chicago medicine
CHICAGO MEDICAL SOCIETY
THE MEDICAL SOCIETY OF COOK COUNTY
Newsletter, 2011, Vol. 114, No. 7

What you should know about electronic health records
(Coverage begins on page 4)

PRESIDENT'S MESSAGE

Help us to engage the forces!

CMS President Dr. Thomas M. Anderson addresses the Council, describing the Society's recent advocacy initiatives on physicians' behalf. He's flanked by *(from left):* Dr. Kenneth G. Busch, secretary; Ted Kanellakes, CMS executive director; Dr. Howard Axe, president-elect; and Dr. Robert W. Panton, chairman of the Council. *Coverage begins on page 22.*

ON THE NATIONAL SCENE THE U.S. Supreme Court has agreed to decide whether and in what form the Court will consider the constitutional issues raised by the Patient Protection and Affordable Care Act, or at least possibly address the riveting problem of the individual mandate to purchase health insurance.

At the local level, the Chicago Medical Society continues to sponsor the educational activities that members have told us they need. Our well-attended programs addressed the OSHA requirements for bloodborne pathogens, patient safety, health information technology, and financial incentives for demonstrating "meaningful use." Physicians and office managers who attended our programs scored them as highly informative. More are being planned to assist you through the bewilderingly complex changes in medical practice. Keep in touch with us at **www.cmsdocs.org** or **ASKCMSDOCS.ORG** and plan to attend!

On the state level, your membership linked to ISMS provides funding for critical activities like watching and nudging our legislators in Springfield, otherwise known as lobbying on your behalf.

The good news is that the Illinois Medical Practice Act has been renewed. That document prevents unlicensed individuals with little or no education or training from legally engaging in the

(continues on page 2)

Inside

PRESIDENT'S MESSAGE *(continued)*

practice of medicine. Better yet, legislators rejected the Illinois Department of Financial and Professional Regulation's proposal to double the current medical licensure renewal fee and reduce the renewal cycle to two years or less. We fought hard on your behalf to achieve these victories.

The bad news is that legislators renewed the Act for only one year, and we expect the demand for a fee increase to resurface next year.

We need your support in this ongoing battle so we can continue to engage the forces that would diminish your ability to treat patients.

You can help by renewing your membership, recruiting your colleagues as new members, and donating to the ISMS PAC. It is an unfortunate fact of political life in Illinois that legislators are too often tone deaf unless the musical quality of the argument is amplified by financial contributions.

Thomas M. Anderson, MD
President,
Chicago Medical Society

NEWS FOR CHICAGO PHYSICIANS

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CHICAGO MEDICAL SOCIETY
THE MEDICAL SOCIETY OF COOK COUNTY

Newsletter, July 2011, Vol. 114, No. 7

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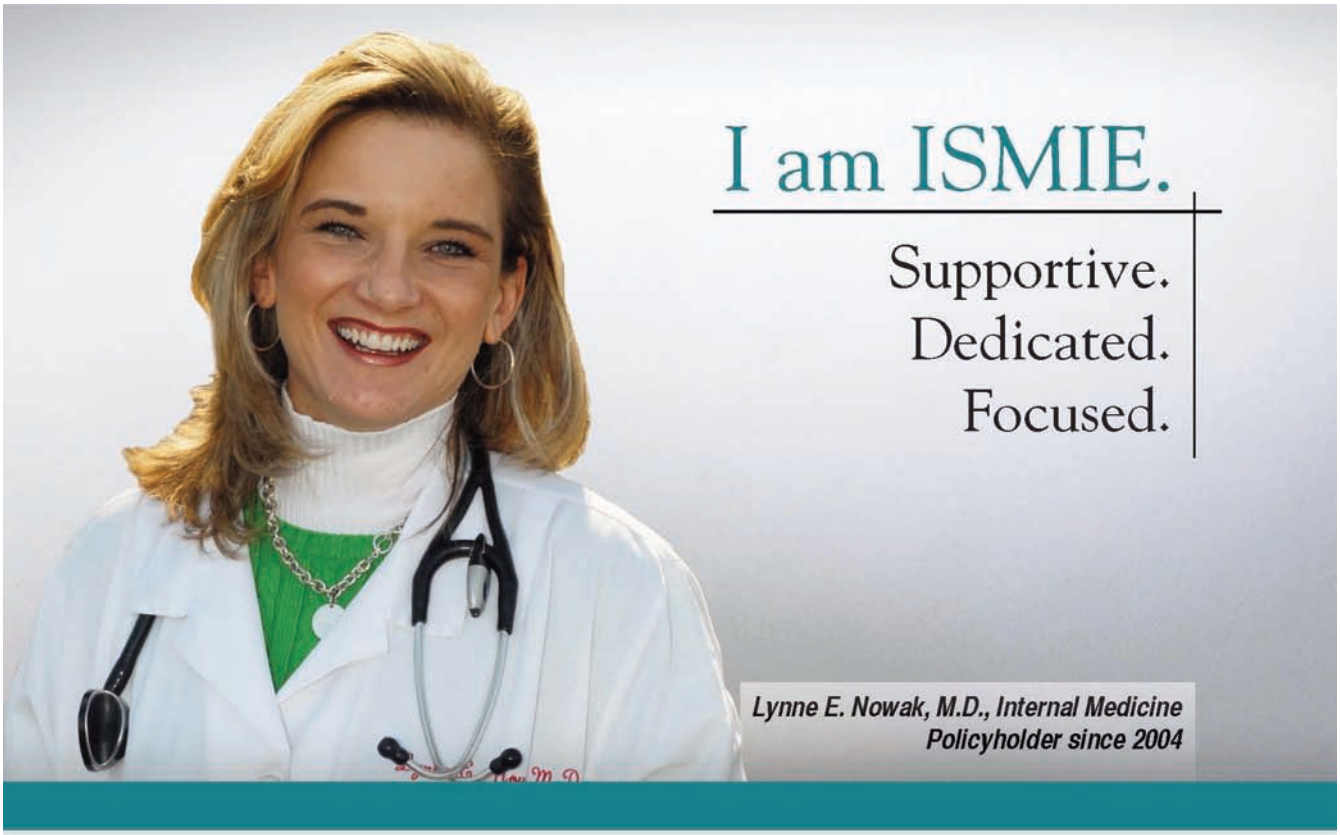

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Protecting the practice of medicine in Illinois

What you should know about electronic health records

By Abel Kho MD, MS
Co-executive Director,
Chicago Health IT Regional Extension Center

The American Recovery and Reinvestment Act (ARRA) of 2009 created an unprecedented federal incentive for physicians to adopt electronic health records (EHRs). The "meaningful use" regulations provide guidance on how to best use an EHR to improve the quality and safety of the care physicians provide to their patients.

Here are 10 practical points physicians should understand:

- EHRs are here to stay – Newly minted physicians trained with them, and expect them as part of their routine practice. Nationwide, EHR adoption rates are approaching 50%.
- Physicians who care for Medicare or Medicaid patients likely qualify for EHR incentive payments of up to or $44,000 (Medicare), or $63,750 dollars (Medicaid). After 2012, Medicare payments decrease yearly, so early is better!
- Physicians who qualify for the Medicaid incentive should pursue this option because it offers more flexibility and funding. The state of Illinois should start dispensing Medicaid EHR incentive payments early next year and registration is already open: **www.cms.gov/EHRIncentivePrograms/**
- Meaningful use is achievable. Many EHRs are designed around these specifications to make it easier for physicians to document appropriately.
- Meaningful use requires use of a certified EHR. Most EHRs are certified but for a complete list go to: **http://onc-chpl.force.com/ehrcert**
- There is not one right EHR solution. How a physician implements an EHR is at least as important as his or her choice of EHR.
- Stark Law relaxation allows not-for-profit hospitals to offset up to 85% of the cost of implementing an EHR for affiliated physicians. Physicians should check with their local hospitals to see if they offer such a program.
- Making the first step and deciding to use an EHR is the hardest. Once one decides, there are local resources to help. The Regional Extension Center (REC) program is the federally funded local resource to help physicians achieve meaningful use of EHRs. **Regional extension centers are NOT vendors**, but are funded by the same legislation that created the EHR incentive payments.

