

PHARMACY PRACTICE OPTIONS™

HYPONATREMIA EDITION

Improving Patient Care Through Increased Practice Efficiency

MARCH 2011

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EDITORIAL

Payment Reform Will Soon Affect All Providers

By Michael Bihari, MD, contributing editor

In the near future, all health care providers can look forward to some type of new payment arrangement for their services. CMS is slated to begin establishing accountable care organizations (ACOs) for Medicare patients in 2012. CMS anticipates that coordination and cooperation among providers will improve quality of care and reduce unnecessary costs.

According to CMS, "for each 12-month period, participating ACOs that meet specified quality performance standards will be eligible to receive a share of any savings if the actual per capita expenditures of their assigned Medicare beneficiaries are a sufficient percentage below their specified benchmark amount." The benchmark for each ACO will be based on the most recent available three years of expenditures for Medicare Parts A and B services for each beneficiary.

Assignment to an ACO will be invisible to Medicare enrollees, and won't affect their benefits or choice of providers. Patients may choose their own health care providers, whether or

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EDITORIAL

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not the provider belongs to your ACO. The organization remains responsible for the costs and quality of service. Most importantly, all providers in a system must agree on



Michael Bihari, MD

common goals and communicate effectively. Without effective health information technology, ACOs likely won't be able to conform to cost and quality regulations.

UnitedHealthcare, the nation's largest health plan, is piloting a new cancer-care payment model that attempts to separate oncologists' income from drug sales. Participating physicians are reimbursed upfront for a patient's entire cycle of treatment.

Massachusetts is debating the next step to improve care quality while reducing costs. Its private health insurance arena has been experimenting with global payments for primary care services. With eight hospitals and physician groups, the state's Blue Cross Blue Shield plan (BCBSMA) is using an "alternative quality contract" that pays a set monthly fee per patient, adjusted for health status. After one year, BCBSMA reports that all groups improved care and came in under budget. At least twice as many patients in the global payment plan than in traditional plans had regular checkups, cancer screenings, and controlled diabetes or heart disease.

Only time will tell if these methods will work outside pilot projects. But you should be ready for changes in how you are paid. ■



HYPONATREMIA STRATEGY

Risk Factors and Management of Hyponatremia in Oncology Patients

H yponatremia has been reported in conjunction with many cancer types, including both hematologic malignancies and solid tumors (*J Am Soc Nephrol.* 2009;20:427A; *Support Care Cancer.* 2007;15:1341-1347). The incidence of hyponatremia in cancer patients is unclear, as reports evaluated varying populations and used different definitions of hyponatremia (Table 1). At the Medical University of South Carolina (MUSC) in Charleston, the staff sees roughly one patient per month on the hematology/bone marrow transplantation (BMT) service and one or two patients per month on the oncology (i.e., solid tumor) service who receive intervention for hyponatremia, said Ashley Glode, PharmD, clinical pharmacy specialist, Hematology/Oncology, and adjunct professor, Clinical Pharmacy and Outcomes Sciences, at MUSC.

Hyponatremia Presentation

Patients on the oncology service typically are admitted to receive chemotherapy requiring frequent administration or 24-hour continuous infusions, or for treatment of chemotherapy complications, Glode said. They usually are hospitalized for one to five days. Patients on the hematology/BMT service often remain in the hospital for two to three weeks, until their blood counts recover from their cancer therapy, Glode said. Many

have been admitted for induction chemotherapy to treat acute leukemia. “The patients on the hematology service are here much longer, so it is easier to see trends in lab values,” she said.

Hyponatremia in cancer patients can be caused by the malignancy, the medications that the patient is receiving (Table 2), or the adverse effects of the medications or malignancy (see sidebar, “Etiologies of Hyponatremia in Cancer Patients,” page 5). At MUSC, the pharmacist becomes more involved in management of hyponatremia attributed to medications. Drug-induced hyponatremia often surfaces a few days to one week after the first chemotherapy treatment, said Glode.

To reduce the risk of hyponatremia, Glode said, “We maximally concentrate any intravenous products to assist with fluid restriction for a patient undergoing treatment associated with hyponatremia from the initiation of therapy.” If hyponatremia is attributed to therapy with an intravenous agent not already maximally concentrated, the pharmacy will minimize the diluent in that medication as well.

Management

Pharmacists at MUSC round daily with a team composed of an attending physician, fellow, resident, intern, pharmacist, and nurse practitioner, said Glode. The team makes decisions about whether and how to treat hyponatremia.

Evaluation of hyponatremia in

oncology patients follows the same principles as in other populations, said Abdullah K. Salahudeen, MD, professor of medicine, Section of Nephrology at University of Texas MD Anderson Cancer Center in Houston. The first step is to determine whether hyponatremia is acute (<48 hours) or chronic in duration. Acute hyponatremia is a medical emergency that requires treatment, usually with hypertonic saline, he said (*Support Care Cancer.* 2007;15:1341-1347). In cancer patients at MD Anderson and MUSC, a record of serum sodium levels often is available, so the duration of hyponatremia can be assessed, Glode and Salahudeen said. Most cases of hyponatremia in the cancer population are gradual as opposed to acute in onset, Glode said.

Patients in whom clinicians suspect hypovolemia receive isotonic saline for fluid resuscitation, Glode said. Hypovolemia is relatively common in cancer patients, she said. “They don’t feel well, so they don’t eat and drink well. They often have nausea and vomiting on admission, especially on the oncology service,” she said. If volume status is unclear or requires confirmation, administration of isotonic saline can alleviate or rule out hypovolemia (*Am J Med.* 2007;120[11A]:S1-S21).

The next step is to assess osmolality. Effective osmolality of less than 275 mOsm/kg H₂O is consistent with a diagnosis of hypotonic hyponatremia (*N Engl J Med.* 2007;356:2064-2072). Euvolemic patients with syndrome of inappropriate antidiuretic hormone (SIADH), serum sodium higher than 120 to 125 mmol/L and no symptoms of hyponatremia would likely be treated with fluid restriction first, Glode said. “We usually wait 24 to 48 hours and see how the serum sodium responds,” she said. If a 1- to 2-mmol/L increase in serum sodium occurs during that time frame, fluid restriction will likely be continued. If the serum sodium level remains stable or declines, alternatives include salt tablets, a vasopressin receptor antagonist, or hypertonic (2% or 3%) saline, Glode

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explained (*Am J Med.* 2007;120[11A]: S1–S21).

Salt tablets offer an option for patients who can tolerate them. Possible adverse effects of this therapy include edema and aggravation of any pre-existing hypertension, Salahudeen said. Salt tablets also may exacerbate nausea, vomiting, and other gastrointestinal symptoms common among patients receiving chemotherapy. At MUSC, clinicians try salt tablets for 48 hours in asymptomatic patients. Those who do not respond are considered for therapy with a vasopressin receptor antagonist,

Glode said. Symptomatic patients with lower serum sodium levels (i.e. <120mmol/L) might receive hypertonic saline with careful monitoring.

