VERMONT

AGENCY OF HUMAN SERVICES

DEPARTMENT OF DISABILITIES, AGING AND INDEPENDENT LIVING

Division of Licensing and Protection
HC 2 South, 280 State Drive
Waterbury, VT 05671-2060
http://www.dail.vermont.gov
Survey and Certification Voice/TTY (802) 241-0480
Survey and Certification Fax (802) 241-0343
Survey and Certification Reporting Line: (888) 700-5330
To Report Adult Abuse: (800) 564-1612

April 5, 2019

Ms. Diana Lafountain, Administrator
Pines Rehab & Health Ctr
601 Red Village Road
Lyndonville, VT 05851-9068

Dear Ms. Lafountain:

Enclosed is a copy of your acceptable plans of correction for the survey conducted on **March 27, 2019.** Please post this document in a prominent place in your facility.

We may follow-up to verify that substantial compliance has been achieved and maintained. If we find that your facility has failed to achieve or maintain substantial compliance, remedies may be imposed.

Sincerely,

Pamela M. Cota, RN
Licensing Chief

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	475044	A. BUILDING _____ B. WING _____	C 03/27/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PINES REHAB & HEALTH CTR	601 RED VILLAGE ROAD LYNDONVILLE, VT 05851

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
F 000	INITIAL COMMENTS	F 000		

An unannounced onsite investigation into two complaints was conducted by the Division of Licensing and Protection from 3/25/19-3/27/19. Regulatory violations at the Immediate Jeopardy level were identified as a result, which also results in a determination of substandard quality of care. The facility was notified of the Immediate Jeopardy (IJ) on 3/26/19 at 1:50 PM. An IJ removal plan was submitted by the facility on 3/27/19, which alleges removal of the IJ by 3/29/19. The following are the regulatory findings:

F 580 SS=J — Notify of Changes (Injury/Decline/Room, etc.)
CFR(s): 483.10(g)(14)(i)-(iv)(15)

§483.10(g)(14) Notification of Changes.
(i) A facility must immediately inform the resident; consult with the resident's physician; and notify, consistent with his or her authority, the resident representative(s) when there is-
(A) An accident involving the resident which results in injury and has the potential for requiring physician intervention;
(B) A significant change in the resident's physical, mental, or psychosocial status (that is, a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications);
(C) A need to alter treatment significantly (that is, a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or
(D) A decision to transfer or discharge the resident from the facility as specified in §483.15(c)(1)(ii).
(ii) When making notification under paragraph (g)(14)(i) of this section, the facility must ensure that

F 580

F580

1. Resident #1 was discharged home with hospice care and passed away.
2. Residents experiencing a clinical change in status have the potential to be affected by the alleged deficient practice.
3. The facility has adopted Interact 4.0 Change in Condition guidelines and the Medical Director has approved.
4. Education has been provided to licensed nurses regarding the Change in Condition guidelines. Any nurse not receiving the education is not permitted to work.
5. Audits will be conducted 3x weekly by the DON or designee for a period of 3 months to monitor effectiveness of the plan. Audits will include review of nursing notes for all residents residing in the facility.

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Diana LaFountain	Administrator	4-01-19

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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F 580	Continued From page 1 all pertinent information specified in §483.15(c)(2) is available and provided upon request to the physician. (iii) The facility must also promptly notify the resident and the resident representative, if any, when there is- (A) A change in room or roommate assignment as specified in §483.10(e)(6); or (B) A change in resident rights under Federal or State law or regulations as specified in paragraph (e)(10) of this section. (iv) The facility must record and periodically update the address (mailing and email) and phone number of the resident representative(s). §483.10(g)(15) Admission to a composite distinct part. A facility that is a composite distinct part (as defined in §483.5) must disclose in its admission agreement its physical configuration, including the various locations that comprise the composite distinct part, and must specify the policies that apply to room changes between its different locations under §483.15(c)(9). This REQUIREMENT is not met as evidenced by: Based on record review and staff interview, facility nursing staff failed to report a significant clinical change in status to the physician for 1 of 3 residents sampled (Resident #1). Findings include: Per record review, Resident #1 was admitted to the facility on 1/3/19 from an acute care hospital after surgical insertion of a Cardiac Pacemaker. According to the Care Plan Discharge Plan, the resident wished to return home to their own apartment after rehab. The resident had been on	F 580	6. The results of the audits will be reported to the QAA committee and after 3 months the committee will determine further frequency of the audits. 7. Corrective action completed 3/27/19 F580 POC accepted 4/4/19 KCamposRN/PMC	