*The REC for Chicago is the Chicago Health IT Regional Extension Center (**www.chitrec.org**). The rest of the state of Illinois is covered by the Illinois Health IT Regional Extension Center or IL-HITREC **(www.il-hitrec.org).***

- What are the most common problems related to achieving meaningful use? Privacy and security assessments, public health reporting, and quality measurement. The RECs have experience navigating these sticking points.
- Physicians will likely never have another opportunity to receive federal funds that help pay for implementing an EHR. But the window is narrow; by 2015 the Medicare EHR incentive will be replaced with penalties.

Physicians will likely never have another opportunity to receive federal funds that help pay for implementing an EHR. But the window is narrow; by 2015 the Medicare EHR incentive will be replaced with penalties.

CHITREC can help you!

CHITREC offers free staff assistance as well as reimbursement for expenses incurred towards achieving "meaningful use." But federally funded slots are limited. Physicians are encouraged to contact CHITREC soon at ***http://chitrec.org/about/contact*** to see if they qualify.

(continues on page 6)

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About the Chicago Health IT Regional Extension Center (CHITREC)

CHITREC is the federally funded* local resource to help primary care providers achieve "meaningful use" of electronic health records. Based at Northwestern University, CHITREC represents a community partnership between Northwestern University, the Alliance of Chicago Community Health Services, and more than 40 local and national collaborators focused on health information technology adoption and use within the city of Chicago.

CHITREC is one of the only regional extension centers led by primary care physicians (internist and pediatrician) and can provide a range of practical services around EHR adoption. CHITREC can assist in selecting a vendor, educating staff, meaningful use training, privacy and security training, and quality measurement. Federal funding allows CHITREC staff to visit a practice and even offset a portion of a physician's costs associated with achieving meaningful use.

To learn more, please contact CHITREC: **www.chitrec.org**

**CHITREC is a federally designated Regional Extension Center funded by a cooperative agreement with the office of the national coordinator, Department of Health and Human Services.*

Learning to adapt to electronic health records: residency redux or pathway to improved effectiveness?

By Margaret Gadon, MD, MPH,
Clinical Director, Telligen

For the public, the big news in health these days is health reform and health care costs. But for many physicians in the front lines, the real story is electronic health records (EHRs).

The idea of EHRs evokes many questions for physicians, including, "Are they really necessary?" "Which vendor should be used?" "How can we fund EHRs?" "How will we learn to use them?" Financial incentives (or are they mandates?) from the federal government offer some promise for recouping the costs of implementation, but the questions, "What exactly is 'meaningful use,' and 'will we ever really receive any money anyway?'" still exist. These are legitimate questions for which medical professional societies, the federally funded Regional Extension Centers (CHITREC) and perhaps health systems are doing their best to provide answers.

Meanwhile, let's start with some basics that should provide concrete and understandable information that can make the path to the implementation of EHRs seem less arduous with the end result being worth the work.

Why is there such a push to move to EHRs from paper records?

There are a multitude of reasons, including improved quality of care and patient safety, improved coordination of care and ease of patient/physician communication.

Providers who have implemented EHRs have derived much value from them. They have experienced improved communication between primary care and specialist physicians and hospitalists and reductions in preventable medical errors. Also, they've seen an increasing number of patient transitions between sites of care and clinicians with the insertion of the hospitalist in many health care systems: these transitions are now impacting patient safety. The current health care system is complex and patients make a journey through this system as they receive their care. As physicians, we are part of a team and share in the responsibility for coordinating this care and ensuring, as much as possible, the safety and well being of those for whom we care. The EHR records this journey; it is our ally in preserving trust and developing strong relationships with our patients.

(continues on page 8)

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Why does it take so much more time and work to use electronic health records?

Like anything that's new to us, implementing an EHR certainly can seem time-consuming at the onset. However, the learning period depends on an individual's comfort level with computers and understanding and acceptance of the requisite changes in practice mandated by an EHR. If we use an EHR simply to type our notes and make no other changes, the EHR is likely to continue to take more time than paper charts. But, if we change the way the office is set up, the way patients move through the office, and the tasks of each staff member, we may be able to see patients more efficiently.

For example, another clinician can document the use of medications and screening tests or immunizations done outside the office and ensure that all data from a referral site is available when the physician enters the exam room. This way, providers can engage patients more easily by jointly viewing their information on the screen, in graphic form with average value comparisons to similar patients. This has been shown to help with treatment adherence and improved outcomes. Such practices also lead to improved physician performance. And with the trend toward increased payment for quality care, the EHR aligns directly with higher physician reimbursement.

What is meaningful use, what is the goal and what do I have to do to achieve this?

The simple answer to this question is that meaningful use is a strategy for encouraging **hospitals and clinicians to use a standard set of processes** that will allow for the creation of population health databases and health information sharing between sites of care. Managing a population's health begins at the practice level. By identifying communities and populations in need, EHRs give us the opportunity to make changes at the system or practice level to improve outcomes. At the state or federal level, health information technology ensures that public funds for health and health care funding are more effectively targeted to populations in need.

There is no doubt that for many physicians who have been in practice for more than 15 years, the transition to EHRs is an unwelcome challenge. Many physicians long for days when the pace of medicine was slower, patients stayed with their physicians for years, and patients were cared for in-hospital as well as in the office. With our technologically sophisticated imaging and communications, electronic recording and sharing of health information is the smart way to proceed. So, yes, it is a steep hill to climb; but the end result--for physicians and patients--is worth the trip.

Dr. Gadon is clinical director of Telligen and adjunct assistant professor in the Department of Medicine at the Feinberg School of Medicine, Northwestern University.

Telligen is a corporation that applies information to health care quality improvement and care management. It contracts with Medicare to provide services for the Illinois Quality Improvement Association.

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ADOPTING EHRS

HHS delays stage 2 meaningful use requirements

TO ENCOURAGE FASTER ADOPTION OF EHRS, the U.S. Department of Health and Human Services delayed the Stage 2 requirements for Medicare and Medicaid EHR Meaningful Use Incentive Programs until 2014.

Under the previous requirement, physicians who began participating in the Medicare EHR incentive program in 2011 would have to meet new standards in 2013, according to the Nov. 30 HHS announcement. If they began participation in 2012, they could wait until 2014 to meet these new standards and still qualify for the same incentive payment.

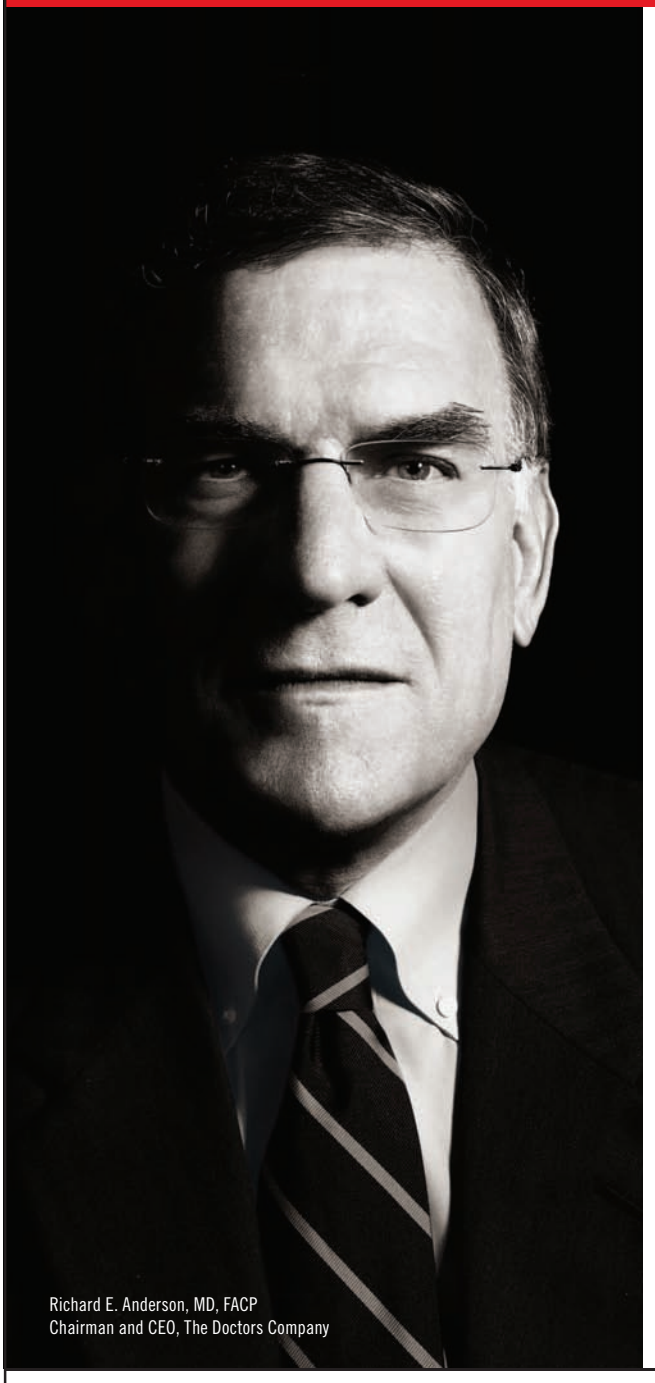
Physicians and hospitals who adopted the Stage 1 standards in 2011 may qualify for incentive payments in 2011 and 2012.. (Eligible physicians may receive as much as $44,000 under the Medicare incentive program, and $63,750 under the Medicaid program.)