Effect on Cancer Management

If a chemotherapeutic agent is believed to cause hyponatremia in a patient, MUSC clinicians try to treat the electrolyte abnormality rather than stop or reduce the dosage of chemotherapy. “We usually manage the side effects rather than alter the initial cancer therapy unless there is an equally effective

alternative. We tend not to change the cancer treatment because it’s the best option the patient has for cure,” Glode said. In some cases, clinicians may delay the next dose of a chemotherapeutic agent that is viewed as clearly causing symptomatic hyponatremia.

Because confusion and other neurologic manifestations of hyponatremia can stem from hyponatremia and certain chemotherapeutic agents, it can be difficult to determine symptom etiology, said Glode. One benefit of promptly treating patients with hyponatremia and neurologic symptoms is to rule out

TABLE 1. RATE OF HYPONATREMIA IN CANCER PATIENTS

Study	Subjects	Definition of hyponatremia	Rate of hyponatremia
<i>Lung Cancer.</i> 2010;68[1]:111–114	453 patients treated for SCLC at a single hospital over 10 years	Serum sodium \leq 135 mmol/L	44% total; 33%, 126–135 mmol/L, 11%, <125 mmol/L
<i>Pediatr Blood Cancer.</i> 2010;54[5]:734–737	63 children admitted to a single hospital for chemotherapy or SCT	N/A; mean serum sodium 128 mmol/L; range, 120–130	63.5%
<i>J Am Soc Nephrol.</i> 2009;20:427A	2,960 patients admitted to a cancer hospital over four months	Serum sodium <135 mmol/L	46.3%
<i>Br J Cancer.</i> 1993;68:767–774	110 evaluable patients with NHL	Serum sodium <137 mmol/L	32%
<i>J Clin Oncol.</i> 1986;4(8):1191–1198	350 patients with SCLC	Serum sodium <130 mmol/L attributed to SIADH	11%

NHL: non-Hodgkins lymphoma; SCLC: small-cell lung cancer; SCT: stem cell transplantation; SIADH: syndrome of inappropriate antidiuretic hormone secretion

HYPONATREMIA AND MORTALITY IN CANCER PATIENTS

Hyponatremia has been associated with mortality in general populations of hospitalized patients. No causal link has been demonstrated, however (*Am J Med.* 2009;122[9]:857–865; *Arch Intern Med.* 2010;170[3]:294–302). Reports about the impact of hyponatremia on prognosis in cancer patients are limited and inconsistent. A review of data from 453 patients treated for small cell lung cancer (SCLC) at a single hospital found that median survival was significantly shorter among patients with hyponatremia (\leq 135 mmol/L; 7.1 months vs 11.2 months, respectively; $P = 0.0001$; *Lung Cancer.* 2010;68[1]:111–114). Analysis of data from 163 patients with extensive SCLC found that serum sodium did not significantly affect survival (*J Cancer Res Clin Oncol.* 2007;133[8]:519–524).

A study of 110 patients with non-Hodgkin’s lymphoma reported that hyponatremia (defined as serum sodium <137 mmol/L) was significantly associated with not achieving complete remission, shorter duration of remission, and poorer survival (*Br J Cancer.* 1993;68:767–774). Rate of death was higher among hyponatremic patients than in the overall population of cancer patients in a specialized oncology hospital (19% vs 6.3%, respectively), though no death was attributed directly to hyponatremia (*Support Care Cancer.* 1999;8[3]:192–197). A preliminary report from an MD Anderson study indicated that hyponatremia was associated with higher risk of in-hospital mortality (22% vs 12%; odds ratio, 2.02; 95% confidence interval 1.3–3.2; $P = 0.002$; *J Am Soc Nephrol.* 2009;20:427A). —EAM

low serum sodium as a cause of the symptoms. “We don’t want any confusion with whether a patient’s neurologic manifestations are a side effect of the chemotherapy or an electrolyte abnormality,” said Glode.

Hyponatremia can lead to delay of nonemergency surgery, Salahudeen noted. All high-risk patients at MD Anderson must undergo a thorough medical evaluation prior to nonemergency surgery, he said. If the serum sodium is less than 130 mmol/L, a nephrology consult will likely be requested to address the issue. Surgery will likely be postponed if serum sodium is less than 125 mmol/L.

Hyponatremia attributed to malignancy often resolves with effective anticancer therapy (*Am J Med.* 2007;120[11A]:S1–S21). It may recur with tumor progression, however. Hyponatremia due to drug therapy begins to wane as the medication in

TABLE 2. MEDICATIONS USED IN CANCER CARE ASSOCIATED WITH HYPONATREMIA

Carbamazepine	Interferon α and γ	Monoclonal antibodies
Carboplatin	Interleukin 2	Opiates (e.g., morphine)
Cisplatin	Levamisole	Pentostatin
Cyclophosphamide (IV)	Melphalan	Vinblastine
Ifosfamide	Methotrexate	Vincristine

Source: *Am J Kidney Dis.* 2008;52:144–153

question is eliminated from the body. As the chemotherapeutic medication is eliminated, the hyponatremia therapy can be drawn down as well, Glode said.

“Most of us are reluctant to discharge a patient with hyponatremia, especially in the presence of symptoms, until we have a correction,” Salahudeen said. Asymptomatic patients with serum sodium of at least 130 mmol/L that is stable might receive nonpharmacologic

interventions only, he said. The goal of treatment is symptom improvement and serum sodium of roughly 135 mmol/L. “We would prefer to have the serum sodium close to normal. That’s why it’s called normal,” he said. ■

Dr. Salahudeen received no remuneration for the interview and preparation of this article.

—Reported and written by Eileen A. McCaffrey, in Whippany, N.J.

ETIOLOGIES OF HYPONATREMIA IN CANCER PATIENTS

Patients with cancer have multiple risk factors for hyponatremia. Syndrome of inappropriate antidiuretic hormone secretion (SIADH) is a common etiology of hyponatremia in cancer patients (*Emerg Med Clin N Am.* 2009;27:257–269). Tumor cells may produce antidiuretic hormone (ADH), also called arginine vasopressin (AVP), even in the presence of serum hypotonicity (*Emerg Med Clin N Am.* 2009;27:257–269). Small-cell lung cancer in particular has been associated with this complication (*Emerg Med Clin N Am.* 2009;27:257–269; *J Clin Oncol.* 1986;4(8):1191–1198). “The patient hoards water, thus diluting the serum sodium,” said Abdullah K. Salahudeen, MD, professor of medicine, Section of Nephrology, at University of Texas MD Anderson Cancer Center in Houston. Many chemotherapeutic agents also lead to AVP production or produce hyponatremia by other mechanisms (Table 2; *Support Care Cancer.* 2007;15:1341–1347). Cyclophosphamide can potentiate the effect of AVP as well as increase its release (*Am J Kidney Dis.* 2008;52:144–153). Methotrexate is thought to adversely affect the neurosecretory areas of the cerebrum and alter body fluid distribution volumes (*Am J Kidney Dis.* 2008;52:144–153).