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F 580	Continued From page 2	F 580		

a long -term therapy of the anticoagulant medication Warfarin for Atrial Fibrillation (A-Fib), and was admitted with orders for 1 mg. daily 6 days per week, with 2 mg. dose to be given on Mondays. The resident was last checked for therapeutic clotting times (PT/INR) by blood draw sent out to the lab on 1/4/19, but those results were not communicated to the facility.

Per review of the record, the resident was sent to the Emergency Room at approximately 3:00 AM on 2/14/19 due to bleeding from the rectum and lethargic state. The resident was diagnosed with a GI (Gastro-intestinal) bleed, and had a critically high PT/INR at the hospital which indicates a very high risk of an abnormal bleeding event. Per review of the nurse progress notes, the nurse working the day shift on 2/13/19 wrote that the resident had "large incontinent BM [bowel movement] in bed which was dark red with blood clots". Per interview on 3/26/19 at 11:05 AM, the nurse stated that they had passed the information to the oncoming nurse at change of shift, and thought that they had told the nurse supervisor, but had not called the physician regarding this finding.

Per review of the evening nurse shift note on 2/13/19, the nurse wrote "Res. had lg. bloody stool prior to returning to bed". Per interview on 3/26/19 at 2:20 PM, the nurse stated that they had not called the physician regarding the bleeding.

Review of the nurse's note dated 2/14/19, it was noted that the resident had "black stool x 1, liquid" and a blood pressure reading 72/50 (abnormally low), and that resident was awake with care (time not indicated). Later at 0245 AM on 2/14/19, the

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F 580	Continued From page 3 nurse documented there was "increased redness in lg. stool" and that resident was not responding to attempts to wake them. The nurse called the physician, called EMS and the resident was transported to the hospital at 0300 AM. The nurse's note also included that the family was notified, and the report from the ED was that the resident was receiving a blood transfusion for a PT/INR of greater than 15. The resident returned to the facilty on comfort care on 2/14/19, was discharged to home on 2/21/19 with a Hospice referral, and died at home on 2/25/19. Per interview on 3/25/19 at 2:40 PM, the Director of Nursing stated that they were not alerted of the transport of Resident #1 to the hospital as staff were instructed to do for any transfer, nor were they aware of the bloody stools noted by three different nurses until the following day, 2/14/19.	F 580		
F 600 SS=J	Free from Abuse and Neglect CFR(s): 483.12(a)(1) §483.12 Freedom from Abuse, Neglect, and Exploitation The resident has the right to be free from abuse, neglect, misappropriation of resident property, and exploitation as defined in this subpart. This includes but is not limited to freedom from corporal punishment, involuntary seclusion and any physical or chemical restraint not required to treat the resident's medical symptoms. §483.12(a) The facility must- §483.12(a)(1) Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion; This REQUIREMENT is not met as evidenced	F 600	F 600 1. Resident #1 was discharged home with hospice care and passed away. 2. Residents receiving anticoagulation therapy with Warfarin (Coumadin) have the potential to be affected by the alleged deficient practice. 3. An initial audit was completed on 3/27/19 to determine other residents receiving Coumadin. One other resident was found to be receiving this therapy. Labs have been done as ordered and Coumadin therapy adjusted based on results.	

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F 600	Continued From page 4	F 600		

by:
Based on record review and interviews, the facility failed to ensure that residents were free from neglect for 1 of 3 residents reviewed (Resident #1). Findings include:

