

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

PRINTED: 06/10/2011
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 345541	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 05/26/2011
NAME OF PROVIDER OR SUPPLIER OLDE KNOX COMMONS AT THE VILLAGES OF MECKLENBURG			STREET ADDRESS, CITY, STATE, ZIP CODE 13826 HUNTON LANE HUNTERSVILLE, NC 28078	
(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 208 SS=D	<p>483.12(d)(1)-(4) PROHIBITING CERTAIN ADMISSION POLICIES</p> <p>The facility must not require residents or potential residents to waive their rights to Medicare or Medicaid; and not require oral or written assurance that residents or potential residents are not eligible for, or will not apply for, Medicare or Medicaid benefits.</p> <p>The facility must not require a third party guarantee of payment to the facility as a condition of admission or expedited admission, or continued stay in the facility. However, the facility may require an individual who has legal access to a resident's income or resources available to pay for facility care to sign a contract, without incurring personal financial liability, to provide facility payment from the resident's income or resources.</p> <p>In the case of a person eligible for Medicaid, a nursing facility must not charge, solicit, accept, or receive, in addition to any amount otherwise required to be paid under the State plan, any gift, money, donation, or other consideration as a precondition of admission, expedited admission or continued stay in the facility.</p> <p>However, a nursing facility may charge a resident who is eligible for Medicaid for items and services the resident has requested and received, and that are not specified in the State plan as included in the term "nursing facility services" so long as the facility gives proper notice of the availability and cost of these services to residents and does not condition the resident's admission or continued stay on the request for and receipt of such additional services; and a nursing facility may</p>	F 208	<p>OLDE KNOX COMMONS' RESPONSE TO THIS REPORT OF SURVEY DOES NOT DENOTE AGREEMENT WITH THE STATEMENT OF DEFICIENCIES; NOR DOES IT CONSTITUTE AN ADMISSION THAT ANY STATED DEFICIENCY IS ACCURATE. WE ARE FILING THE POC BECAUSE IT IS REQUIRED BY LAW.</p> <p>• F208: <u>ADDRESS HOW CORRECTIVE ACTION (S) WILL BE ACCOMPLISHED FOR THOSE RESIDENTS FOUND TO HAVE BEEN AFFECTED BY THE DEFICIENT PRACTICE:</u></p> <p>The S. W. was directed by administration to call the family to see if they would be willing to sit with resident #20 while out of bed, until resident went home the next day to go a graduation and family visit. The family of Resident #20 was contacted by S.W. and asked if someone from the family would be willing to sit with resident while resident #20 is up and out of bed. The family told the facility that they were planning to transfer resident #20 to a facility closer to home and had been offered a bed. The son did tell S.W. that he would have a cousin, his wife and himself who would be willing to sit with resident until they could take him home the next day. The resident's family decided to take him home until placement with the other facility who had already offered a bed. The reason given to administration was that they did not want to rent a truck twice or have to move some of his bulky items twice.</p>	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Mary H. Cellhouse, CDM TITLE: _____ (X6) DATE: 6/17/11

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.