The nausea and vomiting associated with chemotherapy also promote AVP release, as does radiation to the abdomen. Pain has been associated with hyponatremia, as have the morphine and carbamazepine often used to treat cancer pain. Immunomodulators and monoclonal antibody therapies used in

cancer care also have been associated with hyponatremia (*Support Care Cancer.* 2007;15:1341–1347; *Am J Kidney Dis.* 2008;52:144–153). Cisplatin is postulated to induce hyponatremia through renal salt wasting (*Am J Kidney Dis.* 2008;52:144–153).

The hydration administered with cisplatin to prevent nephrotoxicity and other adverse effects of this agent also can promote hyponatremia (*Support Care Cancer.* 2007;15:1341–1347). Patients receiving many types of chemotherapy often are instructed to increase their fluid intake, said Salahudeen. Many people respond by drinking large quantities of water. “Water in a patient with a tendency to retain water is problematic,” he noted. “You are adding fuel to the fire, increasing the risk or severity of hyponatremia.”

Because so many patients with cancer have risk factors for water retention or other mechanisms of hyponatremia, Salahudeen advises patients to drink fluids that contain solutes rather than only water. Beverages with added electrolytes, juices, and decaffeinated coffee or tea offer safer fluid options. He suggests consuming caffeinated beverages in moderation. “Solute will allow for some removal of water from the body,” he explained. This is the mechanism behind the “archaic” use of urea for hyponatremia, he said. Consumption of a low-solute diet also is a risk factor for hyponatremia in cancer patients.

—EAM

PATIENT CARE

Case Study: A 79-Year-Old Woman With Confusion and Hyponatremia

Michael F. Michelis, MD, Chief of Nephrology at Lenox Hill Hospital in New York, N.Y., described the following case.

A 79-year-old woman presented with a complaint of progressive confusion, for which she was hospitalized. Her other recent complaints included poorly controlled blood pressure, difficulties with concentration and walking, and unsteady gait. Medical history was significant for depression, hypertension, hypercholesterolemia, and osteoarthritis. Current medications included a selective serotonin reuptake inhibitor (SSRI), enalapril, hydrochlorothiazide, a statin, and occasional use of non-steroidal anti-inflammatory medications. Her recent history of poorly controlled blood pressure led clinicians to question her adherence to the antihypertensive medication. She lived alone, receiving assistance from a part-time home health aide.

Upon evaluation, the patient was pleasant but slow to respond to questions and directions. Blood pressure, pulse, respiration, and temperature were normal. Physical examination revealed no evidence of hypervolemia. Initial neurologic examination revealed symmetrical reflexes and deficiencies in attention span, including a low score on an informal Mini-Mental State exam. Gait capacity was not evaluated.

Laboratory Findings

A complete blood count (CBC), metabolic panel, and urine studies were ordered and yielded the following findings:

- CBC, unremarkable; no anemia
- Serum sodium, 119 mmol/L
- Serum potassium, 3.8 mmol/L
- Serum uric acid, 3.9 mg/dL
- Blood urea nitrogen (BUN), 10 mg/dL
- Serum creatinine, 0.7 mg/dL
- Urine sodium, 43 mmol/L

- Urine potassium, 18 mmol/L
- Urine osmolality, 424 mOsm/kg H₂O
- Plasma osmolality, 251 mOsm/kg H₂O

The patient's effective osmolality of 247 mOsm/kg H₂O (plasma osmolality minus BUN/2.8) ruled out consideration of pseudohyponatremia (*N Engl J Med.* 2007;356:2064–2072). On the basis of her clinical appearance, the patient was diagnosed with symptomatic euvolemic hypo-osmolar hyponatremia.

Day One

Upon admission, the nephrologist ordered fluid restriction and stopped the hydrochlorothiazide. Thiazide diuretics have been associated with risk of hyponatremia, especially in elderly women (*Am J Kidney Dis.* 2008;52:144–153; *Am J Med.* 2007;120 [11A]:S1–S21). Thiazide-induced hyponatremia is thought to stem in part from impairment of urinary dilution without effect on urinary concentration (*Am J Med.* 2007;120[11A]:S1–S21). The

patient's blood pressure was normal, supporting the safety of stopping the antihypertensive medication.

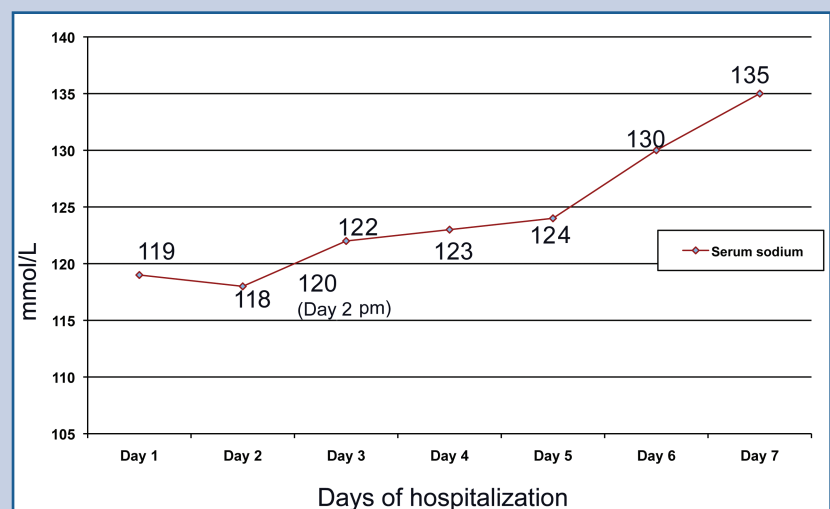
Later in the day, a trial of normal saline (0.9%, given over 12 hours) was initiated in an attempt to rule out hypovolemic hyponatremia and sodium depletion. This procedure is generally safe if urine osmolality is below 500 mOsm/kg H₂O, as in this patient (*N Engl J Med.* 2007;356:2064–2072). Restriction of other fluids continued.

Day Two

Clinical and laboratory evaluation the next morning revealed no change in physical examination, mental status, mobility, or serum sodium (118 mmol/L). Repeated measurement of serum sodium later in the day, to account for the effect of the normal saline trial, showed a relatively minimal response (120 mmol/L).

Given these findings, the SSRI was discontinued despite the patient's primary care physician's concern about exacerbating her prior severe depres-

CHANGES IN SERUM SODIUM



sion. SSRIs have been implicated in causing hyponatremia by leading to syndrome of inappropriate antidiuretic hormone (SIADH) release. Older age and concomitant use of a thiazide diuretic are the most important risk factors for development of SSRI-associated hyponatremia (*Am J Kidney Dis.* 2008;52:144–153; *Am J Med Sci.* 2004;327[2]:109–111). Fluid restriction continued.

