaccination rates and reasons for non-participation by healthcare workers in the facility’s immunization program.

b. The facility will maintain influenza immunization documentation (proof of immunization or documentation of approved exemption) for all healthcare workers for a period of three (3) years.

(Note: Indicate which department is responsible for maintaining the documentation. CDPHE requires maintaining this documentation for three years. The facility may have another policy that designates a longer period for maintaining health records of employees. If so, the facility may elect to change to that longer time period.)

c. Such documentation may be examined by CDPHE via a random audit process.

d. Each year by March 31, the facility will report to CDPHE the qualifying percentage of healthcare workers who were immunized against influenza.

e. Each year by May 15, the facility will report healthcare worker immunization data to Centers for Medicare and Medicaid Services via National Healthcare Safety Network (NHSN) reporting website for the entire influenza season (October 1 through March 31). Healthcare workers included in the report are employees, licensed independent practitioners, adult students/trainees, and volunteers.

f. Each year by March 31 the facility will report influenza vaccination data for employees to CDPHE either through the CDPHE portal or through National Healthcare Safety Network (NHSN) for healthcare workers who received influenza vaccine between October 1 and March 31.

RELATED DOCUMENTS / REFERENCES


B. Centers for Disease Control and Prevention (CDC). Influenza Activity – United States, 2012-2013 Season and Composition of the 2013-2014 Influenza Vaccine, Weekly, June 14, 2013; 62(23); 473-479, accessed at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6223a5.htm?s_cid=mm6223a5_e

C. Centers for Disease Control and Prevention (CDC). Immunization of Health-Care Personnel: Recommendations of the Advisory Committee on Immunization Practices (ACIP); Recommendations and Reports, November 25, 2011; 60(RR07); 1-45, accessed at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6007a1.htm


H. Centers for Medicare and Medicaid Services. Hospital Inpatient Quality Reporting Program, Healthcare Associated Infections (HAI), HAI Reporting Requirements by Fiscal Year, access at: https://www.qualitynet.org/dcs/ContentServer?c=Page&pagemenu=QnetPublic%2FPage%2FQnetTier2&cid=1228760487021


K. United States Department of Labor, Occupational and Safety Health Administration. OSHA QuickTakes. Seasonal Influenza Vaccination - Important Protection for Healthcare Workers, Fact Sheet, accessed at: https://www.osha.gov/Publications/SeasonalInfluenzaVaccination.html


REVIEWED BY: (INSERT DEPARTMENT/COMMITTEE/INDIVIDUAL NAMES HERE)
Exemption from Seasonal Influenza Vaccination
Due to Medical Contraindication

Seasonal influenza vaccination is a condition of employment for all health care workers. Depending on type of vaccination offered, specific medical contraindications may exist for certain individuals. The medical contraindication against seasonal influenza vaccination must be confirmed by a licensed health care provider and must be evidence-based.

This Medical Exemption form must be completed by the employee’s primary healthcare provider and returned to Employee Health Services.

My employer, INSERT FACILITY NAME HERE, has recommended that I receive seasonal influenza vaccination in order to protect myself and the patients I serve.

I understand that because I work in a health care environment I may place patients and co-workers at risk if I work while infected with the influenza virus.

I understand that since I have an evidence-based medical contraindication to influenza vaccination that I will be required to wear a mask when in direct contact with patients and when in common areas of (INSERT FACILITY NAME) through the duration of the influenza season (INSERT DATES HERE).

________________________________________              _____________________________
Employee Name (print)                          Employee ID Number

________________________________________              _____________________________
Employee Signature                                Date

________________________________________________________________________

THIS SECTION SHOULD BE COMPLETED BY THE EMPLOYEE’S HEALTH CARE PROVIDER

I have evaluated ___________________________ and can verify that this employee has a medical contraindication to influenza vaccination.

This employee has one or more of the following contraindications:
☐ Documented severe allergy to eggs or egg products
☐ Personal history of Guillain-Barré Syndrome within 6 weeks of receiving influenza vaccine
☐ Severe allergic reaction to previous influenza vaccine
☐ Other: (please explain – only evidence-based medical contraindications): ___________________________

________________________________________              _____________________________
Healthcare Provider Name (print)                          Date

________________________________________              _____________________________
Healthcare Provider Signature                          Phone Number
Medical Exemption
A sample medical exemption form is available to provide guidance for developing your own form. See previous page to view a copy of this sample exemption form. To download a copy of the exemption form that can be amended, please click here.