Per record review, Resident #1 was admitted to the facility on 1/3/19 from an acute care hospital after surgical insertion of a Cardiac Pacemaker. According to the Discharge Plan, the resident wished to return home after rehab. The resident had been on a long-term therapy of the anticoagulant medication Warfarin for Atrial Fibrillation (A-Fib), and was admitted with orders for continued anticoagulant therapy. The resident was last checked for therapeutic clotting times (PT/INR) by blood draw sent out to the lab on 1/4/19, but the facility or the attending physician did not receive the results. Per review of the record, the resident was sent to the Emergency Room at approximately 3:00 AM on 2/14/19 due to bleeding from the rectum and lethargic state. The resident was diagnosed with a GI bleed, and had an abnormally high PT/INR of 15 at the hospital which indicated a very high risk of an abnormal bleeding event. Resident #1 was treated with Vitamin K Prodium and transfused with 3 units of blood, and returned to the facility on comfort care when the family decided to not put him/her through any further interventions at the hospital. The resident was discharged to home on 2/21/19 with family caregivers and a Hospice referral, and died at home on 2/25/19.

The attending physician visits on 1/11/19, 2/7/19, and 2/11/19 did not document any reference to checking for PT/INR values by lab testing, or the medication adjustments possibly needed related

4. The pharmacist consultant is aware of the findings related to this deficiency and has made a written commitment to include the use of Coumadin in all recommendations for those residents receiving Coumadin.
5. The Medical Director is aware of the findings related to this deficiency and has provided education to practicing physicians the requirement to review the use of Coumadin and lab values with each physician's visit for residents receiving Coumadin.
6. The facility has adopted Interact 4.0 Change in Condition guidelines and the use of the guidelines has been approved by the Medical Director.
7. The Coumadin Management Protocol has been revised to include a stop date when labs are due, and it was approved by the Medical Director and practicing physicians.
8. A "Coumadin Alert" sheet has been created and placed in front of the current resident's MAR that receives Coumadin as well as in the front of the physician order section of the medical record. This sheet alerts licenses nurses to the use of Coumadin and potential adverse effects that require immediate notification to the physician. This alert sheet will be utilized for any resident receiving Coumadin.

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F 600 Continued From page 5
to the results of the test.

The consultant Pharmacist for the facility completed a Medication Regime Review on 1/29/19 and again on 2/14/19, and did not detect that the resident was not receiving PT/INR lab testing per normal protocol for Warfarin treatment and make the recommendation to the MD.

Two of the nurses caring for the patient had noted bloody stools on both the day shift and the evening shift on 2/13/19, and did not notify the physician or the Director of Nursing of the change in condition of the resident. The nurse working overnight who sent the resident to the hospital at 0300 on 2/14/19 also did not alert the Director of Nursing, who had instructed staff to notify them of any transfers to the hospital even at night.

The care plan for Anticoagulant use was not followed for the proper monitoring of the medication and reporting bleeding to the physician.

Per review of this record, and multiple interviews, there was a facility multi-system failure to prevent medical neglect of Resident #1, and there was serious harm as a result. See citations at F580, F656, F658, F711, F756, and F757 for more detail and confirmations.

F 656 SS=J Develop/Implement Comprehensive Care Plan CFR(s): 483.21(b)(1)

§483.21(b) Comprehensive Care Plans
§483.21(b)(1) The facility must develop and implement a comprehensive person-centered care plan for each resident, consistent with the resident rights set forth at §483.10(c)(2) and

F 600

9. Education has been provided to licensed nurses regarding the use of the Change in Condition guidelines, the revised Coumadin Management Protocol, and the alert sheet. Any nurse that has not received the education is not permitted to work.
10. Audits will be conducted for a minimum of 3 months to monitor effectiveness of the plan. Audits will include review of nursing notes for all residents 3x weekly, review of pharmacy recommendation sheets for residents receiving Coumadin at each visit, and review of physician visit notes for those residents receiving Coumadin at each visit. The audits will be conducted by the DON or designee.
11. The results of the audits will be reported to the QAA committee. After 3 months the committee will determine further frequency of the audits.
12. Corrective action was completed on 3/27/19.