RECEIVED
JUN 20 2011
BY: MH

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F 208	<p>Continued From page 1</p> <p>solicit, accept, or receive a charitable, religious, or philanthropic contribution from an organization or from a person unrelated to a Medicaid eligible resident or potential resident, but only to the extent that the contribution is not a condition of admission, expedited admission, or continued stay in the facility for a Medicaid eligible resident.</p> <p>States or political subdivisions may apply stricter admissions standards under State or local laws than are specified in this section, to prohibit discrimination against individuals entitled to Medicaid.</p> <p>This REQUIREMENT is not met as evidenced by: Based on medical record review and staff interviews, the facility failed to provide personal care services for one (1) of one (1) resident on Medicaid services. (Resident # 20)</p> <p>The findings are:</p> <p>A review of Resident # 20's closed medical record revealed Resident # 20 was readmitted to the facility on 09/21/10 with diagnoses that included stage 3 chronic kidney disease and Alzheimer's disease. The closed medical record further revealed Resident # 20 was a Medicaid recipient. Resident # 20 discharged from the facility on 05/25/11.</p> <p>A review of Resident # 20's most recent quarterly Minimum Data Set (MDS) assessment dated 04/06/11 revealed Resident # 20's cognition was</p>	F 208	<p>Administration has refunded the monies that the family paid to a personal care aide and resident #20 was placed in another facility near the east coast near wife's home.</p> <p><u>ADDRESS HOW CORRECTIVE ACTION WILL BE ACCOMPLISHED FOR THOSE RESIDENTS HAVING POTENTIAL TO BE AFFECTED BY THE SAME DEFICIENT PRACTICE:</u> No other residents were affected by this deficient practice. If the facility is requesting that a Medicaid resident require a personal care sitter, the facility will not make the family responsible for paying for personal care services. The S.W. and other administrative staff have been educated to the fact that we cannot require a Medicaid resident to pay for a private sitter, if required by the facility, for continued stay under 483.12 (d)(1).</p> <p><u>ADDRESS WHAT MEASURES WILL BE PUT INTO PLACE OR SYSTEMIC CHANGES MADE TO ENSURE THAT THE DEFICIENT PRACTICE WILL NOT OCCUR:</u> The administrator, DON and S.W. SOC committee will discuss and evaluate all future situations to determine if behaviors of any Medicaid residents warrant the services of a personal care aide. If it is determined that administration/committee is requiring the personal care sitter/aide, then the facility will be responsible for payment of these services for Medicaid residents not family members.</p>	6/15/11

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F 208	<p>Continued From page 2</p> <p>intact. The MDS further revealed Resident # 20 required extensive assistance with activities of daily except for feeding himself, and no documentation of behaviors.</p> <p>A review of social services' progress notes dated 04/18/11 revealed Resident # 20's family requested for him to be transferred to another facility, and the plan for discharge was for June 2011.</p> <p>A continued review of Resident # 20's closed medical record revealed a psychiatric consult dated 05/02/11 which revealed Resident # 20 was being followed for a diagnosis of Alzheimer's dementia. The consultation further revealed an assessment for mood changes secondary to Alzheimer's type dementia. It stated Resident # 20 was tolerating his medication well and he was hopeful with plans to move to a facility closer to his family.</p> <p>A review of Resident # 20's nurse's progress notes dated 05/22/11 revealed Resident # 20 had a confrontation in the dining room at 8:00AM with another resident. A further review of nurse's progress notes dated 05/23/11 revealed Resident # 20 reported to be regretful with the altercation with the other resident, and revealed no aggressive or agitated behavior from Resident # 20.</p> <p>A further review of social services' notes dated 05/23/11 revealed the social worker spoke with Resident # 20's family regarding the incident that occurred on 05/22/11. The social services' notes revealed facility administration requested the resident's family to provide personal care</p>	F 208	<p><u>INDICATE HOW THE FACILITY PLANS TO MONITOR ITS PERFORMANCE TO MAKE SURE THAT SOLUTIONS ARE SUSTAINED. THE FACILITY MUST DEVELOP A PLAN FOR ENSURING THAT CORRECTION IS ACHIEVED AND SUSTAINED. THE PLAN MUST BE IMPLEMENTED AND THE CORRECTIVE ACTION EVALUATED FOR ITS EFFECTIVENESS. THE POC IS INTEGRATED INTO THE QUALITY ASSURANCE SYSTEM OF THE FACILITY:</u></p> <p>The administrator/DON/S.W. will monitor/evaluate and will Make the determination and/or decision if any Medicaid resident needs someone to have a personal care aide and will ensure that the family is not responsible to pay for these personal care services. Any questions, problems, concerns will be about behaviors/personal care aides will be discussed at the weekly SOC Meeting and quarterly Q/A Committee meeting. THE ADMINISTRATOR WILL BE CHARGED WITH THE RESPONSIBILITY TO ENSURE THAT CORRECTION IS ACHIEVED AND SUSTAINED.</p>	6/15/11