While expressing support for the delay, the AMA encouraged HHS to continue evaluating Stage 1 and work on increasing the number of physicians participating in the programs before finalizing requirements for Stage 2.

A CDC survey found that 52% of office-based physicians in the U.S. plan to take advantage of the incentive payments available through Medicare and Medicaid EHR Incentive Programs.

The CDC data also show the percentage of physicians who have adopted basic EHRs in their practice has doubled from 17 to 34% between 2008 and 2011 (with the percent of primary care doctors using this technology nearly doubling from 20 to 39%).

Why choose between national resources and local clout?



Richard E. Anderson, MD, FACP
Chairman and CEO, The Doctors Company

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Medicare e-prescribing payment

STARTING WITH THE NEW YEAR, PAYMENT reductions set in for eligible physicians who have not become "successful" electronic prescribers in Medicare's eRx Incentive Program and have not applied for the hardship exemption. The 1% payment reduction is for Part B-covered professional services.

Eligible doctors and practices will see further reductions in 2013 (98.5%) and 2014 (2%) if they have not met the electronic prescribing requirement.

For additional information, please visit ***http://www.cms.gov/erxincentive***

Revised ABN form

The revised Advanced Beneficiary Notice (ABN) of Non-coverage goes into effect Jan. 1, 2012. The ABN, which is required whenever Medicare is expected to deny payment, is available for immediate use and can be accessed via the link below. Medicare will consider the old forms invalid.

For more information, and details on mandatory and voluntary use, go to ***http://www.cms.gov***

HIPAA 5010 standards compliance

Enforcement of the updated HIPAA 5010 electronic transmission standards begins March 31, 2012, according to the Centers for Medicare & Medicaid Services (CMS).

The Jan. 1 compliance date remains in effect, however.

Nonetheless, the federal agency encourages physicians to continue their version 5010 implementation programs as planned.

CMS announced the delay in enforcement after determining that some covered entities and their trading partners will not be compliant by Jan. 1. Many are still awaiting software upgrades, according to CMS.

The following organizations offer resources to help with the 5010 transition and future ICD-10 adoption.

Centers for Medicare and Medicaid Services
Electronic Billing & EDI Transactions

Illinois Department of Healthcare and Family Services

Companion Guide Updates for HIPAA 5010 - Transactions

CDC's National Center for Health Statistics

ICD-10-CM Guidelines, List of Codes & Descriptions, and General Equivalency Mappings

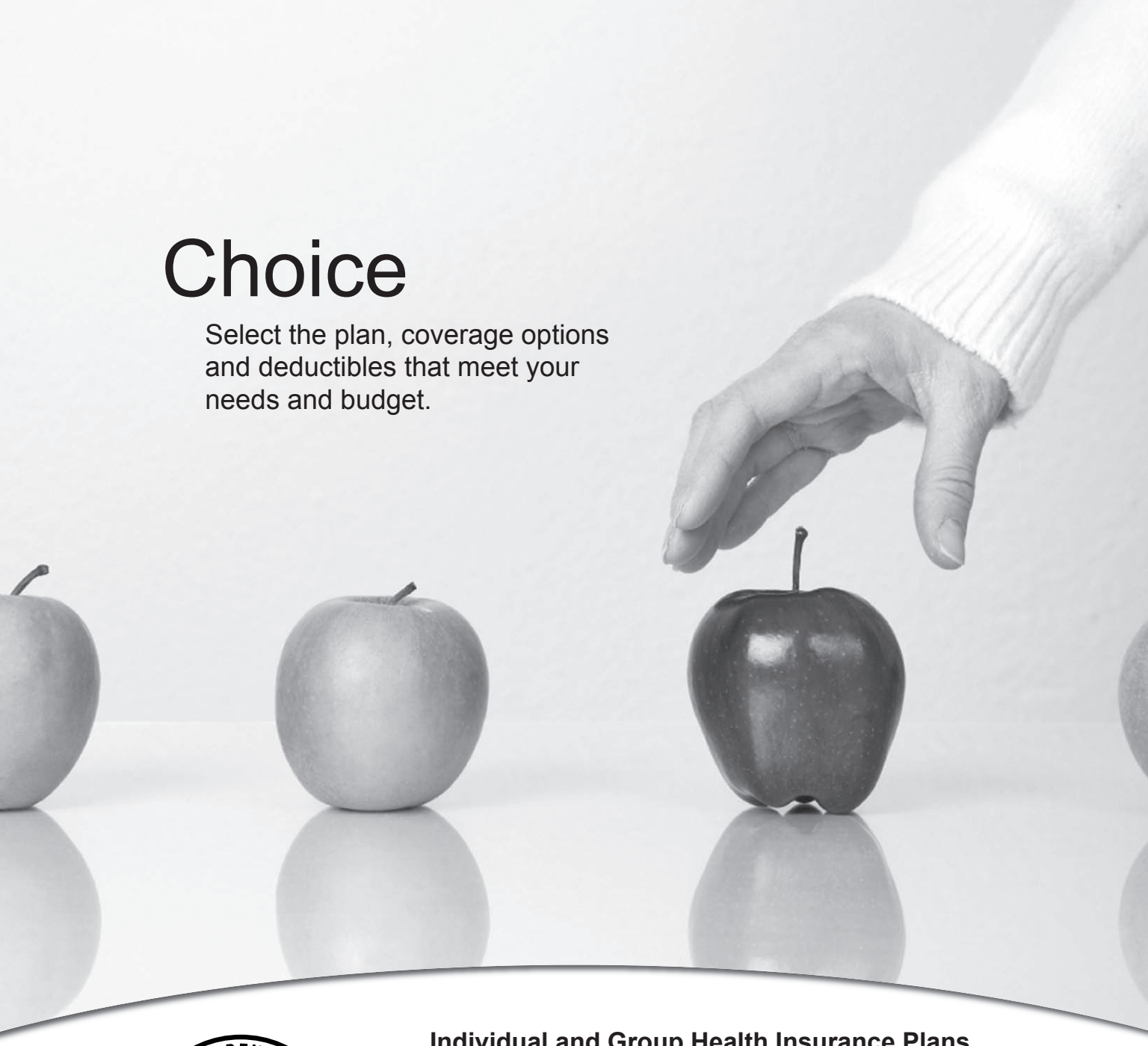
Insurance coding exchange to benefit members

AT MEMBERS' BEHEST, CMS IS BUILDING A service to help the medical team avoid coding pitfalls that can end up costing time and money.

With the redesign of the Society's website, members can soon access a password-protected coding exchange to share their coding experiences and suggestions. A medical billing company will answer specific questions about the utilization and interpretation of various medical codes.