Day Three

The patient's mobility and mental symptoms remained unchanged as of the next morning. Serum sodium was 122 mmol/L, despite continued attempts at fluid restriction. The patient was not in a monitored area of the hospital, which complicated enforcement of fluid restriction.

A complete neurologic examination was performed, revealing evidence of a low-grade, relatively small, chronic subdural hematoma. The hematoma was thought to result from old trauma and the consulting neurologist decided against surgical intervention. Chronic subdural hematoma of unknown cause can be seen in the elderly, said Michelis. Reported frequency for adults 70 to 79 years old is 7.35 cases/100,000 individuals (<http://tinyurl.com/4j5kk9b>). The hematoma was not viewed as a likely major contributor to either the patient's symptoms or the

hyponatremia.

Use of tolvaptan was considered but the agent was not immediately available. Demeclocycline 300 mg three times daily therefore was begun.

Days Four Through Seven

On day five, serum sodium was measured at 124 mmol/L. Mental and mobility symptoms persisted, essentially unaffected. The nephrologist obtained access to tolvaptan, and the agent was initiated at a dose of 15 mg/day on the morning of hospital day six. Demeclocycline and fluid restriction were discontinued. Serum sodium was monitored every eight hours. After 24 hours of tolvaptan therapy, serum sodium measured 130 mmol/L. After 48 hours of tolvaptan therapy (hospital day seven), serum sodium had risen to 135 mmol/L. The patient's mental acuity, reactivity, and responses to questioning had improved substantially, as had her ability to walk and her gait. Tolvaptan was discontinued and the patient was discharged. Neither the SSRI nor the hydrochlorothiazide therapy was resumed. The nephrologist recommended that her blood pressure and mental status, along with her serum sodium, be monitored.

Commentary

Multiple factors likely contributed to the symptomatic hyponatremia

observed in this patient, Michelis explained. The nephrologist in turn implemented multiple interventions sequentially: stopping the diuretic and starting fluid restriction, initiating a trial of normal saline, stopping the SSRI, giving demeclocycline for two days, then stopping fluid restriction and switching to tolvaptan. Fluid restriction was difficult to enforce given that the patient was not in a monitored area. In addition, the patient found the fluid restriction uncomfortable, he said.

This patient had risk factors for hypovolemia and salt depletion. Hydrochlorothiazide can induce solute loss (*Am J Kidney Dis.* 2008;52:144–153). Older patients with poor mental acuity, living alone and feeling ill, may not eat well, Michelis noted. Low solute intake can contribute to hyponatremia (*Clin J Am Soc Nephrol.* 2008;3:1175–1184). Saline replacement therapy had little effect on the serum sodium in this case, however.

The patient's laboratory values suggest the diagnosis of SIADH. Urine sodium greater than 40 mmol/L with normal dietary salt intake, inadequate dilution of the urine, and serum uric acid less than 4.0 mg/dL, BUN of less than 10 mg/dL are consistent with a diagnosis of SIADH (*N Engl J Med.* 2007;356:2064–2072). ■

—Reported and written by Eileen A. McCaffrey, in Whippany, N.J.

STUDY PRESENTED AT RENAL WEEK 2010

Renal Week, the American Society of Nephrology annual scientific meeting, was held from November 16–21 in Denver, Colorado.

Mild Hyponatremia and Fracture Risk: The Rotterdam Study

Analysis of data from the prospective, population-based Rotterdam Study found that mild hyponatremia (serum sodium <136 mmol/L; mean 133.4 ± 2.0 mmol/L) in older adults (n = 5,208, >55 years) was associated with increased risk of vertebral fractures, incident nonvertebral fractures, and mortality. Hyponatremia was not associated with bone mineral density. Risk of vertebral fractures remained significant after adjustment for all

covariates (odds ratio 1.61; 95% confidence interval 1.00–2.59; $P = 0.049$). Risk of incident nonvertebral fractures (HR=1.39; 95% CI 1.11–1.73; $P = 0.004$) remained significant after adjustment for age, sex and body mass index. Mean follow-up period for vertebral fractures was 6.4 years; for incident nonvertebral fractures, 7.4 years. Risk of all-cause mortality was higher in subjects with hyponatremia (HR=1.21; 95% CI 1.03–1.43; $P = 0.022$). Subjects with hyponatremia had more recent falls (23.8% vs 16.4%; $P < 0.001$), but the increased fracture risk seen in hyponatremia was independent of recent falls.

Source: "Mild Hyponatremia as a Risk Factor for Fractures: The Rotterdam Study," Hoorn EJ, Zietse R, Carola Zillikens M. *J Am Soc Nephrol.* 2010;21:F-FC232.

CARE MODELS

Pharmacy Managing Partner Sees Opportunities Now for Pharmacists to Expand Their Role

The United States over the past several years has begun to experience a shortage of primary care providers in health care. Physicians complain of overwhelming patient loads, unreasonable numbers of hours worked, and decreasing practice revenue. This shortage of primary care providers has led to the implementations of new models of care delivery, such as the accountable care organization (ACO) and the patient-centered medical home (PCMH). As health care reform has brought more attention to medication therapy management (MTM) and the multidisciplinary collaborative care that pharmacists can participate in, it is not surprising that innovative pharmacy practices have begun pursuing ACOs and PCMHs in an effort to provide new and expanded services to patients in these large health systems.

Goodrich Pharmacy, Inc., based in Minnesota, has been actively involved in pursuing business arrangements with ACOs and PCMHs for several years. At present, the company provides MTM and pharmacy consultation services for patients in a number of large health systems, both in clinic and community pharmacy settings. Steve Simenson, BSPharm, FAPhA, FACA, FACVP, Goodrich's president and managing partner, sees such partnerships as an opportunity for pharmacists both to expand the types of care they provide and to help fill crucial gaps in patients' care. The time is now, Simenson says, for pharmacists to make the business case for medical groups to capitalize on their skills.

Outsourced MTM Service

Simenson credits the increase in opportunities to provide more

advanced services to a higher level of training in recent pharmacy school graduates. "The training now compared to what I received when I graduated is phenomenal," he says. "The students graduating in the last five to ten years really are helping drive practice. They're trained to work more closely with other health care providers. My colleagues and I have learned by trial and error and in the school of hard knocks, but the recent graduates have learned it in college before graduating, together with the training they get in required advanced care rotations and postgraduate residency rotations."

According to Simenson, the key for a pharmacy group seeking to provide MTM to a large health system is to form relationships with the types of groups that might be interested in such services. "You have to have the relationships," he says. "For a while now the large systems have understood more and more that they aren't the medication experts that pharmacists are. It's not working for them, just having internal people handling MTM, leaving many gaps in patient care. We're making inroads with a clinic system that's part of a large health system in our area. We staff it with dedicated MTM pharmacists and a resident."