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F 208	<p>Continued From page 3</p> <p>services when Resident # 20 was outside of his room. The social services' notes also revealed the other resident involved in the confrontation was moved to another table while both residents were in the dining room.</p> <p>A continued review of social services' progress notes dated 05/24/11 revealed Resident # 20's family requested for the resident to be discharged from the facility and to return home with home health and private care until Resident # 20 could be transferred to the other planned facility. The social services' notes further revealed Resident # 20's family provided personal care services at the facility through a private agency, and the nursing assistant from the agency was present.</p> <p>A review of nurse's and social services' notes dated 05/25/11 revealed Resident # 20 was discharged home with his family and with home health services and durable medical equipment.</p> <p>An interview with the facility's Vice President (VP) on 05/26/11 at 5:45 PM revealed the altercation with Resident # 20 would have resulted in an automatic 30 day discharge notice, but Resident # 20 was scheduled to transfer permanently to another facility. The VP reported Resident # 20's family was contacted to see if they could sit with and monitor the resident because of the risk of him hitting someone else. The family could also assist in diffusing any aggressive behavior from Resident # 20 and would make him more comfortable. The VP stated the facility was aware that they could not make the family responsible for paying for personal care services. The VP further revealed there must have been some miscommunication about Resident # 20's family</p>	F 208			

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F 208	<p>Continued From page 4</p> <p>having to provide personal care services. The VP reported Resident # 20's family made the decision to have the resident discharged home. The VP reported if the family decided to bring Resident # 20 back to the facility, the facility would have had to provide the personal care services to monitor the resident. The VP concluded the facility never intended for Resident # 20's family to pay for a sitter through personal care services.</p> <p>An interview with the Social Worker (SW) on 05/26/11 at 5:50 PM revealed she heard of the altercation with Resident # 20 on Monday, 05/23/11 and she consulted with his family. The SW reported she assisted the family with setting up personal care services for Resident # 20 and the family paid for the services for one day before Resident # 20 discharged home with the family. The SW stated she was directed by facility administration to consult the family and the family had to provide a sitter for the resident. The SW further revealed she was not aware as a Medicaid recipient, his family could not be held responsible for paying for personal care services, and the facility should have provided the services.</p> <p>An interview with Resident # 20's family on 06/09/11 at 6:43PM revealed they were informed by the facility on Monday, 05/23/11 that the resident had to be supervised due to an incident with another resident and for liability reasons. The family reported they were told by the facility that they were responsible to pay for a sitter to supervise Resident # 20 because he could not be left alone, and the facility could not make the resident stay in his room. The family also stated if they could not provide a sitter, the facility would</p>	F 208			

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F 208	Continued From page 5 provide a sitter and bill the family for the services. The family stated they could not afford to pay for the personal care services for Resident # 20 at the facility, and they felt like they had no choice then to take the resident home until his bed at another facility was available.	F 208	<p>• F428; <u>ADDRESS HOW CORRECTIVE ACTION (S) WILL BE ACCOMPLISHED FOR THOSE RESIDENTS FOUND TO HAVE BEEN AFFECTED BY THE DEFICIENT PRACTICE:</u></p> <p>THE MMR FOR RESIDENT #9 WAS COMPLETED BY CONSULTANT PHARMACIST ON 2/8/11, & 4/14/11 AND 6/15/11. REVIEWED ERROR WITH PHARMACY CONSULTANT.</p> <p>THE MARCH MONTHLY MMR WAS INADVERTENTLY MISSED BY PHARMACY CONSULTANT ON RESIDENT #9. ALL OTHER RESIDENTS WERE REVIEWED FOR THE MONTH OF MARCH WITH RECOMMENDATIONS BY THE PHARMACY CONSULTANT FOR THE MMR. NEW MMR COMPLETED BY PHARMACY CONSULTANT ON 6/15/11.</p> <p><u>ADDRESS HOW CORRECTIVE ACTION WILL BE ACCOMPLISHED FOR THOSE RESIDENTS HAVING POTENTIAL TO BE AFFECTED BY THE SAME DEFICIENT PRACTICE:</u></p> <p>A CHART AUDIT REVIEW NOTED THAT THERE WERE NO OTHER RESIDENTS AFFECTED BY THIS PRACTICE. AN IN-SERVICE WAS CONDUCTED BY DON ON 6/15/11 FOR NURSING STAFF CONCERNING MMRS TO ENSURE THAT CONSULTANT PHARMACIST RECEIVES A CENSUS REPORT/FORM FOR THE CURRENT CENSUS FOR THAT HALL. THE UNIT COORDINATORS NURSING STAFF AND/OR MEDICAL RECORDS STAFF HAVE BEEN RE-TRAINED ON THE IMPORTANCE OF ENSURING CONSULTANT PHARMACIST RECEIVES AND SIGNS THIS CENSUS FORM TO ENSURE COMPLETION OF MMR FOR CURRENT RESIDENTS.</p>	6/15/11
F 428 SS=D	483.60(c) DRUG REGIMEN REVIEW, REPORT IRREGULAR, ACT ON The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist. The pharmacist must report any irregularities to the attending physician, and the director of nursing, and these reports must be acted upon. This REQUIREMENT is not met as evidenced by: Based on medical record reviews and staff interviews, the consultant pharmacist failed to complete monthly Medication Monitoring Reviews (MMR) for more than 70 days for one (1) of nineteen (19) sampled residents reviewed for medication monitoring. (Resident #9) The findings include: Resident #9 was admitted to the facility on 12/8/2010. The Resident's diagnoses included diabetes mellitus-II, seizure disorder, gastrointestinal bleeding, chronic heart failure, hypertension, encephalopathy and peripheral neuropathy.	F 428		