F600 POC accepted 4/4/19 KCampbell RN

F 656

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F 656	Continued From page 6	F 656	F 656	

§483.10(c)(3), that includes measurable objectives and timeframes to meet a resident's medical, nursing, and mental and psychosocial needs that are identified in the comprehensive assessment. The comprehensive care plan must describe the following -
(i) The services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under §483.24, §483.25 or §483.40; and
(ii) Any services that would otherwise be required under §483.24, §483.25 or §483.40 but are not provided due to the resident's exercise of rights under §483.10, including the right to refuse treatment under §483.10(c)(6).
(iii) Any specialized services or specialized rehabilitative services the nursing facility will provide as a result of PASARR recommendations. If a facility disagrees with the findings of the PASARR, it must indicate its rationale in the resident's medical record.
(iv)In consultation with the resident and the resident's representative(s)-
(A) The resident's goals for admission and desired outcomes.
(B) The resident's preference and potential for future discharge. Facilities must document whether the resident's desire to return to the community was assessed and any referrals to local contact agencies and/or other appropriate entities, for this purpose.
(C) Discharge plans in the comprehensive care plan, as appropriate, in accordance with the requirements set forth in paragraph (c) of this section.
This REQUIREMENT is not met as evidenced by:
Based on record review and staff interview, the facility failed to ensure that the care plan

1. Resident #1 was discharged home with hospice care and passed away.
2. Residents with care plan interventions for medication monitoring have the potential to be affected by the alleged deficient practice.
3. An initial audit was completed to identify other residents receiving Coumadin. There is currently one resident residing in the facility that receives Coumadin.
4. The Coumadin Management Protocol has been revised to include stop dates when labs are due and directs nursing to receive new orders before administering another dose of Coumadin.
5. A "Coumadin Alert" sheet has been created and placed in front of the MAR that identifies potential adverse effects that require immediate notification to the physician.
6. Education will be provided to licensed nurses regarding care plan interventions to address potential adverse effects and lab monitoring related to the use Coumadin.
7. Audits will be conducted 3x weekly for a minimum of 3 months by the DON or designee to monitor effectiveness of the plan. Audits will include review of nursing notes to identify potential adverse effects, lab results, and new orders received.

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F 656	Continued From page 7	F 656		

interventions were implemented for 1 of 3 residents reviewed (Resident #1). Findings include:

Per record review, Resident #1 was admitted to the facility on 1/3/19 from an acute care hospital after surgical insertion of a Cardiac Pacemaker. The resident had been living alone in their own apartment, and it was his/her wish to go back there after rehab. The resident had been on a long-term therapy of the anticoagulant medication Warfarin for Atrial Fibrillation (A-Fib), and was admitted with orders for 1 mg. daily 6 days per week, with 2 mg. dose to be given on Mondays.

The plan of care included the use of anticoagulant medication and listed:
Problem/Need related to: New Pacemaker, A-Fib, resulting in Risk of bleeding;
Goal listed related to the care plan area was: Will be free of bleeding;
The following interventions in this care plan were listed:
Provide anticoagulant therapy per physician order,
Monitor for bruising,
If bleeding noted, contact physician and follow first aide measures to stop bleeding,
Monitor and report lab results to physician,
Avoid bumping and handle gently when hands on care provided,
Monitor blood pressure every shift.

Problem/Need related to: New Pacemaker, A-Fib, resulting in Risk of bleeding;
Goal listed related to the care plan area was: Will be free of bleeding
Per review of the resident's record, the appropriate lab monitoring was not completed

8. The results of the audits will be reported to the QAA committee and after 3 months the committee will determine further frequency of the audits to be conducted.
9. Corrective action to be completed by 4/4/19.

F656 POC accepted 4/4/19 K Campos RN/ PMC

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F 656	Continued From page 8 since 1/4/19, and the physician was not notified when bleeding was noted by nursing on 2/13/19. Per interview on 3/26/19, the Director of Nursing confirmed that the plan of care was not implemented as written. The resident was seen by the physician at the facility on 1/4/19 for the new admission, and ordered therapeutic clotting times testing (PT/INR) by blood draw sent out to the lab on 1/4/19. Per review of the record, the resident's lab results were not sent to the facility or the attending physician. There was no evidence of any physician orders for further monitoring of PT/INR. Nursing did not monitor lab results as directed by the plan of care, so did not detect missing lab tests for a period of almost 6 weeks. When the resident had bloody stools noted by two different nurses on day and evening shifts on 2/13/19, the physician was not notified of the change in condition as required by the plan of care. The resident was sent to the hospital for treatment on 2/14/19 which included Vitamin K and 3 units of blood transfused. The resident returned to the facility on comfort care, went back to their apartment with Hospice services on 2/21/19, and died there on 2/25/19.	F 656		
F 658 SS=J	Services Provided Meet Professional Standards CFR(s): 483.21(b)(3)(i) §483.21(b)(3) Comprehensive Care Plans The services provided or arranged by the facility, as outlined by the comprehensive care plan, must- (i) Meet professional standards of quality. This REQUIREMENT is not met as evidenced by: Based on record review and staff interview, the	F 658	F 658 1. Resident #1 was discharged home with hospice care and passed away. 2. Residents receiving anticoagulation therapy with Coumadin have the potential to be affected by the alleged deficient practice.	