Featuring a forum area and blog for posting coding updates, the new section will help small groups and solo practices that lack the resources to implement coding costly updates. CMS will routinely circulate or email blast updates by specialty as they become available

According to members who advocated for this benefit, medical coding is increasingly complex and each insurance company interprets codes differently. Mistakes can lead to audits and fines, along with demands for recoupment. Insurance companies have stepped up their audits and penalties on physicians.



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The service helps iron out problems with government agencies (Medicaid and Medicare), private insurers, HMOs, PPOs, IPAs, etc.

Physicians will need to complete the ISMS Hassle Factor Log to facilitate the tracking, monitoring and resolving of issues presented. Data provided may be shared with specific payers, state agencies or internal ISMS councils in order to address, track, and resolve problems. Upon submission of this data, ISMS advocacy staff will contact the physician to discuss his or her concern.

CMS/ISMS members can also request to have an ISMS Hassle Factor Log sent to them via fax or mail.

For information, please contact the ISMS Division of Member Advocacy (800) 782-ISMS; or e-mail: advocacy@isms.org.

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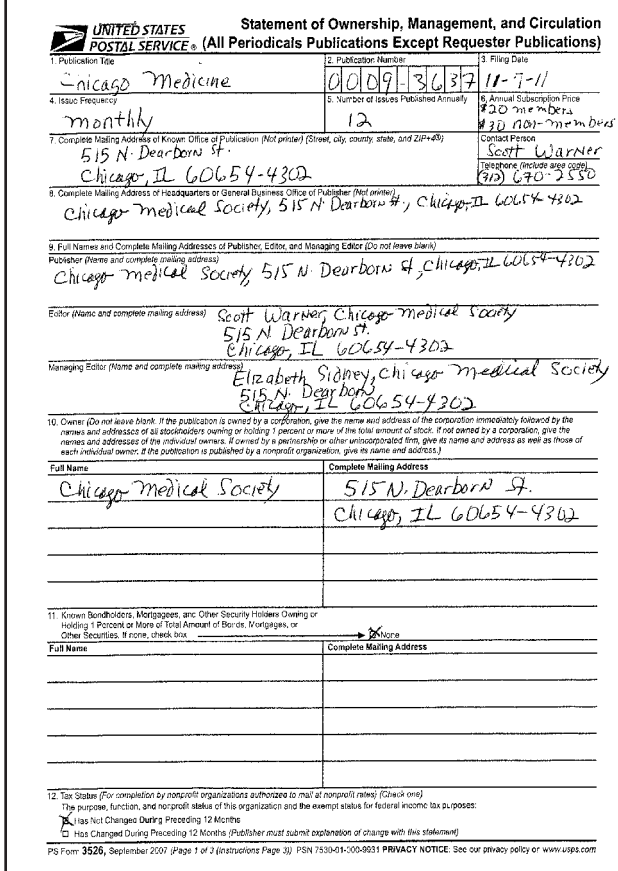

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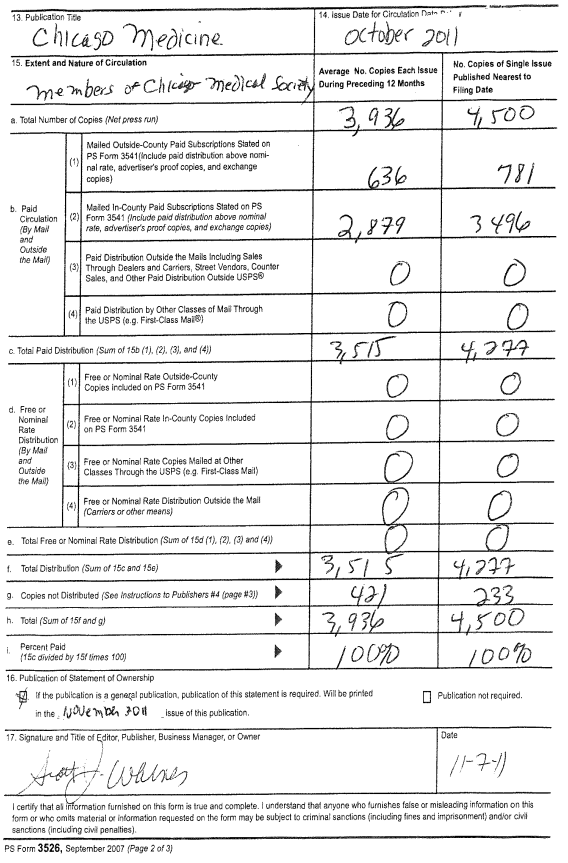

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PS Form **3526**, September 2007 (Page 2 of 3)

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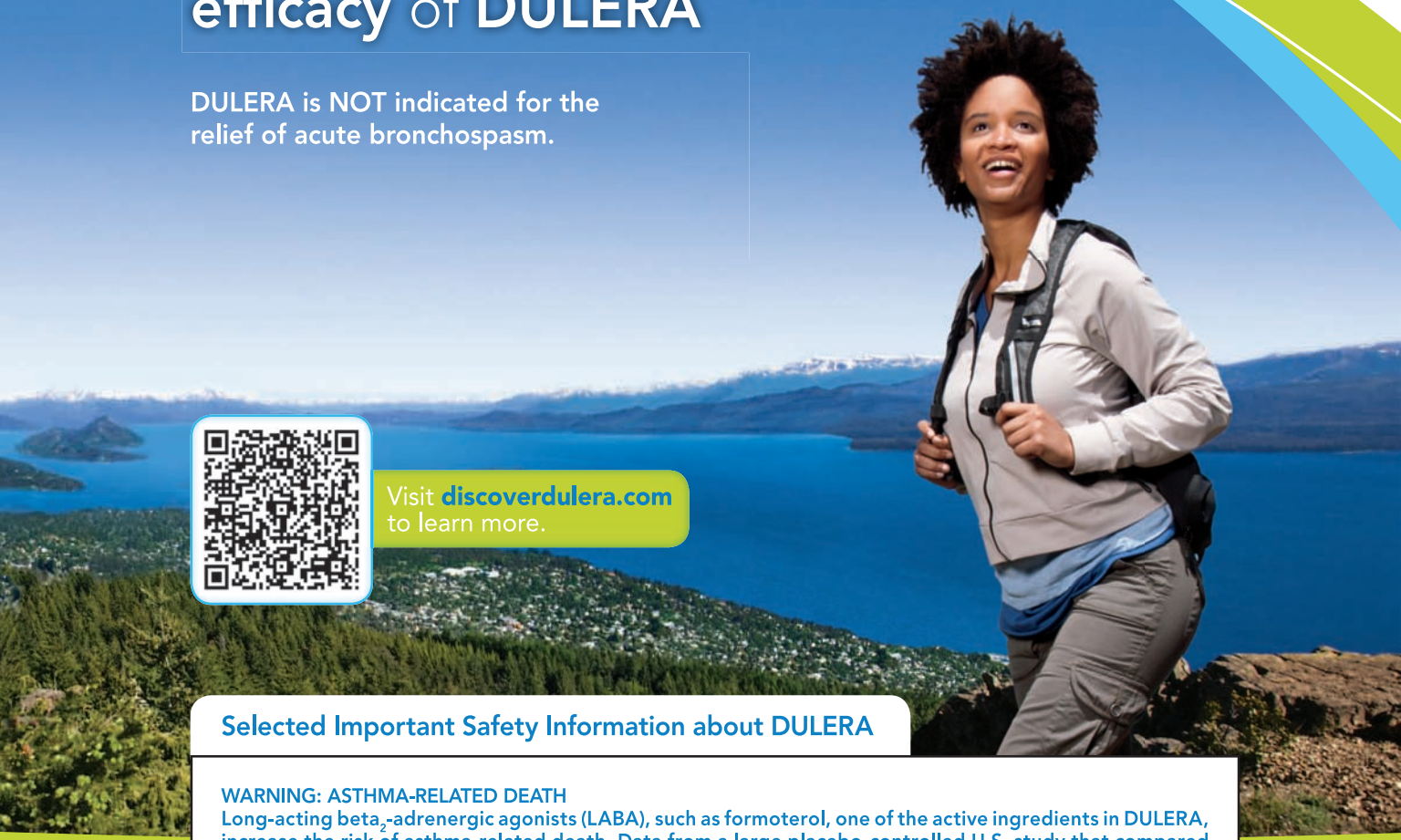

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BRIEF SUMMARY (For full Prescribing Information, see package insert.)