Religious Exemptions
CHA’s resolution did not include a religious exemption. Per the resolution outlined on page 2, only evidence-based medical contraindications are valid exemptions. Research by CHA as well as member infection control physicians and nurses has not produced any valid and documented religious exemptions from specific religious faiths. However, anecdotal reports have indicated that some religious faiths such as Christian Scientists or Native Americans that have specific ties to certain tribes and their shaman may be religiously opposed to vaccines.

It is CHA’s recommendation to evaluate the internal needs of your organization when considering a religious exemption. If your organization does decide to allow a religious exemption, it is recommended that your organizational policy is clear on the documentation that needs to be provided as well as the specific steps that should be taken to discuss religious exemption.

Education of Healthcare Personnel
Education of facility staff is an important component to any mandatory influenza vaccination policy. Unfortunately, there is a tremendous amount of misinformation about the influenza vaccine and misperceptions about both the vaccine’s side effects and medical contraindications are common in both the healthcare community as well as in the general public. See “Additional Resources” below for websites to help educate your healthcare personnel.

Providing Vaccine to Healthcare Workers
Organizational policy that requires influenza vaccination of all healthcare workers must ensure that that vaccine is available and accessible in order to enable compliance. One of the first steps is to verify that there is adequate vaccine in-stock within your individual facility to ensure that all required healthcare workers can be vaccinated.
Stocking requests for vaccine typically occur in December through a variety of distributors. If you require vaccine, a helpful resource to determine availability is the *Influenza Vaccine Availability Tracking System (IVATS)*. The link below provides a spreadsheet of distributors with contact information as well as a listing of available and/or backordered vaccine. It is unclear how often this spreadsheet is updated and does not appear to be an exhaustive list, but nonetheless is a helpful place to start. [http://www.preventinfluenza.org/ivats/ivats_healthcare.asp](http://www.preventinfluenza.org/ivats/ivats_healthcare.asp).

Assuming that adequate vaccination supply is available, individual facilities need to ensure that ability to access vaccine is widely known and available in multiple areas. Your facility (depending on size) might want to set up designated areas for influenza vaccination stations throughout the facility that are staffed consistently for certain times of the day. Vaccination stations are very successful tools for achieving high compliance and depending on how they are staffed and the number of available stations, vaccination should be quick and easy. It is important to remember to have certain stations available during evening and night shifts and on weekends.

Another useful mechanism to facilitate in the wide-spread vaccination of healthcare workers is to train and designate “vaccination captains” that are assigned to various parts of the facility. The vaccination captains can help administer vaccine and can be useful personnel that have the ability to offer vaccine in less central areas of the facility and outside of normal business hours.

**Tracking Compliance**

Organizations that have a mandatory influenza vaccination policy in place must also have a good system for tracking compliance within your facility. This is critical to be able to report immunization program data to CDPHE and CMS. Depending on the sophistication of some internal facility systems, human resource tracking systems or employee health might be a good mechanism to track annual influenza vaccination. However, it is important to have a record of annual influenza vaccination or medical exemption in each employee’s file.

**Additional Resources**

The following websites are excellent resources for development of an influenza vaccination program and education of healthcare workers about influenza and influenza vaccine:


http://www.cdc.gov/flu/professionals/acip/2013-summary-recommendations.htm (Summary Recommendations from APIC with detailed information about the various vaccines, including contraindications to each type of vaccine)

www.anaimmunize.org/flutoolkit (American Nurse Association flu vaccine toolkit)

http://www.anaimmunize.org/flu-video (ANA video explaining myths and truths about influenza vaccine)

http://www.flu.gov/prevention-vaccination/prevention/index.html# (General influenza vaccine information, including safety, effectiveness, side effects, and other information)


www.immunize.org/catg.d/p3094.pdf (Information about vaccinating people with a history of egg allergy)

www.immunize.org/catg.d/p4066.pdf (Screening checklist for contraindications to inactivated injectable influenza vaccine)

www.immunize.org/catg.d/p4067.pdf (Screening checklist for contraindications to live intranasal influenza vaccine)

www.immunize.org/catg.d/p3074.pdf (Standing orders for administering influenza vaccine to adults)

http://www.immunize.org/catg.d/p2020a.pdf (Instructions regarding how to administer injectable vaccine)

http://www.immunize.org/askexperts/experts_inf.asp ("Ask the Expert" questions & answers regarding influenza vaccine)
Questions

If you have any questions regarding CHA’s resolution or clarification regarding this tool kit, please contact Nancy Griffith, Director of Quality Improvement and Patient Safety at 720.330.6067 or by email at nancy.griffith@cha.com.