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F 428	Continued From page 6 A review of the medical record revealed that during February 2011, March 2011 and April 2011 several medication changes were made to meet the clinical needs of Resident #9. The medication changes included changes in doses for Depakote, adding or discontinuing medications with physician interventions during February 2011 to April 2011. Further review of the consultant pharmacist's monthly MMRs between February 2011 and April 2011 there was no MMR completed. After the monthly MMR completed on 2/8/11 the next MMR was completed on 4/14/11. The review revealed that a required MMR in the month of March 2011 was not done resulting in a missed pharmacy MMR for Resident #9's for over 70 days. Further there was no other documentation provided as a proof of review for this period in question. An interview with Director of Nursing (DON) on 5/26/2011 at 9:25 AM revealed the pharmacist was in the facility on 3/14/2011 to 3/16/2011 and a census was provided including Resident #9's name to complete the medication review process. The DON also stated that Resident #9 was not out of the facility in March 2011. The DON was not sure how this review was missed. A telephone interview with the consultant pharmacist on 5/26/2011 at 10:05 AM confirmed that she had missed the MMR of Resident #9's chart by oversight in March 2011. The pharmacist stated that she was in the facility on 3/14/2011 to 3/16/2011 but did not review Resident #9's chart. No other information was provided.	F 428	WHEN THE PHARMACY CONSULTANT ENTERS THE BUILDING HE/SHE WILL REQUEST THE CURRENT CENSUS BE GIVEN TO HER/HIM. AFTER COMPLETION THE CONSULTANT PHARMACIST WILL MEET WITH DON AND/OR DESIGNEE TO DISCUSS COMPLETION OF MONTHLY MMR TO ENSURE COMPLIANCE. <u>ADDRESS WHAT MEASURES WILL BE PUT INTO PLACE OR SYSTEMIC CHANGES MADE TO ENSURE THAT THE DEFICIENT PRACTICE WILL NOT OCCUR:</u> A COMPLETED DAILY CENSUS FORM/REPORT WILL BE COMPLETED AND DOCUMENTED BY THE MEDICAL RECORDS AND UNIT NURSE COORDINATORS. ANY CONCERNS WILL BE BROUGHT TO THE STANDARD OF CARE (SOC) MEETING FOR REVIEW, RECOMMENDATIONS AND/OR AMENDMENTS. ANY CONCERNS WILL BE FORWARDED FROM THE SOC COMMITTEE TO THE QUARTERLY QA COMMITTEE WHERE THEY WILL BE REVIEWED TO ENSURE THAT THE DEFICIENT PRACTICE WILL NOT OCCUR AGAIN.		