WARNING: ASTHMA-RELATED DEATH

Long-acting beta$_2$-adrenergic agonists (LABA), such as formoterol, one of the active ingredients in DULERA, increase the risk of asthma-related death. Data from a large placebo-controlled U.S. study that compared the safety of another long-acting beta$_2$-adrenergic agonist (salmeterol) or placebo added to usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol. This finding with salmeterol is considered a class effect of the LABA, including formoterol. Currently available data are inadequate to determine whether concurrent use of inhaled corticosteroids or other long-term asthma control drugs mitigates the increased risk of asthma-related death from LABA. Available data from controlled clinical trials suggest that LABA increase the risk of asthma-related hospitalization in pediatric and adolescent patients. Therefore, when treating patients with asthma, DULERA should only be used for patients not adequately controlled on a long-term asthma control medication, such as an inhaled corticosteroid or whose disease severity clearly warrants initiation of treatment with both an inhaled corticosteroid and LABA. Once asthma control is achieved and maintained, assess the patient at regular intervals and step down therapy (e.g., discontinue DULERA) if possible without loss of asthma control, and maintain the patient on a long-term asthma control medication, such as an inhaled corticosteroid. Do not use DULERA for patients whose asthma is adequately controlled on low or medium dose inhaled corticosteroids. ***[See Warnings and Precautions (5.1)]***

1 INDICATIONS AND USAGE

1.1 Treatment of Asthma

DULERA is indicated for the treatment of asthma in patients 12 years of age and older.

Long-acting beta$_2$-adrenergic agonists, such as formoterol, one of the active ingredients in DULERA, increase the risk of asthma-related death. Available data from controlled clinical trials suggest that LABA increase the risk of asthma-related hospitalization in pediatric and adolescent patients *[see Warnings and Precautions (5.1)]*. Therefore, when treating patients with asthma, DULERA should only be used for patients not adequately controlled on a long-term asthma control medication, such as an inhaled corticosteroid or whose disease severity clearly warrants initiation of treatment with both an inhaled corticosteroid and LABA. Once asthma control is achieved and maintained, assess the patient at regular intervals and step down therapy (e.g., discontinue DULERA) if possible without loss of asthma control, and maintain the patient on a long-term asthma control medication, such as an inhaled corticosteroid. Do not use DULERA for patients whose asthma is adequately controlled on low or medium dose inhaled corticosteroids.

Important Limitation of Use

- DULERA is NOT indicated for the relief of acute bronchospasm.

4 CONTRAINDICATIONS

4.1 Status Asthmaticus

DULERA is contraindicated in the primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required.

4.2 Hypersensitivity

DULERA is contraindicated in patients with known hypersensitivity to mometasone furoate, formoterol fumarate, or any of the ingredients in DULERA *[see Warnings and Precautions (5.10)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Asthma-Related Death

Long-acting beta$_2$-adrenergic agonists, such as formoterol, one of the active ingredients in DULERA, increase the risk of asthma-related death. Currently available data are inadequate to determine whether concurrent use of inhaled corticosteroids or other long-term asthma control drugs mitigates the increased risk of asthma-related death from LABA. Available data from controlled clinical trials suggest that LABA increase the risk of asthma-related hospitalization in pediatric and adolescent patients. Therefore, when treating patients with asthma, physicians should only prescribe DULERA for patients with asthma not adequately controlled on a long-term asthma control medication, such as an inhaled corticosteroid or whose disease severity clearly warrants initiation of treatment with both an inhaled corticosteroid and LABA. Once asthma control is achieved and maintained, assess the patient at regular intervals and step down therapy (e.g., discontinue DULERA) if possible without loss of asthma control, and maintain the patient on a long-term asthma control medication, such as an inhaled corticosteroid. Do not use DULERA for patients whose asthma is adequately controlled on low or medium dose inhaled corticosteroids.

A 28-week, placebo-controlled US study comparing the safety of salmeterol with placebo, each added to usual asthma therapy, showed an increase in asthma-related deaths in patients receiving salmeterol (13/13,176 in patients treated with salmeterol vs. 3/13,179 in patients treated with placebo; RR 4.37, 95% CI 1.25, 15.34). This finding with salmeterol is considered a class effect of the LABAs, including formoterol, one of the active ingredients in DULERA. No study adequate to determine whether the rate of asthma-related death is increased with DULERA has been conducted.

Clinical studies with formoterol suggested a higher incidence of serious asthma exacerbations in patients who received formoterol fumarate than in those who received placebo. The sizes of these studies were not adequate to precisely quantify the differences in serious asthma exacerbation rates between treatment groups.

5.2 Deterioration of Disease and Acute Episodes

DULERA should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of asthma. DULERA has not been studied in patients with acutely deteriorating asthma. The initiation of DULERA in this setting is not appropriate.

Increasing use of inhaled, short-acting beta$_2$-agonists is a marker of deteriorating asthma. In this situation, the patient requires immediate re-evaluation with reassessment of the treatment regimen, giving special consideration to the possible need for replacing the current strength of DULERA with a higher strength, adding additional inhaled corticosteroid, or initiating systemic corticosteroids. Patients should not use more than 2 inhalations twice daily (morning and evening) of DULERA.

DULERA is not indicated for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. An inhaled, short-acting beta$_2$-agonist, not DULERA, should be used to relieve acute symptoms such as shortness of breath. When prescribing DULERA, the physician must also provide the patient with an inhaled, short-acting beta$_2$-agonist (e.g., albuterol) for treatment of acute symptoms, despite regular twice-daily (morning and evening) use of DULERA.

When beginning treatment with DULERA, patients who have been taking oral or inhaled, short-acting beta$_2$-agonists on a regular basis (e.g., 4 times a day) should be instructed to discontinue the regular use of these drugs.

5.3 Excessive Use of DULERA and Use with Other Long-Acting Beta$_2$-Agonists

As with other inhaled drugs containing beta$_2$-adrenergic agents, DULERA should not be used more often than recommended, at higher doses than recommended, or in conjunction with other medications containing long-acting beta$_2$-agonists, as an overdose may result. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. Patients using DULERA should not use an additional long-acting beta$_2$-agonist (e.g., salmeterol, formoterol fumarate, arformoterol tartrate) for any reason, including prevention of exercise-induced bronchospasm (EIB) or the treatment of asthma.

5.4 Local Effects

In clinical trials, the development of localized infections of the mouth and pharynx with *Candida albicans* have occurred in patients treated with DULERA. If oropharyngeal candidiasis develops, it should be treated with appropriate local or systemic (i.e., oral) antifungal therapy while remaining on treatment with DULERA therapy, but at times therapy with DULERA may need to be interrupted. Advise patients to rinse the mouth after inhalation of DULERA.

5.5 Immunosuppression

Persons who are using drugs that suppress the immune system are more susceptible to infections than healthy individuals.

Chickenpox and measles, for example, can have a more serious or even fatal course in susceptible children or adults using corticosteroids. In such children or adults who have not had these diseases or who are not properly immunized, particular care should be taken to avoid exposure. How the dose, route, and duration of corticosteroid administration affect the risk of developing a disseminated infection is not known. The contribution of the underlying disease and/or prior corticosteroid treatment to the risk is also not known. If exposed to chickenpox, prophylaxis with varicella zoster immune globulin (VZIG) or pooled intravenous immunoglobulin (IVIG) may be indicated. If exposed to measles, prophylaxis with pooled intramuscular immunoglobulin (IG) may be indicated. (See the respective package inserts for complete VZIG and IG prescribing information.) If chickenpox develops, treatment with antiviral agents may be considered.

DULERA should be used with caution, if at all, in patients with active or quiescent tuberculosis infection of the respiratory tract, untreated systemic fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex.