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facility failed to provide services that meet professional standards of quality regarding nursing practice for a resident on anticoagulant therapy for 1 of 3 residents reviewed (Resident #1). Findings include:

Per record review, Resident #1 was admitted to the facility on 1/3/19 from an acute care hospital after surgical insertion of a Cardiac Pacemaker. The resident had been on a long-term therapy of the anticoagulant medication Warfarin for Atrial Fibrillation (A-Fib), and was admitted with orders for 1 mg. daily 6 days per week, with 2 mg. dose to be given on Mondays. The resident was seen by the physician at the facility on 1/4/19 for the new admission, and ordered therapeutic clotting times testing (PT/INR) by blood draw sent out to the lab on 1/4/19. Per review of the record, the resident's lab results were not sent to the facility or the attending physician.

The Warfarin was administered daily to the resident for nearly 6 weeks, and nursing staff failed to identify that there was no PT/INR results on file and no orders for labs to monitor the PT/INR level, which is typically monitored at the very least on a monthly basis. Nursing staff did not ensure a prompt response to the resident having bloody stools by failing to call the physician to report the change in condition, resulting in a delay of treatment.

Per review of the nurse progress notes, the nurse working the day shift on 2/13/19 wrote that the resident had "large incontinent BM [bowel movement] in bed which was dark red with blood clots". Per interview on 3/26/19 at 11:05 AM, the nurse stated that they had passed the information to the oncoming nurse at change of shift, and

3. An initial audit was completed to identify other residents in the facility that receive Coumadin.
4. The Coumadin Management Protocol was revised to include a stop date for Coumadin when there are labs due pending further orders from the physician. The protocol also determines frequency at which the labs are to be drawn.
5. A "Coumadin Alert" sheet was created that identifies potential adverse effects and directs the nurse to immediately notify the physician if any of these symptoms are present. The alert sheet is placed in the front of the MAR as well as in the front of the physician order section of the medical record.
6. The facility has adopted the Interact 4.0 Change in Condition guidelines and the guidelines have been approved by the Medical Director.
7. Education has been provided to licensed nurses regarding the Coumadin Management Protocol, the Alert sheet, and the Change in Condition guidelines. Any nurse that has not received the education is not permitted to work.
8. Audits will be conducted by the DON or designee to monitor effectiveness of the plan. The audits will include review of nursing notes for all residents 3x weekly for a minimum of 3 months as well as review of labs and new physician orders for residents receiving Coumadin.

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F 658	Continued From page 10	F 658		

thought that they had told the nurse supervisor, but had not called the physician regarding this finding.

Per review of the evening nurse shift note on 2/13/19, the nurse wrote "Res. had lg. bloody stool prior to returning to bed". Per interview on 3/26/19 at 2:20 PM, the nurse stated that they had not called the physician regarding the bleeding.

Per review of the record, the resident was sent to the Emergency Room at approximately 3:00 AM on 2/14/19 due to bleeding from the rectum and lethargic state. The resident was diagnosed with a GI (Gastro-intestinal) bleed, and had a critically high PT/INR at the hospital which indicates a very high risk of an abnormal bleeding event. The resident required Vitamin K therapy and a transfusion of 3 units of blood to be stabilized with adequate clotting ability. The resident returned to the facility on 2/14/19 with comfort care orders, went home with family on 2/21/19 with a Hospice referral, and died at home on 2/25/19.

Reference for nursing care of a patient on anticoagulant therapy: Lippincott Manual of Nursing Practice (8th ed.). Wolters Kluwer Health/ Lippincott Williams & Wilkins. pg 432-433.