F428 CONTINUED

INDICATE HOW THE FACILITY
PLANS TO MONITOR ITS
PERFORMANCE TO MAKE SURE THAT
SOLUTIONS ARE SUSTAINED. THE
FACILITY MUST DEVELOP A PLAN
FOR ENSURING THAT CORRECTION
IS ACHIEVED AND SUSTAINED.
THE PLAN MUST BE IMPLEMENTED
AND THE CORRECTIVE ACTION
EVALUATED FOR ITS
EFFECTIVENESS. THE POC IS
INTEGRATED INTO THE QUALITY
ASSURANCE SYSTEM OF THE
FACILITY:

MONTHLY AUDITS WILL BE
CONDUCTED BY EACH UNIT NURSE
COORDINATOR, DON, AND PHARMACY
CONSULTANT TO ENSURE MMRS ARE
COMPLETED AS REQUIRED BY
PHARMACY CONSULTANT. ANY
CONCERNS WILL BE BROUGHT TO
THE STANDARD OF CARE (SOC)
MEETING FOR REVIEW,
RECOMMENDATIONS AND/OR
INTERVENTIONS. ANY CONCERNS
WILL BE FORWARDED FROM THE SOC
COMMITTEE TO THE QUARTERLY QA
COMMITTEE WHERE THEY WILL BE
REVIEWED FOR FARTHER
RECOMMENDATIONS THE DON
AND/OR THE PHARMACY CONSULTANT
WILL BE CHARGED TO ENSURE THAT
CORRECTIVE ACTION IS ACHIEVED
AND SUSTAINED.

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F 431 SS=D	<p>483.60(b), (d), (e) DRUG RECORDS, LABEL/STORE DRUGS & BIOLOGICALS</p> <p>The facility must employ or obtain the services of a licensed pharmacist who establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.</p> <p>Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.</p> <p>In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys.</p> <p>The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.</p> <p>This REQUIREMENT is not met as evidenced by:</p>	F 431	<p>• F431</p> <p><u>ADDRESS HOW CORRECTIVE ACTION (S) WILL BE ACCOMPLISHED FOR THOSE RESIDENTS FOUND TO HAVE BEEN AFFECTED BY THE DEFICIENT PRACTICE:</u></p> <p>THE PHARMACY AND REGISTERED PHARMACIST WILL LABEL ALL STEROID BASED INHALERS (SYMBICORT) ACCURATELY FOR ALL NEW PRESCRIPTIONS FILLED AND ALL NEW REORDERS. AFTER EACH NEW PRESCRIPTION AND NEW REFILL OCCURS THE PHARMACY AND REGISTERED PHARMCIST WILL ENSURE THE LABEL STATES "RINSE MOUTH OUT AFTER USE AND SPIT OUT." MEDICATION ADMINISTRATION RECORD CURRENTLY STATES, "RINSE MOUTH AND SPIT OUT AFTER ADMINISTRATION." LN#1 ADMINISTERED 2ND DOSE OF SYMBICORT TO RESIDENT #7 AND INSTRUCTED THE RESIDENT TO RINSE MOUTH OUT AND SPIT OUT (CORRECTED 5/25/11).</p> <p><u>ADDRESS HOW CORRECTIVE ACTION WILL BE ACCOMPLISHED FOR THOSE RESIDENTS HAVING POTENTIAL TO BE AFFECTED BY THE SAME DEFICIENT PRACTICE:</u></p> <p>A VISUAL MAR AND MED CART REVIEW WAS CONDUCTED BY UNIT COORDINATORS AND CHARGE NURSES. NO OTHER RESIDENTS WERE FOUND TO BE AFFECTED. TO PREVENT THIS PRACTICE FROM REOCCURRING FOR ANY RESIDENTS WHO MIGHT BE AFFECTED IN THE FUTURE, THE PHARMACY WILL PRINT THE MAR'S AND LABELS FOR RESIDENTS RECEIVING STEROID BASED INHALERS, SUCH AS SYMBICORT.</p>	6/23/11