5.6 Transferring Patients from Systemic Corticosteroid Therapy

Particular care is needed for patients who are transferred from systemically active corticosteroids to DULERA because deaths due to adrenal insufficiency have occurred in asthmatic patients during and after transfer from systemic corticosteroids to less systemically available inhaled corticosteroids. After withdrawal from systemic corticosteroids, a number of months are required for recovery of hypothalamic-pituitary-adrenal (HPA) function.

Patients who have been previously maintained on 20 mg or more per day of prednisone (or its equivalent) may be most susceptible, particularly when their systemic corticosteroids have been almost completely withdrawn. During this period of HPA suppression, patients may exhibit signs and symptoms of adrenal insufficiency when exposed to trauma, surgery, or infection (particularly gastroenteritis) or other conditions associated with severe electrolyte loss. Although DULERA may improve control of asthma symptoms during these episodes, in

recommended doses it supplies less than normal physiological amounts of corticosteroid systemically and does NOT provide the mineralocorticoid activity necessary for coping with these emergencies.

During periods of stress or severe asthma attack, patients who have been withdrawn from systemic corticosteroids should be instructed to resume oral corticosteroids (in large doses) immediately and to contact their physicians for further instruction. These patients should also be instructed to carry a medical identification card indicating that they may need supplementary systemic corticosteroids during periods of stress or severe asthma attack.

Patients requiring systemic corticosteroids should be weaned slowly from systemic corticosteroid use after transferring to DULERA. Lung function (FEV_1 or PEF), beta-agonist use, and asthma symptoms should be carefully monitored during withdrawal of systemic corticosteroids. In addition to monitoring asthma signs and symptoms, patients should be observed for signs and symptoms of adrenal insufficiency such as fatigue, lassitude, weakness, nausea and vomiting, and hypotension.

Transfer of patients from systemic corticosteroid therapy to DULERA may unmask allergic conditions previously suppressed by the systemic corticosteroid therapy, e.g., rhinitis, conjunctivitis, eczema, arthritis, and eosinophilic conditions.

During withdrawal from oral corticosteroids, some patients may experience symptoms of systemically active corticosteroid withdrawal, e.g., joint and/or muscular pain, lassitude, and depression, despite maintenance or even improvement of respiratory function.

5.7 Hypercorticism and Adrenal Suppression

Mometasone furoate, a component of DULERA, will often help control asthma symptoms with less suppression of HPA function than therapeutically equivalent oral doses of prednisone. Since mometasone furoate is absorbed into the circulation and can be systemically active at higher doses, the beneficial effects of DULERA in minimizing HPA dysfunction may be expected only when recommended dosages are not exceeded and individual patients are titrated to the lowest effective dose.

Because of the possibility of systemic absorption of inhaled corticosteroids, patients treated with DULERA should be observed carefully for any evidence of systemic corticosteroid effects. Particular care should be taken in observing patients postoperatively or during periods of stress for evidence of inadequate adrenal response.

It is possible that systemic corticosteroid effects such as hypercorticism and adrenal suppression (including adrenal crisis) may appear in a small number of patients, particularly when mometasone furoate is administered at higher than recommended doses over prolonged periods of time. If such effects occur, the dosage of DULERA should be reduced slowly, consistent with accepted procedures for reducing systemic corticosteroids and for management of asthma symptoms.

5.8 Drug Interactions with Strong Cytochrome P450 3A4 Inhibitors

Caution should be exercised when considering the coadministration of DULERA with ketoconazole, and other known strong CYP3A4 inhibitors (e.g., ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, saquinavir, telithromycin) because adverse effects related to increased systemic exposure to mometasone furoate may occur *[see Drug Interactions (7.1) and Clinical Pharmacology (12.3)]*.

5.9 Paradoxical Bronchospasm and Upper Airway Symptoms

DULERA may produce inhalation induced bronchospasm with an immediate increase in wheezing after dosing that may be life-threatening. If inhalation induced bronchospasm occurs, it should be treated immediately with an inhaled, short-acting inhaled bronchodilator. DULERA should be discontinued immediately and alternative therapy instituted.

5.10 Immediate Hypersensitivity Reactions

Immediate hypersensitivity reactions may occur after administration of DULERA, as demonstrated by cases of urticaria, flushing, allergic dermatitis, and bronchospasm.

5.11 Cardiovascular and Central Nervous System Effects

Excessive beta-adrenergic stimulation has been associated with seizures, angina, hypertension or hypotension, tachycardia with rates up to 200 beats/min, arrhythmias, nervousness, headache, tremor, palpitation, nausea, dizziness, fatigue, malaise, and insomnia. Therefore, DULERA should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

Formoterol fumarate, a component of DULERA, can produce a clinically significant cardiovascular effect in some patients as measured by pulse rate, blood pressure, and/or symptoms. Although such effects are uncommon after administration of DULERA at recommended doses, if they occur, the drug may need to be discontinued. In addition, beta-agonists have been reported to produce ECG changes, such as flattening of the T wave, prolongation of the QTc interval, and ST segment depression. The clinical significance of these findings is unknown. Fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs.

5.12 Reduction in Bone Mineral Density

Decreases in bone mineral density (BMD) have been observed with long-term administration of products containing inhaled corticosteroids, including mometasone furoate, one of the components of DULERA. The clinical significance of small changes in BMD with regard to long-term outcomes, such as fracture, is unknown. Patients with major risk factors for decreased bone mineral content, such as prolonged immobilization, family history of osteoporosis, or chronic use of drugs that can reduce bone mass (e.g., anticonvulsants and corticosteroids) should be monitored and treated with established standards of care.

In a 2-year double-blind study in 103 male and female asthma patients 18 to 50 years of age previously maintained on bronchodilator therapy (Baseline FEV_1 85%-88% predicted), treatment with mometasone furoate dry powder inhaler 200 mcg twice daily resulted in significant reductions in lumbar spine (LS) BMD at the end of the treatment period compared to placebo. The mean change from Baseline to Endpoint in the lumbar spine BMD was -0.015 (-1.43%) for the mometasone furoate group compared to 0.002 (0.25%) for the placebo group. In another 2-year double-blind study in 87 male and female asthma patients 18 to 50 years of age previously maintained on bronchodilator therapy (Baseline FEV_1 82%-83% predicted), treatment with mometasone furoate 400 mcg twice daily demonstrated no statistically significant changes in lumbar spine BMD at the end of the treatment period compared to placebo. The mean change from Baseline to Endpoint in the lumbar spine BMD was -0.018 (-1.57%) for the mometasone furoate group compared to -0.006 (-0.43%) for the placebo group.

5.13 Effect on Growth

Orally inhaled corticosteroids, including DULERA, may cause a reduction in growth velocity when administered to pediatric patients. Monitor the growth of pediatric patients receiving DULERA routinely (e.g., via stadiometry). To minimize the systemic effects of orally inhaled corticosteroids, including DULERA, titrate each patient's dose to the lowest dosage that effectively controls his/her symptoms *[see Use in Specific Populations (8.4)]*.

5.14 Glaucoma and Cataracts

Glaucoma, increased intraocular pressure, and cataracts have been reported following the use of long-term administration of inhaled corticosteroids, including mometasone furoate, a component of DULERA. Therefore, close monitoring is warranted in patients with a change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts *[see Adverse Reactions (6)]*.

5.15 Coexisting Conditions

DULERA, like other medications containing sympathomimetic amines, should be used with caution in patients with convulsive disorders or thyrotoxicosis; and in patients who are unusually responsive to sympathomimetic amines. Doses of the related $beta_2$-agonist albuterol, when administered intravenously, have been reported to aggravate preexisting diabetes mellitus and ketoacidosis.

5.16 Hypokalemia and Hyperglycemia

$Beta_2$-agonist medications may produce significant hypokalemia in some patients, possibly through intracellular shunting, which has the potential to produce adverse cardiovascular effects. The decrease in serum potassium is usually transient, not requiring supplementation. Clinically significant changes in blood glucose and/or serum potassium were seen infrequently during clinical studies with DULERA at recommended doses.