9. The results of the audit will be reported to the QAA committee and after 3 months the committee will determine further frequency of the audits.
10. Corrective action was completed on 3/27/19.

F658 POC accepted 4/4/19 KCampos RN/PNE

F 711 SS=J Physician Visits - Review Care/Notes/Order
CFR(s): 483.30(b)(1)-(3)

§483.30(b) Physician Visits
The physician must-

§483.30(b)(1) Review the resident's total program of care, including medications and treatments, at

F 711

F 711

1. Resident #1 was discharged home with hospice care and passed away.
2. Residents receiving care in the facility requiring lab monitoring related to Coumadin therapy have the potential to be affected by the alleged deficient practice.

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F 711	Continued From page 11 each visit required by paragraph (c) of this section; §483.30(b)(2) Write, sign, and date progress notes at each visit; and §483.30(b)(3) Sign and date all orders with the exception of influenza and pneumococcal vaccines, which may be administered per physician-approved facility policy after an assessment for contraindications. This REQUIREMENT is not met as evidenced by: Based on record review and staff interview, the physician failed to ensure that the onsite review of the resident's total program of care included necessary lab testing and medication adjustments for 1 of 3 residents reviewed (Resident #1). Findings include: Per record review, Resident #1 was admitted to the facility on 1/3/19 from an acute care hospital after surgical insertion of a Cardiac Pacemaker. The resident had been on a long -term therapy of the anticoagulant medication Warfarin for Atrial Fibrillation (A-Fib), and was admitted with orders for 1 mg. daily 6 days per week, with 2 mg. dose to be given on Mondays. The resident was seen by the physician at the facility on 1/4/19 for the new admission, and ordered therapeutic clotting times testing (PT/INR) by blood draw sent out to the lab on 1/4/19. Per review of the record, the resident's lab results were not sent to the facility or the attending physician. There was no evidence that the physician had reviewed the results to make possible adjustments to the Warfarin dosage. The resident was seen at the facility by the same physician on 1/11/19,	F 711	3. Federal Regulation F711 will be reviewed with the Medical Director to ensure understanding of all components. The Medical Director will share this regulatory requirement with other physicians that practice at the facility. 4. The Medical Director is aware of the findings related to this deficiency and has provided education to the practicing physicians regarding the requirement to include review of medications and monitoring in the physician visit notes. 5. The Coumadin Management Protocol has been revised and approved by the Medical Director and the other practicing physicians. 6. An audit will be conducted by the DON or designee 3x weekly for a minimum of 3 months to monitor effectiveness of the plan. The audits will include review of physician progress notes to ensure compliance is met. The results of the audits will be reviewed with the Medical Director at each visit. 7. The results of the audits will be reported to the QAA committee. After 3 months the committee will determine further frequency of the audits. 8. Corrective action for the education was completed on 3/29/2019 9. Corrective action for the review of F711 will be completed by 4/4/19. F711 POC accepted 4/4/19 KCampos RN/PMC	

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F 711	Continued From page 12	F 711		

discussing the resident's general status, as well as family plan to have the resident discharge to home with their support, and that the Pacemaker was working well. There was no mention of the Warfarin therapy or necessary lab monitoring associated with use.

On 2/1/19, this same attending physician made a facility visit to the resident, commenting that the resident was not feeling well, and that their appetite was poor. The MD questioned a Urinary Tract Infection (UTI), and ordered a urinalysis. There was no mention in the visit notes regarding the Warfarin Therapy or associated lab testing.

On 2/7/19, a different attending physician from the same medical practice made a visit to the resident. The physician noted that the resident had blisters on both heels presumably from their footwear and refusing to remove them. The MD also noted that there was a probable UTI but that the lab results had not returned from the urinalysis. Again there was no mention of the Warfarin use, PT/INR testing, and possible adjustment made to the Warfarin based on the results.