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F 431	<p>Continued From page 8</p> <p>Based on observations, record reviews and staff interviews the facility pharmacy failed to label a steroid based inhaler (Symbicort) accurately for one (1) of two (2) sampled residents observed for inhaler administration during medication pass. (Resident #7)</p> <p>The findings include: A review of the product insert of Symbicort Inhaler included instructions: "After inhalation, the patient should rinse the mouth with water without swallowing to avoid fungal infections in the mouth.</p> <p>Resident #7 was re-admitted to the facility on 5/12/2011 with admitting diagnoses including Chronic Obstructive Pulmonary Disease and Bronchitis. Licensed Nurse #1 (LN #1) was observed administering medications to Resident #7. LN #1 was observed administering a steroid based inhaler, Symbicort 160/4.5 (Budesonide 160 mcg (microgram)/Formoterol 4.5 mcg) to Resident #7 on 5/25/2011 at 8:40 AM. LN #1 prepared the inhaler and gave one puff to Resident #7 and walked away with out rinsing the Resident's mouth.</p> <p>A review of the admission physician orders dated 5/12/2011 included an order to administer Symbicort 160/4.5 one inhalation two times daily. Further review of the pharmacy label instructions by the provider pharmacy and the instructions in the Medication Administration Record (MAR) did not reveal any information related to the rinsing of mouth after inhaler administration. The dispensed product label had no auxiliary label related to the rinsing of mouth with water after usage.</p>	F 431	<p>THESE NEW MARS AND LABELS PRINTED BY THE PHARMACY WILL REFLECT INSTRUCTIONS FOR USE ON THE LABELS AND NEW MEDICATION ADMINISTRATION RECORDS TO INCLUDE RINSE MOUTH OUT AFTER USE AND SPIT OUT. DURING THE MONTHLY REVIEW FOR THE NEW MARS, TWO (2) NURSES WILL REVIEW, AND CORRECT ANY DISCREPANCIES ON THE MAR AS NECESSARY PRIOR TO PHYSICIAN SIGNING. ANY NEW MEDS (STEROID BASED INHALERS) LABELS WILL BE CHECKED DAILY FOR COMPLIANCE FOR INSTRUCTIONS AND USE WHEN RECEIVED FROM PHARMACY.</p> <p><u>ADDRESS WHAT MEASURES WILL BE PUT INTO PLACE OR SYSTEMIC CHANGES MADE TO ENSURE THAT THE DEFICIENT PRACTICE WILL NOT OCCUR:</u></p> <p>THE PHARMACY HAS IMPLEMENTED "RINSE MOUTH OUT AFTER USE AND SPIT OUT" ON ALL LABELS AND WILL ENSURE THAT THE LABELS ARE AFFIXED TO THE PRESCRIPTION BEING FILLED. THE MARS WILL BE REVIEWED MONTHLY BY A TWO NURSE CHECK TO ENSURE THE MARS FOR THE RESIDENT WHO ARE RECEIVING STEROID BASED INHALER, SUCH AS SYMBICORT, REFLECT INSTRUCTIONS TO RINSE MOUTH OUT AFTER USE AND SPIT OUT." THE NURSES WHO RECEIVED FILLED PRESCRIPTIONS FROM THE PHARMACY WILL CONDUCT A VISUAL ASSESSMENT OF PACKAGING LABELS TO ENSURE LABELS CONTAIN THE CORRECT INSTRUCTIONS FOR STEROID BASED INHALERS, SUCH AS SYMBICORT.</p>		