The newer models of pharmacy care afford a pharmacist the opportunity to work in a variety of settings, Simenson says. "You can be in the community setting, you can practice in clinics, and you can participate in hybrid settings. There are many opportunities the PCMH is going to provide, while not necessarily being an employee of the PCMH," he says.

One challenge Simenson recognizes in providing advanced pharmacy services to large health care systems is in



Steve Simenson
BSPharm, FAPhA

developing a payment model. "If you're a large organization and you employ pharmacists to provide clinical services, you're only paying them a salary," he says. "Then you reap the benefits and lower costs that come directly back to the organization. But we think we can provide more comprehensive patient benefits with our patient access in the community pharmacy. By working from inside and outside the organization, we're not putting a value on the pharmacist's salary; we're putting a value on their services. There is no defined formula like there is with other providers. They're used to paying us for the drug product, not the care and the clinical knowledge we provide.

"Currently we get capitated fees or contract for blocks of time, for providing various services to the clinic system," he continues. "They pay us for ordering labs and approving refills. We get paid for MTM services that we provide both in the clinic or where the patient wants to be seen. The best way to describe what we do is a medication

driven patient visit. We get referrals from physicians indicating the primary complaint, like with any other specialist. We look at the patient's total health, with an emphasis on proper medication use. The advantage of being in the community is the convenience of access. If a patient doesn't want to go back to the clinic, they can go to a pharmacy location close to their home or workplace and get the same service."

Sharing Data

Simenson and his colleagues at Goodrich are currently collaborating on creating a documentation system for use by pharmacists involved in providing advanced care. The new electronic system would be in essence a pharmacy-based electronic health record (EHR) that views and documents patients' care from a pharmacist's perspective, Simenson says. "It's designed to manage pharmacy practice more efficiently," he states. "The goal is to document just like any other provider would what you do in the patient's EHR, the electronic chart. The system can send a PDF to

one of the major medical groups. That's how they get most of their information now, from the hospitals and physician specialists they send patients to." In the near future these pharmacy-based EHRs will need to be certified and will be required to be able to share patient-specific information with other health care providers' EHR systems.

"With the clinical skills pharmacists have to offer, they are in a unique position right now to help put a thumb in the dike for the shortage of primary care providers."

—Steve Simenson, BSPHarm, FAPhA, FACA, FACVP,
Goodrich Pharmacy

Using information gathered with the new pharmacy EHR, Goodrich pharmacists hope to be able to provide large health organizations with data that will prove the business case for pharmacists seeking to expand into collaborative care and MTM roles. "We're hoping to be able to increase our capacity to see more patients as a result of efficiencies

in this and other systems," Simenson says. "At the same time, we'll be able to pull out specific information on those value measures and reveal meaningful outcomes. Our goal in the next years is to collect statistical evidence that will stand up to critical evaluation and peer review. Most information in support of advanced pharmacist practice in most pharmacies is still anecdotal."

In the past, Simenson says, pharmacy and medical groups were reluctant to share population data, making it difficult to support the business case for advanced pharmacist care models. "There is still some reluctance even among health systems about sharing their information," he says. "But that will be eliminated as Medicare starts requiring 'meaningful use' over the next two to three years in EHR systems that share patient information. Some providers think an EHR is their record, not the patient's. But it's the patient's record, not yours.

"The question is, will other systems want to integrate with our system?" he

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AMPLE PHARMACIST SUPPLY WILL BENEFIT PHARMACISTS AND PATIENTS

Between the pharmacists currently in practice and the new pharmacists entering practice after graduating from pharmacy school, the U.S. health care system should have a more adequate supply of pharmacists to fill the profession's expanding roles of providing medication therapy management (MTM) services and other specialized patient care in accountable care organizations (ACOs), patient-centered medical homes (PCMHs), large health systems, and community pharmacies, says Steve Simenson, BSPHarm, FAPhA, FACA, FACVP, the president and managing partner of Minn.-based Goodrich Pharmacy, Inc. Goodrich pharmacists have been aggressive about working with ACOs, PCMHs, and other large systems in providing MTM services and clinical pharmacy consultations, both in the clinic and the community pharmacy setting.

Simenson says the ample supply of pharmacist labor is obvious in the hiring practices of large pharmacy chains. "This year, for

the first time, there were no signing bonuses," he says. "Even the large chains like CVS and Walgreens were starting many new hires at lower hours: 24 hours or 30 hours per week rather than 40. I think in most areas of the country there will be an overabundance of pharmacists, and they will be forced to look for work in less traditional roles, which is a good thing for pharmacy and patient care.

"With automation correctly used, there are lots of ways to get a prescription to a patient," Simenson continues. "I am still an advocate for pharmacy keeping a hand on that, because what has made our practice rewarding has been the regular direct patient contact, helping patients recognize the gaps in their care, and triaging them to the care they need. Part of our job is being advocates for them with their other providers, and making sure they get the best possible medication outcomes. I think that is part of the value pharmacists can provide in the future." —RD

Continued from page 9

continues. "Because of health care reform and health information technology legislation, I think they'll have to, because Medicare will start paying them less per patient if they don't demonstrate meaningful use. Every day we get two, three, four, or five copies of patients' records, unnecessary stacks of paper and staff time, because we need those data to provide the kind of quality patient care we provide at our pharmacies. That's a cumbersome workload to a large system. Once providers see EHRs are not just a temporary phenomenon, they're going to start sharing data with us electronically on a regular basis."

Opportunities Abound

MTM and collaborative care models have been gaining ground for a long time now, and can only continue to expand, Simenson feels. The success of these care models comes from a recog-

inition among patients and providers of the value that pharmacists bring to a practice, he says. "Once the physician makes the effort to say the patient

"By working from outside the organization, we're not putting a value on the pharmacist's salary; we're putting a value on their services," Simenson says.

needs to see a pharmacist, the patient recognizes the pharmacist as a necessary part of their health care," he says. "It's about patient care, pure and simple. And it's about pharmacists being medication experts and good managers of care. They really have the skills to coordinate and provide excellent patient care. Pharmacists can assess, monitor, modify and fine tune patients' care to their specific medication response and needs. The providers that have good skills seem to realize and

accept what we can do for them, which is an interesting phenomenon.

"Minnesota has a lot of health systems and insurance plans that are willing to try the MTM model," Simenson concludes. "Therefore pharmacists are finding themselves in management positions in all kinds of health systems. With the clinical skills pharmacists have to offer, pharmacists

are in a unique position right now to help put a thumb in the dike for the shortage of primary care providers. They need to be proud of what they can do and not sell themselves short if right now their opportunity is in a more traditional dispensing pharmacy. There's so much more they can do, and it's so much more professionally rewarding if they can start developing some of those opportunities." ■

—Reported by Joseph Burns. Written by Editor Rev DiCerto.