6 ADVERSE REACTIONS

Long-acting $beta_2$-adrenergic agonists, such as formoterol, one of the active ingredients in DULERA, increase the risk of asthma-related death. Currently available data are inadequate to determine whether concurrent use of inhaled corticosteroids or other long-term asthma control drugs mitigates the increased risk of asthma-related death from LABA. Available data from controlled clinical trials suggest that LABA increase the risk of asthma-related hospitalization in pediatric and adolescent patients. Data from a large placebo-controlled US trial that compared the safety of another long-acting $beta_2$-adrenergic agonist (salmeterol) or placebo added to usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol *[see Warnings and Precautions (5.1)]*.

Systemic and local corticosteroid use may result in the following:

- *Candida albicans* infection *[see Warnings and Precautions (5.4)]*
- Immunosuppression *[see Warnings and Precautions (5.5)]*
- Hypercorticism and adrenal suppression *[see Warnings and Precautions (5.7)]*
- Growth effects in pediatrics *[see Warnings and Precautions (5.13)]*
- Glaucoma and cataracts *[see Warnings and Precautions (5.14)]*

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

6.1 Clinical Trials Experience

The safety data described below is based on 3 clinical trials which randomized 1913 patients 12 years of age and older with asthma, including 679 patients exposed to DULERA for 12 to 26 weeks and 271 patients exposed for 1 year. DULERA was studied in two placebo- and active-controlled trials (n=781 and n=728, respectively) and in a long term 52-week safety trial (n=404). In the 12 to 26-week clinical trials, the population was 12 to 84 years of age, 41% male and 59% female, 73% Caucasians, 27% non-Caucasians. Patients received two inhalations twice daily of DULERA (100 mcg/5 mcg or 200 mcg/5 mcg), mometasone furoate MDI (100 mcg or 200 mcg), formoterol MDI (5 mcg) or placebo. In the long term 52-week active-comparator safety trial, the population was 12 years to 75 years of age with asthma, 37% male and 63% female, 47% Caucasians, 53% non-Caucasians and received two inhalations twice daily of DULERA 100 mcg/5 mcg or 200 mcg/5 mcg, or an active comparator.

The incidence of treatment emergent adverse reactions associated with DULERA in Table 2 below is based upon pooled data from 2 clinical trials 12 to 26-week in duration in patients 12 years and older treated with two inhalations twice daily of DULERA (100 mcg/5 mcg or 200 mcg/5 mcg), mometasone furoate MDI (100 mcg or 200 mcg), formoterol MDI (5mcg) or placebo.

Table 2: Treatment-emergent adverse reactions in DULERA groups occurring at an incidence of ≥3% and more commonly than placebo

Adverse Reactions	DULERA*		Mometasone Furoate*		Formoterol*	Placebo*
	100 mcg/ 5 mcg n=424 n (%)	200 mcg/ 5 mcg n=255 n (%)	100 mcg n=192 n (%)	200 mcg n=240 n (%)	5 mcg n=202 n (%)	n=196 n (%)
Nasopharyngitis	20 (4.7)	12 (4.7)	15 (7.8)	13 (5.4)	13 (6.4)	7 (3.6)
Sinusitis	14 (3.3)	5 (2.0)	6 (3.1)	4 (1.7)	7 (3.5)	2 (1.0)
Headache	19 (4.5)	5 (2.0)	10 (5.2)	8 (3.3)	6 (3.0)	7 (3.6)
Average Duration of Exposure (days)	116	81	165	79	131	138

*All treatments were administered as two inhalations twice daily.

Oral candidiasis has been reported in clinical trials at an incidence of 0.7% in patients using DULERA 100 mcg/5 mcg, 0.8 % in patients using DULERA 200 mcg/5 mcg and 0.5 % in the placebo group.

Long Term Clinical Trial Experience

In a long term safety trial in patients 12 years and older treated for 52 weeks with DULERA 100 mcg/5 mcg (n=141), DULERA 200 mcg/5 mcg (n=130) or an active comparator (n=133), safety outcomes in general were similar to those observed in the shorter 12 to 26 week controlled trials. No asthma-related deaths were observed. Dysphonia was observed at a higher frequency in the longer term treatment trial at a reported incidence of 7/141 (5%) patients receiving DULERA 100 mcg/5 mcg and 5/130 (3.8%) patients receiving DULERA 200 mcg/5 mcg. No clinically significant changes in blood chemistry, hematology, or ECG were observed.

7 DRUG INTERACTIONS

In clinical trials, concurrent administration of DULERA and other drugs, such as short-acting beta$_2$-agonist and intranasal corticosteroids have not resulted in an increased frequency of adverse drug reactions. No formal drug interaction studies have been performed with DULERA. The drug interactions of the combination are expected to reflect those of the individual components.

7.1 Inhibitors of Cytochrome P450 3A4

The main route of metabolism of corticosteroids, including mometasone furoate, a component of DULERA, is via cytochrome P450 (CYP) isoenzyme 3A4 (CYP3A4). After oral administration of ketoconazole, a strong inhibitor of CYP3A4, the mean plasma concentration of orally inhaled mometasone furoate increased. Concomitant administration of CYP3A4 inhibitors may inhibit the metabolism of, and increase the systemic exposure to, mometasone furoate. Caution should be exercised when considering the coadministration of DULERA with long-term ketoconazole and other known strong CYP3A4 inhibitors (e.g., ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, saquinavir, telithromycin) *[see Warnings and Precautions (5.8) and Clinical Pharmacology (12.3)]*.

7.2 Adrenergic agents

If additional adrenergic drugs are to be administered by any route, they should be used with caution because the pharmacologically predictable sympathetic effects of formoterol, a component of DULERA, may be potentiated.

7.3 Xanthine derivatives

Concomitant treatment with xanthine derivatives may potentiate any hypokalemic effect of formoterol, a component of DULERA.

7.4 Diuretics

Concomitant treatment with diuretics may potentiate the possible hypokalemic effect of adrenergic agonists. The ECG changes and/or hypokalemia that may result from the administration of non-potassium sparing diuretics (such as loop or thiazide diuretics) can be acutely worsened by beta-agonists, especially when the recommended dose of the beta-agonist is exceeded. Although the clinical significance of these effects is not known, caution is advised in the coadministration of DULERA with non-potassium sparing diuretics.

7.5 Monoamine oxidase inhibitors, tricyclic antidepressants, and drugs known to prolong the QTc interval

DULERA should be administered with caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known to prolong the QTc interval or within 2 weeks of discontinuation of such agents, because the action of formoterol, a component of DULERA, on the cardiovascular system may be potentiated by these agents. Drugs that are known to prolong the QTc interval have an increased risk of ventricular arrhythmias.

7.6 Beta-adrenergic receptor antagonists

Beta-adrenergic receptor antagonists (beta-blockers) and formoterol may inhibit the effect of each other when administered concurrently. Beta-blockers not only block the therapeutic effects of beta$_2$-agonists, such as formoterol, a component of DULERA, but may produce severe bronchospasm in patients with asthma. Therefore, patients with asthma should not normally be treated with beta-blockers. However, under certain circumstances, e.g., as prophylaxis after myocardial infarction, there may be no acceptable alternatives to the use of beta-blockers in patients with asthma. In this setting, cardioselective beta-blockers could be considered, although they should be administered with caution.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

DULERA: Teratogenic Effects: Pregnancy Category C

There are no adequate and well-controlled studies of DULERA, mometasone furoate only or formoterol fumarate only in pregnant women. Animal reproduction studies of mometasone furoate and formoterol in mice, rats, and/or rabbits revealed evidence of teratogenicity as well as other developmental toxic effects. Because animal reproduction studies are not always predictive of human response, DULERA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Mometasone Furoate: Teratogenic Effects

When administered to pregnant mice, rats, and rabbits, mometasone furoate increased fetal malformations and decreased fetal growth (measured by lower fetal weights and/or delayed ossification). Dystocia and related complications were also observed when mometasone furoate was administered to rats late in gestation. However, experience with oral corticosteroids suggests that rodents are more prone to teratogenic effects from corticosteroid exposure than humans.

In a mouse reproduction study, subcutaneous mometasone furoate produced cleft palate at approximately one-third of the maximum recommended daily human dose (MRHD) on a mcg/m^2 basis and decreased fetal survival at approximately 1 time the MRHD. No toxicity was observed at approximately one-tenth of the MRHD on a mcg/m^2 basis.