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

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 345541	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 05/26/2011
NAME OF PROVIDER OR SUPPLIER OLDE KNOX COMMONS AT THE VILLAGES OF MECKLENBURG			STREET ADDRESS, CITY, STATE, ZIP CODE 13825 HUNTON LANE HUNTERSVILLE, NC 28078	
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F 431	Continued From page 9 An interview with LN #1 on 5/25/2011 at 9:15 AM revealed that she was aware that all steroid based inhalers needed rinsing of the mouth after the use and stated that she had been in-serviced recently related to the use of inhalers. She stated all inhalers that needed to be rinsed with water after usage had bright colored auxiliary labels reminding the nursing staff. She stated, in the these of Symbicort no such auxiliary label was observed on the product. The interview revealed that she was not aware that rinsing the mouth was needed for Symbicort inhaler. A telephone interview with the pharmacist on 5/26/2011 at 9:40 AM revealed that all inhalers with steroids were labeled with an auxiliary label with instructions to rinse the mouth. She stated that she was not sure why such a label was not affixed for the Symbicort inhaler. All the auxiliary labels printed at the time of dispensing included "rinse mouth with water after use." The pharmacist was not sure why the label was missing on the product.	F 431	A CERTIFIED MEDICATION TECH WILL CONDUCT A Q/A OF ALL STEROID BASED INHALERS PRESCRIPTIONS AND LABELS WHEN FILLED AT THE PHARMACY TO ENSURE LABELS ARE CORRECTLY AND CONTAIN THE NEW INSTRUCTIONS OF RINSE MOUTH OUT AFTER USE AND SPIT OUT. THEN, THE REGISTERED PHARMACIST WILL DO THE FINAL Q/A OF ALL STEROID BASED INHALERS LABELS TO ENSURE THE LABELS ARE AFFIXED TO THE BOTTLE/PACKAGE CORRECTLY AND CONTAIN THE CORRECT WORDING/INSTRUCTIONS FOR USE. <u>HOW THE FACILITY PLANS TO MONITOR ITS PERFORMANCE TO MAKE SURE THAT SOLUTIONS ARE SUSTAINED. THE FACILITY MUST DEVELOP A PLAN FOR ENSURING THAT CORRECTION IS ACHIEVED AND SUSTAINED. THE PLAN MUST BE IMPLEMENTED AND THE CORRECTIVE ACTION EVALUATED FOR ITS EFFECTIVENESS. THE POC IS INTEGRATED INTO THE QUALITY ASSURANCE SYSTEM OF THE FACILITY:</u> DURING THE MONTHLY REVIEW FOR THE NEW MARS, TWO (2) NURSES WILL REVIEW, AND CORRECT ANY DISCREPANCIES ON THESE MARS AS NECESSARY PRIOR TO THE PHYSICIAN SIGNING THEM. COMPLIANCE WILL BE MONITORED AND REVIEWED MONTHLY BY PHARMACY PRIOR TO SENDING NEW MARS TO FACILITY.	

F 431 CONTINUED

ALL NEW MEDICATIONS (i.e. SYMBICORT) WILL BE MONITORED FOR COMPLIANCE FOR USE BY REGISTERED PHARMACIST PRIOR TO SENDING TO FACILITY. WHEN FACILITY RECEIVES SHIPMENT OF NEW MEDICATIONS THE NURSES WHO RECEIVES THESE MEDS WILL REVIEW

THE LABELS FOR SYMBICORT TO ENSURE LABELING IS CORRECT AND INCLUDES CORRECT WORDING FOR USE ON THE LABELS AND THAT LABELS DO NOT COVER UP INSTRUCTIONS FOR USE OF ANY MEDICATIONS.

A MONTHLY Q/A WILL ALSO BE CONDUCTED BY TWO (2) NURSES ON ALL NEW MARS TO ENSURE THEY CONTAIN CORRECT WORDING AND INSTRUCTIONS FOR USE FOR STEROID BASED INHALERS-- "RINSE MOUTH OUT AFTER USE AND SPIT OUT" PRIOR TO PHYSICIAN SIGNING.

THE UNIT COORDINATORS AND/OR NURSES ON UNITS WILL PRESENT ANY CONCERNS/PROBLEMS TO THE DON AND INTERDISCIPLINARY TEAM MEMBER AT THE STANDARD OF CARE (SOC) COMMITTEE MEETING AND QUARTERLY Q/A MEETING AND PHARMACY FOR REVIEW AND RECOMMENDATIONS. THE PHARMACY, REGISTERED PHARMICIST, AND Q/A COMMITTEE WILL BE CHARGED WITH ENSURING DEFICIENT PRACTICE IS ACHIEVED AND SUSTAINED.

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