Consideration Template: Immunizations and Medical Interventions/Therapeutics

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This document is to be used as a **template** and to serve as a tool to help facilities to set up best practices within their organization to residents, patients and/or families. Facilities should copy the template on to their own letterhead before using.

Who should sign a consent for vaccination or treatment?
Facilities should always read the Centers for Medicare & Medicaid Services (CMS) regulatory language found in the F tags as well as the guidance to surveyors. These can be found in the State Operations Manual Appendix PP - Guidance to Surveyors for Long Term Care Facilities.

This is the link to both the F tag and guidance for surveyors and facilities to consider. Below are several F tags that may be considered when developing policies, documents and education regarding vaccinations or treatment as well as who can sign for such treatment.

F551: Resident right to appoint a representative who may exercise the resident's rights to the extent provided by state law.

Residents have the right to appoint a decision maker or person(s) to be included in making decisions regarding care.

Things to consider:

- Competency (legal capacity to make one's own decisions). Facilities should have a written policy on resident decision making that includes a legal definition of competency.
- Review this policy annually and provide it to both residents and families at admission.
- **Residents may fluctuate in capacity due to diagnosis or treatment.**
- At quarterly Minimum Data Set (MDS) review the Brief Interview for Mental Status (BIMS) score or other recognized brief mental status test should be used to assess residents cognitive functioning.
- In the event cognition has improved the facility may want to consider a request for medical review of the resident's competency/capacity.

F552: Planning and implementing care

Things to Consider:

- Creating a consent policy that provides for resident education and witness or signature of resident once treatment is agreed to or refused.
- Including guidance to the staff seeking the consent on the form.
- Residents should be informed using a communication means they would best understand.
- Include in your policy the frequency that education regarding treatment will occur.
- Consent may change from quarter to quarter or based on the season (example COVID-19 updates or influenza updated formula) or with change of resident's condition.

Documentation:
Things to consider: Who, What, When, Where, Why, How

- Who was the information provided too?
- What information was provided-including any handouts that were given?
- Why were these individuals informed or involved in the treatment or care discussion?
- How was the information provided including what language or device for communication was used? Was the information provided via telephone, email, in person or by video?
- When was the information or discussion held-date, time and location.
- Where will the information be documented; is it accessible?

F883: Influenza and Pneumococcal Immunizations

Things to Consider:

- Prior to administering immunization, did the resident receive education of benefits and side effects of immunization ("risk vs benefit")? Each resident/resident representative has a right to be fully informed.
- Risk versus benefit forms consideration should be based on, but not limited to the facility's policies and procedures as well as the regulatory system within the facility's state. Risk versus benefits should consider the resident's current medical condition, risk within the facility, demographic risk, and comorbidities and quality of life. The risk versus benefit should be documented in the resident's medical records as well as the medical provider records.
- Is this an immunization period for influenza, was this a recommendation/an updated guideline to immunize, is there communal outbreak to consider? Influenza immunization periods are October 1-March 31 annually.
- Was the resident or resident representative given the right to refuse immunization?
- Was documentation of education, refusal, and/or acceptance of immunization documented in medical record?

Documentation:

Things to consider: Who, What, When, Where, Why, How

- Who was the information provided to?
- What information was provided-including any handouts that were given?
- Why were these individuals informed or involved in the treatment or care discussion?
- How was the information provided including what language or device for communication was used?
- Was the information provided in the language the resident or resident representative understood?
- Was an interpreter used?
- Was the information provided via telephone, email, in person or by video?
- When was the information or discussion held-date, time and location.
- Where will the information be documented; is it accessible?
- Was the documentation of education, refusal and/or acceptance of immunization documented in medical record?
- Did resident or resident representative provide a reason for declination to consider in future approaches such as religious, personal beliefs or misinformation?

Immunization and Medical Interventions/Therapeutics Consent Document

This document is intended to support a resident to give a one-time consent to be provided immunizations necessary within a facility during the duration of their stay. This document provides an informed consent to the immunization requirements set by the state and local regulatory system to ensure a positive outcome for resident's overall wellbeing. This document also gives the resident's consent to have current, standard of practice interventions related to COVID-19 therapeutic interventions that are the current guidelines and recommendations from state and local entities such as the Department of Health, Center for Disease and Prevention and Control (CDC), World Health Organization (WHO) and National Institute of Health (NIH).

A copy of this form will be included in your medical chart. (**Note**: if your wishes change, you may revoke this consent form at any time and in any manner sufficient to communicate an intent to revoke).

I, _____(name) on this date, _____ give the facility _____ my full consent to receive CDC recommended immunizations.