OPPORTUNITY EXISTS NOW FOR PHARMACISTS TO SELL THEIR SKILLS, EXPERT SAYS

As the managing partner of a pharmacy group that has had considerable success at providing medication therapy management (MTM) services for accountable care organizations (ACOs) and patient-centered medical homes in both clinic and community pharmacy settings in the Minnesota area, Steve Simenson, BSPHarm, FAPhA, FACA, FACVP, of Goodrich Pharmacy, Inc., is an expert on selling the concept of MTM to large health care organizations. The key, according to Simenson, is for pharmacists to develop a network of relationships with large provider organizations and to demonstrate the value a pharmacist's skills can deliver to providers, lowering costs while improving outcomes.

"The providers have to see you as a health professional that can provide services that augment their care," he says. "They aren't always looking, or don't know what pharmacists can do. I think pharmacy has a big public relations challenge. We have to let the providers and the patients know that we're not tied to the dispensing counter like we have been in the past. The level of care that can be provided both by recent graduates and older graduates who have kept up their skills is light years ahead of

what the expectations are for them in the public and among people working in specialized health systems.

"Make sure to try to sell your training, skills and knowledge," Simenson continues. "If you want the opportunity to provide MTM and other services, sell them to providers that are receptive to utilizing your services and recognize the need for them. In the next two or three years, many barriers will be removed and opportunities provided, enabling pharmacists to advance patient care and improve medication outcomes. There's a unique alignment of the planets with increased access to medical records, pharmacists in ACOs and medical homes, and the emergence of a large supply of pharmacists to answer the challenge.

"The more information that's conveyed about health care reform, the better it is for us," he concludes. "There's an opportunity to inform primary care providers and other health care providers that we are the medication experts. We have the chance to show them our skills go beyond just filling prescriptions. We need to sell the clinical care side of what pharmacists can do. Pharmacists' many contributions to improving medication outcomes have the most potential in the future." —RD

PHARMACY TRENDS

ASHP Report Is a Valuable Resource for Pharmacists Considering Joining ACOs

Among other new care models, the Affordable Care Act of 2010 (ACA) provides for the establishment of accountable care organizations (ACOs) as a means to improve patients' health care outcomes while reducing costs and rates of hospitalizations and hospital readmissions. An ACO can best be described as a health care organization or group of providers who share the responsibility and accountability for a patient's care, focusing on improvements in care quality and reductions in health care expenditures.

Because a large portion of patients' care and health care expenditures, particularly in patients with chronic conditions such as chronic heart failure or diabetes, center on medications and the medical management of their conditions, pharmacists are a logical addition to the care team in an ACO setting. Clinical pharmacists' expertise with medication review and medication therapy management (MTM) can easily contribute to the improved health outcomes and reductions in unnecessary expenditures and adverse drug events that are a focus of the ACO strategy.

The American Society of Health-System Pharmacists (ASHP; www.ashp.org) in January released a report titled *ASHP Policy Analysis: Pharmacists' Role in Accountable Care Organizations*. Authored by Lisa Daigle, MA, ASHP's policy analyst, the report seeks to provide pharmacists with a solid understanding of the way ACOs will be structured, how payment and reimbursement will be handled within them, and the ways pharmacists can get involved in working with them and the types of services they might be enlisted to provide. The report is available as a free download on the ASHP Web site.

ACO and Medical Home Structure

According to the report, every ACO will be accountable for the care of at least 5,000 Medicare patients. This includes controlling health care costs and quality, and this level of care must be maintained for at least three years, the report says. "Each ACO must promote evidence-based medicine and patient engagement, report quality and cost measures, and coordinate care," the report says. "To do this, medical homes could be included in an ACO. Through a medical home, a patient's care is coordinated by a team led by the patient's physician."

It is in the context of the medical home that the report sees the pharmacist's greatest opportunity of becoming involved in an ACO. "As physicians establish medical homes, pharmacists have an opportunity to become involved as part of the health care team by providing MTM services to patients, especially patients diagnosed with multiple chronic conditions," the report says. "Those patients have a greater need for medication selection, dose adjustment, laboratory monitoring, drug interaction identification, and patient medication counseling, all of which are also key requirements of a medical home. [A] Medicare medical home's responsibility for patient medication reviews should be coordinated with a pharmacist."

Roles and Opportunities

Pharmacists can participate in ACOs by "ensuring appropriate medication use, reducing medication-related adverse events, preventing hospital readmissions, and helping patients manage chronic conditions," the report says. "MTM services should be provided to hospitalized patients as well as to patients visiting a clinic or a primary care office." Selecting or recommending

initial medication, and reviewing patients' medications and recommending needed changes to patients' physicians are additional services pharmacists could provide in an ACO, the report says. Further, pharmacists should "be available to answer patients' questions," the report says.

"Physicians, nurses, and other health care team members will ideally rely on pharmacists' medication expertise in determining appropriate treatments," the report says. As ACOs work to reduce hospital readmissions, "many hospital pharmacists may eventually find even more opportunities in ambulatory care settings as they follow the patients."

Supporting Data

The report includes a number of case studies, citing data from health organizations that have begun the process of forming ACOs ahead of ACA's stated start date. On the basis of these organizations' experiences, the report lists eight fundamental principles that must be observed in the formation of an ACO. A new ACO should "build on existing programs," the report says. Identifying patients with high degrees of medical need, developing medical homes, collaborating with other health systems and providers, and creating integrated and personal electronic health records (EHRs) for patients are other principles listed in the report.

In addition, the report stresses the ACO's need to be able to support its improved care and savings with evidence-based data, and the need to measure performance. In every area, it points out the pharmacist's ability to contribute value to the care delivery team and to control costs. The report is an important resource for any pharmacist considering becoming involved with an ACO in the coming months. ■

—Editor Rev DiCerto

U.S. Pharmacopeia Test Chapter Suggests New Standards for Prescription Labels

According to data from the United States Institutes of Medicine (IOM), there are currently more than 1 million adverse drug events per year in the United States attributable to the misuse of medication. Often a patient's only source of information on their prescription medications is that which is provided in the prescription label, the Rockville, Md.-based United States Pharmacopeia (USP) says in a recent proposed general test chapter on prescription container labeling. USP is a nongovernmental, official public standards-setting authority for prescription and over-the-counter medicines manufactured or sold in the United States.

The test chapter lays out a series of suggestions for new standards intended to make the information on prescription medication labels easier for patients to read and understand. By making this information more easily understood, USP hopes to improve patients' compliance and reduce medication errors and adverse drug events. The test chapter is available as a free download on the USP Web site (www.usp.org). USP is accepting comments on the test chapter through March 31, 2011, and it could become official policy in November of this year. Many USP policies have been voted into law at the state and national levels.