The resident was sent to the hospital emergently on 2/14/19 with Gastro- Intestinal bleeding, where they received Vitamin K Prodium and 3 Units of blood transfused, and sent back to the facility with Comfort Care orders from the Medical Director who saw them at the Emergency Department. The resident was discharged to home on 2/21/19 with a Hospice referral, and died at home on 2/25/19.. The Medical Director is also an attending physician in the same practice as the previous physicians, and in a note written on 2/16/19, stated to the family that the

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F 711	Continued From page 13 anticoagulation therapy is usually strictly monitored but was not done. Per review of the other residents (one current and one discharged to home) at the facility taking Warfarin, the lab testing intervals were ordered between 1 -3 weeks apart depending on the PT/INR results. Resident #1 had not been tested since 1/4/19, a time period of almost 6 weeks, prior to the GI bleed identified on 2/13/19. Per interview on 3/27/19 at 8:40 AM, the consultant Pharmacist confirmed that the longest gap recommended for a very stable recipient of Warfarin would be 4 weeks at the longest, but is usually done 1 -3 weeks apart per the results of the lab reports and MD decision of when to test again next. Per interview on 3/25/19, the Director of Nursing confirmed that the resident had not had a PT/INR ordered since 1/4/19.	F 711		
F 756 SS=J	Drug Regimen Review, Report Irregular, Act On CFR(s): 483.45(c)(1)(2)(4)(5) §483.45(c) Drug Regimen Review. §483.45(c)(1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist. §483.45(c)(2) This review must include a review of the resident's medical chart. §483.45(c)(4) The pharmacist must report any irregularities to the attending physician and the facility's medical director and director of nursing, and these reports must be acted upon. (i) Irregularities include, but are not limited to, any drug that meets the criteria set forth in paragraph (d) of this section for an unnecessary drug.	F 756	F 756 1. Resident #1 was discharged home with hospice care and passed away. 2. Residents receiving medication in the facility have the potential to be affected by the alleged deficient practice. 3. The consultant Pharmacist has reviewed and is aware of the requirement to review lab values, possible medication interactions and adverse effects in the medication regimen. 4. The consultant Pharmacist has committed to including in the recommendations review of the use of Coumadin regardless of irregularities found.	

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F 756 Continued From page 14

(ii) Any irregularities noted by the pharmacist during this review must be documented on a separate, written report that is sent to the attending physician and the facility's medical director and director of nursing and lists, at a minimum, the resident's name, the relevant drug, and the irregularity the pharmacist identified.
(iii) The attending physician must document in the resident's medical record that the identified irregularity has been reviewed and what, if any, action has been taken to address it. If there is to be no change in the medication, the attending physician should document his or her rationale in the resident's medical record.

§483.45(c)(5) The facility must develop and maintain policies and procedures for the monthly drug regimen review that include, but are not limited to, time frames for the different steps in the process and steps the pharmacist must take when he or she identifies an irregularity that requires urgent action to protect the resident.
This REQUIREMENT is not met as evidenced by:
Based on record review and interview, the Licensed Pharmacist failed to ensure that an irregularity was identified and reported to the facility for 1 of 3 residents reviewed (Resident #1). Findings include:

Per record review, Resident #1 was admitted to the facility on 1/3/19 from an acute care hospital after surgical insertion of a Cardiac Pacemaker. The resident had been on a long -term therapy of the anticoagulant medication Warfarin for Atrial Fibrillation (A-Fib), and was admitted with orders for 1 mg. daily 6 days per week, with 2 mg. dose to be given on Mondays. The resident was seen

F 756

5. Recommendations will be reviewed between the consultant Pharmacist and the DON with each Pharmacist visit to monitor effectiveness of the plan for a minimum of 3 months.
6. The results of this review will be reported to the QAA committee and after 3 months the committee will determine further frequency of the reviews.
7. Corrective action was completed on 3/27/2019

F756 PoC accepted 4/4/19 KCampos RN/PMC

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F 756	Continued From page 15	F 756		

by the physician at the facility on 1/4/19 for the new admission, and was ordered therapeutic clotting times testing (PT/INR) by blood draw sent out to the lab on 1/4/19. Per review of the record, the resident's lab results were not sent to the facility or the attending physician. There was no evidence that the physician had reviewed the results to make possible adjustments to the Warfarin dosage. The facility did not monitor lab results to detect missing lab tests for almost 6 weeks. When the resident had bloody stools noted by two different nurses on day and evening shifts on 2/13/19, the physician was not notified of the change in condition. The resident was sent to the hospital for treatment for a critically high PT/INR, which included Vitamin K and 3 units of blood transfused. The resident returned to the facility on comfort care, went back to their apartment with Hospice services on 2/21/19, and died there on 2/25/19.