Please indicate below immunizations that you are consenting to:

- ☐ Influenza
- ☐ Tetanus
- ☐ Diphtheria
- ☐ Pertussis
- ☐ Zoster recombinant
- ☐ Pneumococcal
- ☐ COVID-19 immunizations, including all recommended boosters

I also give my full consent to receive medical interventions/therapeutics in the event that I develop an active infection.

- ☐ Therapeutics include, but are not limited to the following: (antiviral medications for COVID-19: Paxlovid, Remdesivir, and Lagevrio; antiviral medications for flu: oseltamivir (Tamiflu), zanamivir (Relenza), peramivir (Rapivab); medical interventions: convalescent plasma, and experimental clinical trials if applicable).

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Screening Questions

COVID-19 Questions	Yes	No	Do Not Know
1. In the past 90 days, have you tested positive for COVID-19 or are you currently being monitored for COVID-19?			
2. In the past two weeks, have you had contact with anyone who tested positive for COVID-19?			
3. Have you had new onset of fever, chills, cough, shortness of breath, difficulty breathing, fatigue, muscle/body aches, headache, new loss of taste or smell, sore throat, nausea, vomiting or diarrhea?			
4. Are you currently sick? For example, are you currently experiencing fever, chills, cough, shortness of breath, difficulty breathing, fatigue, muscle or body aches, etc.?			
5. Have you had a severe allergic reaction (e.g., anaphylaxis, trouble breathing) to any vaccine or injectable therapy, or a history of anaphylaxis due to any cause?			
6. Do you have long-term health problems such as heart disease, lung disease, liver disease, asthma, kidney disease, metabolic disease (e.g. diabetes), or anemia?			
7. Do you have a bleeding disorder or are you taking a blood thinner?			
8. Do you have cancer, leukemia, HIV/AID, rheumatoid arthritis, ankylosing spondylitis, Crohn's disease, or any other immune system problems?			
9. Do you have a weakened immune system or in the past 3 months, taken medications that weaken it such as cortisone, prednisone, other steroids, anticancer drugs or radiation treatment?			
10. In the past 90 days have you received convalescent plasma, monoclonal/polyclonal antibody infusions or PAXLOVID for the treatment of COVID-19?			
11. Have you received any other vaccine within the past 28 days or are scheduled to receive any vaccine in the next 28 days?			
12. For women, are you pregnant/breastfeeding? Or is there a chance you could become pregnant in the next month?			

	Date of Primary Dose	Date of Secondary Dose	Date of First Booster	Date of Last Booster
COVID-19				

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Influenza Questions	Yes	No	Do Not Know
1. Is the person to be vaccinated sick today?			
2. Does the person to be vaccinated have an allergy to a component of the vaccine?			
3. Has the person to be vaccinated ever had a serious reaction to the influenza vaccine?			
4. Has the person to be vaccinated ever had Guillain-Barre Syndrome?			

Secondary Decision Makers

If a Medical Power of Attorney (POA) is activated, the following section can be omitted.

First Alternate (Successor) Patient Treatment Advocate (strongly advise)

- If Patient Advocate is not capable or willing to make these choices for me, OR is divorced or legally separated from me, then I designate the following person to serve as my Patient Advocate.

Name: _____ Relationship: _____

Phone (Day): _____ (Evening): _____ (Cell): _____

Address: _____

City: _____ State: _____ Zip Code: _____

Second Alternate (Successor) Patient Treatment Advocate (strongly advise)

- If Patient Advocate is not capable or willing to make these choices for me, OR is divorced or legally separated from me, then I designate the following person to serve as my Patient Advocate.

Name: _____ Relationship: _____

Phone (Day): _____ (Evening): _____ (Cell): _____

Address: _____

City: _____ State: _____ Zip Code: _____

Signatures

- Signature of the Individual in the Presence of the Following Witnesses I am providing these instructions of my own free will. I have not been required to give them to receive care or have care withheld or withdrawn. I am at least eighteen (18) years old and of sound mind.

Signature: _____ Date: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Signatures of Witnesses:

- I know this person to be the individual identified as the "Individual" signing this form. I believe they are of sound mind and at least eighteen (18) years of age. I personally saw them sign this form, and I believe that they did so voluntarily and without duress, fraud or undue influence. By signing this document as a witness, I certify that I am:
  - At least 18 years of age.
  - Not the Patient Advocate or alternate Patient Advocate appointed by the person signing this document.
  - Not the patient's spouse, parent, child, grandchild, sibling or presumptive heir.
  - Not listed to be a beneficiary of, or entitled to, any gift from the patient's estate.
  - Not directly financially responsible for the patient's health care.
  - Not a health care provider directly serving the patient at this time.
  - Not an employee of a health care or insurance provider directly serving the patient currently.

First Witness

Signature: _____ Date: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Second Witness

Signature: _____ Date: _____

Address: _____

City: _____ State: _____ Zip Code: _____

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