Prioritizing Information

The test chapter lists eight proposed standards for improving the readability of prescription labels for patients. The eight proposed standards are organizing prescription labels in a patient-centered manner; emphasizing instructions and other information that is important to patients; simplifying language; giving explicit instructions;

including the purpose for which the medication is to be used; limiting auxiliary or nonessential information; addressing limited English proficiency; and improving readability. Each proposed standard and how it might be achieved is described in detail.

"Prescription container labeling should feature only the most important patient information needed for safe and effective understanding and use," the test chapter says. "Place at the top of the label the patient's name, drug name and strength, and explicit clear directions for use in simple language.... Other less critical but important content should not supersede critical patient information. Such less critical information should be placed away from dosing instructions..." The test chapter suggests putting such information as the pharmacy's name and phone number and the prescriber's name at the bottom of the label or in another, less prominent location.

Clear and Concise

The language used on the label "should be clear, simplified, concise, and familiar, and should be used in a standard manner," the test chapter stresses, while calling for the use of "only common terms and sentences." Pharmacists are discouraged from using Latin terms and other words that would be unfamiliar to patients. "Consumer feedback should also be sought," the test chapter states.

The test chapter places strong emphasis on the need for instructions to be explicit. "Instructions for use shall clearly separate the dose itself from the timing of each dose in order to explicitly convey the number of dosage units to be taken and when," it says. It suggests using numerals rather than alphabetic characters and phrasing such as

"Take 2 tablets in the morning and 2 tablets in the evening" rather than "Take two tablets twice daily."

Further Suggestions

The test chapter suggests including the purpose for taking a medication, to help eliminate confusion among patients who may be using multiple prescriptions. "Current evidence supports inclusion of purpose-for-use language in clear, simple terms (e.g., 'for high blood pressure' rather than 'for hypertension')," it says. "Auxiliary information on the prescription container label should be evidence-based on simple explicit language that is minimized to avoid distracting patients with nonessential information."

Labels should be made in "an individual's preferred language," the test chapter says, in order to maximize patients' ability to read and comprehend instructions. "Standardized translated instructions and technology advances are needed to ensure the accuracy and safety of prescription labeling for patients with low English proficiency." To improve readability, the test chapter suggests using high-contrast print; simple, familiar fonts; sentence case; large font size (12-point Times Roman minimum, no type smaller than 10-point Times Roman); and horizontal text only.

Comments on the test chapter can be submitted through the USP Web site. Whether the test chapter is adopted as official policy or not, and whether in part or in whole it is adopted as law in any parts of the United States, the suggestions laid out in it are common-sense measures that can help improve patients' adherence and reduce medication errors. It is worth the time to read for any pharmacist. ■

—Editor Rev DiCerto

PHARMACEUTICAL CARE

Study Finds Tablet Splitting Is Inaccurate, Potentially Dangerous

Most pharmacists are familiar with the practice of tablet splitting, breaking solid tablets into smaller pieces for the purpose of either reducing a medication's dosage or making it easier for patients to ingest. However, in a study published in the January issue of the *Journal of Advanced Nursing* (JAN), researchers found that nearly a third of the split fragments deviated from recommended dosages by 15% or more. These findings have raised concerns about physicians' and patients' ability to comply with dosage recommendations when using tablets that have been split, prompting a warning from medical experts, who "are calling on manufacturers to produce greater dose options and liquid alternatives to make the practice unnecessary," according to a release from JAN. The study "points out that the practice could have serious clinical consequences for tablets that have a narrow margin between therapeutic and toxic doses," the release states.

Study Findings

Researchers asked five volunteers to split eight different-sized tablets using three techniques commonly used in nursing homes. The drugs were prescribed for a range of health conditions, including Parkinson's, congestive heart failure, thrombosis and arthritis. After splitting, each fragment was weighed to see how much it deviated from its target weight. Thirty-one percent of the tablet fragments were found to deviate from their predicted weight by more than 15%, while 14% were found to deviate by more than 25%. "Even the most accurate method produced error margins of 21% and 8% respectively," the report states.

The most accurate method of splitting tablets was found to be with the use of a splitting device. This method produced a 15% to 25% error margin in 13% of cases; the margin for scissors was 22%, while the margin using a knife was 17%.

In 8% of cases, the splitting device produced a deviation of more than 25%. This high level of deviation was seen in 19% of cases using scissors and in 17% of cases using a knife.

Some medications were found to be easier to split accurately than others. The easiest medications to split were associated with an overall error margin (15% deviation or more) of 2%. The most difficult tablets to split were associated with an error margin of 19%.

"Even the most accurate method [of splitting tablets] produced error margins of 21% and 8% respectively," the report states.

"Tablet splitting is daily practice in nursing homes" says study lead Dr. Charlotte Verrue. "However, not all formulations are suitable for splitting and, even when they are, large dose deviations or weight losses can occur. This could have serious clinical consequences for drugs where there is a small difference between therapeutic and toxic doses."

Research Methods

The volunteers included a professor, a pharmacy student, an administrative worker, a researcher, and a laboratory technician. They ranged in age from 21 to 55 years. Among the volunteers only the technician had any experience at splitting tablets. The authors of the study chose this group of volunteers in

an attempt to replicate the conditions in a nursing home, where tablet splitting is often not performed by professional nurses.

All together, the five volunteers split tablets into 3,600 separate quarters or halves. The tools used to split tablets included a splitting device, a kitchen knife, and scissors. Eight different tablets were used. They were in a variety of different shapes and sizes. Three of the tablets were unscored, while three had one score line and two had two score lines.

Recommendations

The research was conducted by the Faculty of Pharmaceutical Sciences at Ghent University, Belgium. Tablets are split for many reasons, says Verrue. It is done "to increase dose flexibility, to make tablets easier to swallow and to save money for both patients and health care providers," she says. "However, the split tablets are often unequal sizes

and a substantial amount of the tablet can be lost during splitting. Based on our results, we recommend use of a splitting device when splitting cannot be avoided, for example when the prescribed dose is not commercially available or where there is no alternative formulation, such as a liquid."

"Staff who are responsible for splitting tablets should receive training to enable them to split as accurately as possible," Verrue continues. "They should also be made aware of the possible clinical consequences of dose deviations. We would also like to see manufacturers introduce a wider range of tablet doses or liquid formulations."■

—Editor Rev DiCerto

PHARMACY NEWS

Health Care Groups Seek to Ease Drug Shortage Problems

Released in January, the report from a November summit held by health care stakeholder organizations includes suggestions on how to develop a more coordinated effort to address the issue of drug shortages. The summit was convened by the American Society of Anesthesiologists (ASA), the American Society of Clinical Oncology (ASCO), the American Society of Health-System Pharmacists (ASHP), and the Institute for Safe Medication Practices (ISMP).