Per the Consultant Pharmacist report made on 1/29/19, there were no irregularities noted, despite the fact that there were no results of lab monitoring required for the safe and therapeutic use of Warfarin since the resident's admission. The consultant Pharmacist also did a review on 2/14/19, and also had no recommendations or noted any irregularities in the resident's medication review.

Per interview on 3/27/19 at 8:40 AM, the consultant Pharmacist confirmed that part of the required monthly consult is to review lab values, possible medication interactions and adverse effects in the medication regime. The Pharmacist confirmed that they had not addressed the lack of lab testing and monitoring of the therapeutic levels of the anticoagulant in the monthly review

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report.

F 757 SS=J Drug Regimen is Free from Unnecessary Drugs
CFR(s): 483.45(d)(1)-(6)

§483.45(d) Unnecessary Drugs-General.
Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used-

§483.45(d)(1) In excessive dose (including duplicate drug therapy); or

§483.45(d)(2) For excessive duration; or

§483.45(d)(3) Without adequate monitoring; or

§483.45(d)(4) Without adequate indications for its use; or

§483.45(d)(5) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or

§483.45(d)(6) Any combinations of the reasons stated in paragraphs (d)(1) through (5) of this section.
This REQUIREMENT is not met as evidenced by:
Based on record review and staff interview, the facility failed to ensure that residents were free from unnecessary drugs for 1 of 3 residents reviewed (Resident #1), who did not have adequate monitoring of lab values to ensure medications were in therapeutic ranges. Findings include:

Per record review, Resident #1 was admitted to the facility on 1/3/19 from an acute care hospital

F 757

F 757

1. Resident #1 was discharged home with hospice care and passed away.
2. Residents receiving medication in the facility that requires monitoring of lab values for therapeutic ranges have the potential to be affected by the alleged deficient practice.
3. The consultant Pharmacist has reviewed and is aware of the requirement to review lab values, possible medication interactions, and adverse effects in the medication regimen.
4. Recommendations will be reviewed between the consultant Pharmacist and the DON with each Pharmacist visit to monitor effectiveness of the plan for a minimum of 3 months.
5. The results of the reviews will be reported to the QAA committee and after 3 months the committee will determine further review frequency.
6. Corrective action was completed on 3/27/19.

F757 POC accepted 4/4/19 KCampo, RN/PMA

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F 757	Continued From page 17 after surgical insertion of a Cardiac Pacemaker, and was admitted on a long -term therapy of the anticoagulant medication Warfarin for Atrial Fibrillation (A-Fib). The Resident was admitted with orders for Warfarin 1 mg. daily 6 days per week, with 2 mg. dose to be given on Mondays. The resident was seen by the physician at the facility on 1/4/19 for the new admission, and ordered therapeutic clotting times testing (PT/INR) by blood draw sent out to the lab on 1/4/19. Per review of the record, the resident's lab results were not sent to the facility or the attending physician. There was no evidence that the physician had reviewed the results to make possible adjustments to the Warfarin dosage. Per the Consultant Pharmacist report made on 1/29/19, there were no irregularities noted, despite the fact that there were no results of lab monitoring required for the safe and therapeutic use of Warfarin since the resident's admission. The consultant Pharmacist also did a review on 2/14/19, and also had no recommendations or noted any irregularities in the resident's medication review. The resident had not received the necessary lab monitoring for close to 6 weeks, and ended up being sent to the hospital on 2/14/19 with Gastro-Intestinal bleeding that required 3 units of blood transfused and Vitamin K therapy. The resident was put on comfort care at that time, and returned to the facility on 2/14/19. Resident #1 was discharged to home with family on 2/21/19 with a Hospice referral, and died at home on 2/25/19. Per interview on 3/27/19 at 8:40 AM, the consultant Pharmacist confirmed that part of the required monthly consult is to review lab values, possible medication interactions, and adverse	F 757		

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F 757	Continued From page 18 effects in the medication regime. The Pharmacist confirmed that they had not addressed the lack of lab testing and monitoring of the therapeutic levels of the anticoagulant in the monthly review report.	F 757		