Problems caused by drug shortages have caused disruptions in patient care, including canceled or delayed medical procedures and adverse events caused by medications that may have the potential for greater harm than the unavailable first line therapy.

The goals of the summit were to discuss the scope and causes of drug shortages; shed light on the harm to patients that occurs due to drug shortages; discuss the potential need for changes in public policy and stakeholder practices to prevent harm from shortages; and develop an action plan that reflects the recommendations and

intent of stakeholders to work together to stop patient harm and disruptions in care caused by shortages.

The summit report outlines 21 proposed recommendations to improve communication among stakeholders and to remove barriers faced by the FDA and drug manufacturers, including:

- Expanding FDA authority to require manufacturer notification of shortages and market withdrawals;
- Providing incentives to manufacturers of critical drug products in exchange for guarantee of continued production;
- Requiring manufacturing redundancies to minimize the impact of quality issues; and
- Considering distribution options for products in short supply.

The next steps for the co-conveners include ongoing stakeholder collaboration, establishing workgroups to create action plans, and advocacy to Congress, the FDA, and other federal agencies. The Drug Shortages Summit Summary Report can be found online at www.ashp.org/drugshortages/summitreport.

NACDS LAUNCHES MOBILE WEB SITE

The National Association of Chain Drug Stores (NACDS) in January launched NACDS Mobile (<http://m.NACDS.org>), a new mobile Web site intended to serve as a guide to NACDS meetings, advocacy, and public relations. The site is designed for ease of use on any smart phone with a Web browser.

Features of the site include a designated section for each of NACDS's conferences and meetings, and the most recent news on NACDS's public policy advocacy and advancement of pharmacy. It also provides a hub to NACDS's social media presence on Twitter and Facebook.

NACDS Mobile complements the smart phone apps that were introduced for use at select NACDS meetings and conferences in 2010, and which will remain in use for select meetings in 2011. These free apps are designed to enhance attendees' efficiency and experience at NACDS conferences and meetings with speaker information, interactive site maps, schedules, and more.

NCPA ESTABLISHES LONG-TERM CARE ADVISORY BOARD, EXPANDS LTC PROGRAMMING FOR PHARMACISTS

The National Community Pharmacists Association (NCPA; www.ncpanet.org) in January announced changes to its new Long-Term Care (LTC) Division, which seeks to advance the interests of independent long-term care pharmacy providers and their patients. NCPA has established an LTC advisory board to help address the business impact of proposed government policy on independents. The board will serve as a sounding board assisting NCPA in understanding the marketplace and the effect on long-term care residents.

NCPA also has reformatted and improved its Community Aging, Assisted Living, and Long-Term Care (CAALLTC) program to include education opportunities for both beginning and seasoned practitioners. New elements include CAALLTC "Essentials," a 1.5-

day live entry-level program that introduces attendees to the opportunities of providing long-term care services and the business efficiencies necessary for success, and CAALLTC "Advanced," a two-day live program to teach "seasoned" providers about LTC growth opportunities disguised as problems.

The LTC Division's advocacy efforts include providing a community pharmacy perspective to CMS on the potential impacts of proposed short-cycle dispensing rules; working to find a compromise on the LTC nurse-as-agent issue that ensures patients get needed medications in a timely manner; and submitting recommendations to ensure the smooth implementation of e-prescribing rules in LTC settings. The new LTC Web site is at www.ncpaltc.org.

NACDS, NCPA Endorse Senate MTM Legislation

The National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) in February announced their endorsement for the Medication Therapy Management Empowerment Act of 2011 introduced by Senator Kay Hagan (D-NC). Senators Al Franken (D-MN), Sherrod Brown (D-OH) and Tim Johnson (D-SD) are original cosponsors of this legislation. Congress created the medication therapy management (MTM) benefit under the Medicare Modernization Act of 2003 for Medicare beneficiaries by requiring MTM services for patients on multiple medications suffering from chronic conditions or diseases.

Only 50% of Americans adhere to

their prescription drug regimens. A July 2009 report by the New England Health Institute estimated that the overall cost of poor medication adherence is as much as \$290 billion per year, or 13% of total health care expenditures. These costs include increased hospitalizations, doctor and emergency room visits, and factors related to preventable disease progression.

“Neighborhood pharmacies can provide MTM services to help patients manage their health, especially for those patients who suffer from chronic diseases,” said NACDS President and CEO Steven C. Anderson, IOM, CAE. “This commonsense legislation can help patients understand the importance of taking their medications as prescribed.”

FREE PATIENT CARE DATABASE DOUBLES IN SIZE AND SCOPE

The National Association of Chain Drug Stores (NACDS) Foundation in February announced that the NACDS Foundation’s Patient Care Database has more than doubled in size since its launch in February 2010. The free, publicly accessible, searchable database is intended to provide a convenient portal to information on pharmacist-provided patient care services beyond dispensing prescription medications. It features a collection of articles on strategies and interventions community pharmacists have tested with the goal of improving patient adherence to their medication regimens. It can be accessed at www.nacdsfoundation.org/PCD.

The database is a collaborative effort between the NACDS Foundation and the University of Tennessee Center for Medication Therapy Management.

APPLICATION PROCESS FOR PHARMACY RESIDENCY EXPANSION PROJECT

The National Association of Chain Drug Stores (NACDS) Foundation announced in February the grant application, review and approval process for the Community Pharmacy Residency Expansion Project (Community PREP), which seeks to contribute \$1.5 million in grants to expand the capacity of community pharmacy residency programs for recent pharmacy school graduates. Community PREP seeks to fund 30 new com-

munity pharmacy residency positions through grants to non-profit academic institutions totaling \$50,000 each. Fifteen grants will be available in 2011.

An additional 15 Community PREP grants will be available through the NACDS Foundation in 2012.

The application can be viewed at <http://tinyurl.com/4tt1aj8>.

CONTINUING EDUCATION ON BIOSIMILARS AVAILABLE THROUGH ASHP ADVANTAGE

ASHP Advantage in January launched an educational initiative to provide a detailed review of the clinical and regulatory aspects concerning the introduction of biosimilars in the United States. Featured CE programming includes three Web-based home study activities. Podcast dialogs and e-newsletters are also available on the Web site www.BiosimCentral.org.

Health care providers will play a major role in patient safety efforts for biosimilars through enhanced vigilance as well as education to policymakers, patients, and decision-makers in the health system. Physicians and pharmacists will need to be knowl-

edgeable regarding the unique characteristics of biologics, understand the developing regulatory system for biosimilars, and know which questions must be posed as biosimilars are considered.

The Patient Protection and Affordable Care Act establishes an abbreviated approval pathway (the BPCI Act) for biological products demonstrated to be “highly similar” to an FDA-approved biological product. The BPCI Act is consistent with the goal of FDA to allow the use of established knowledge of a drug, thereby avoiding unnecessary duplication of effort for clinical research and saving time and resources.

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