In a rat reproduction study, mometasone furoate produced umbilical hernia at topical dermal doses approximately 6 times the MRHD on a mcg/m^2 basis and delays in ossification at approximately 3 times the MRHD on a mcg/m^2 basis.

In another study, rats received subcutaneous doses of mometasone furoate throughout pregnancy or late in gestation. Treated animals had prolonged and difficult labor, fewer live births, lower birth weight, and reduced early pup survival at a dose that was approximately 8 times the MRHD on an area under the curve (AUC) basis. Similar effects were not observed at approximately 4 times MRHD on an AUC basis.

In rabbits, mometasone furoate caused multiple malformations (e.g., flexed front paws, gallbladder agenesis, umbilical hernia, hydrocephaly) at topical dermal doses approximately 3 times the MRHD on a mcg/m^2 basis. In an oral study, mometasone furoate increased resorptions and caused cleft palate and/or head malformations (hydrocephaly and domed head) at a dose less than the MRHD based on AUC. At a dose approximately 2 times the MRHD based on AUC, most litters were aborted or resorbed *[see Nonclinical Toxicology (13.2)]*.

Nonteratogenic Effects:

Hypoadrenalism may occur in infants born to women receiving corticosteroids during pregnancy. Infants born to mothers taking substantial corticosteroid doses during pregnancy should be monitored for signs of hypoadrenalism.

Formoterol Fumarate: Teratogenic Effects

Formoterol fumarate administered throughout organogenesis did not cause malformations in rats or rabbits following oral administration. When given to rats throughout organogenesis, oral doses of approximately 80 times the MRHD on a mcg/m^2 basis and above delayed ossification of the fetus, and doses of approximately 2,400 times the MRHD on a mcg/m^2 basis and above decreased fetal weight. Formoterol fumarate has been shown to cause stillbirth and neonatal mortality at oral doses of approximately 2,400 times the MRHD on a mcg/m^2 basis and above in rats receiving the drug during the late stage of pregnancy. These effects, however, were not produced at a dose of approximately 80 times the MRHD on a mcg/m^2 basis.

In another testing laboratory, formoterol was shown to be teratogenic in rats and rabbits. Umbilical hernia, a malformation, was observed in rat fetuses at oral doses approximately 1,200 times and greater than the MRHD on a mcg/m^2 basis. Brachygnathia, a skeletal malformation, was observed in rat fetuses at an oral dose approximately 6,100 times the MRHD on a mcg/m^2 basis. In another study in rats, no teratogenic effects were seen at inhalation doses up to approximately 500 times the MRHD on a mcg/m^2 basis. Subcapsular cysts on the liver were observed in rabbit fetuses at an oral dose approximately 49,000 times the MRHD on a mcg/m^2 basis. No teratogenic effects were observed at oral doses up to approximately 3,000 times the MRHD on a mcg/m^2 basis *[see Nonclinical Toxicology (13.2)]*.

8.2 Labor and Delivery

There are no adequate and well-controlled human studies that have studied the effects of DULERA during labor and delivery.

Because beta-agonists may potentially interfere with uterine contractility, DULERA should be used during labor only if the potential benefit justifies the potential risk *[see Nonclinical Toxicology (13.2)]*.

8.3 Nursing Mothers

DULERA: It is not known whether DULERA is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when DULERA is administered to a nursing woman.

Since there are no data from well-controlled human studies on the use of DULERA on nursing mothers, based on data for the individual components, a decision should be made whether to discontinue nursing or to discontinue DULERA, taking into account the importance of DULERA to the mother.

Mometasone Furoate: It is not known if mometasone furoate is excreted in human milk. However, other corticosteroids are excreted in human milk.

Formoterol Fumarate: In reproductive studies in rats, formoterol was excreted in the milk. It is not known whether formoterol is excreted in human milk.

8.4 Pediatric Use

The safety and effectiveness of DULERA have been established in patients 12 years of age and older in 3 clinical trials up to 52 weeks in duration. In the 3 clinical trials, 101 patients 12 to 17 years of age were treated with DULERA. Patients in this age-group demonstrated efficacy results similar to those observed in patients 18 years of age and older. There were no obvious differences in the type or frequency of adverse drug reactions reported in this age group compared to patients 18 years of age and older. Similar efficacy and safety results were

observed in an additional 22 patients 12 to 17 years of age who were treated with DULERA in another clinical trial. The safety and efficacy of DULERA have not been established in children less than 12 years of age.

Controlled clinical studies have shown that inhaled corticosteroids may cause a reduction in growth velocity in pediatric patients. In these studies, the mean reduction in growth velocity was approximately 1 cm per year (range 0.3 to 1.8 per year) and appears to depend upon dose and duration of exposure. This effect was observed in the absence of laboratory evidence of hypothalamic-pituitary-adrenal (HPA) axis suppression, suggesting that growth velocity is a more sensitive indicator of systemic corticosteroid exposure in pediatric patients than some commonly used tests of HPA axis function. The long-term effects of this reduction in growth velocity associated with orally inhaled corticosteroids, including the impact on final adult height, are unknown. The potential for "catch up" growth following discontinuation of treatment with orally inhaled corticosteroids has not been adequately studied.

The growth of children and adolescents receiving orally inhaled corticosteroids, including DULERA, should be monitored routinely (e.g., via stadiometry). If a child or adolescent on any corticosteroid appears to have growth suppression, the possibility that he/she is particularly sensitive to this effect should be considered. The potential growth effects of prolonged treatment should be weighed against clinical benefits obtained and the risks associated with alternative therapies. To minimize the systemic effects of orally inhaled corticosteroids, including DULERA, each patient should be titrated to his/her lowest effective dose *[see Dosage and Administration (2.2)]*.

8.5 Geriatric Use

A total of 77 patients 65 years of age and older (of which 11 were 75 years and older) have been treated with DULERA in 3 clinical trials up to 52 weeks in duration. Similar efficacy and safety results were observed in an additional 28 patients 65 years of age and older who were treated with DULERA in another clinical trial. No overall differences in safety or effectiveness were observed between these patients and younger patients, but greater sensitivity of some older individuals cannot be ruled out. As with other products containing $beta_2$-agonists, special caution should be observed when using DULERA in geriatric patients who have concomitant cardiovascular disease that could be adversely affected by $beta_2$-agonists. Based on available data for DULERA or its active components, no adjustment of dosage of DULERA in geriatric patients is warranted.

8.6 Hepatic Impairment

Concentrations of mometasone furoate appear to increase with severity of hepatic impairment *[see Clinical Pharmacology (12.3)]*.

10 OVERDOSAGE

10.1 Signs and Symptoms

DULERA: DULERA contains both mometasone furoate and formoterol fumarate; therefore, the risks associated with overdosage for the individual components described below apply to DULERA.

Mometasone Furoate: Chronic overdosage may result in signs/symptoms of hypercorticism *[see Warnings and Precautions (5.7)]*. Single oral doses up to 8000 mcg of mometasone furoate have been studied on human volunteers with no adverse reactions reported.

Formoterol Fumarate: The expected signs and symptoms with overdosage of formoterol are those of excessive beta-adrenergic stimulation and/or occurrence or exaggeration of any of the following signs and symptoms: angina, hypertension or hypotension, tachycardia, with rates up to 200 beats/min., arrhythmias, nervousness, headache, tremor, seizures, muscle cramps, dry mouth, palpitation, nausea, dizziness, fatigue, malaise, hypokalemia, hyperglycemia, and insomnia. Metabolic acidosis may also occur. Cardiac arrest and even death may be associated with an overdose of formoterol.

The minimum acute lethal inhalation dose of formoterol fumarate in rats is 156 mg/kg (approximately 63,000 times the MRHD on a mcg/m^2 basis). The median lethal oral doses in Chinese hamsters, rats, and mice provide even higher multiples of the MRHD.

10.2 Treatment

DULERA: Treatment of overdosage consists of discontinuation of DULERA together with institution of appropriate symptomatic and/or supportive therapy. The judicious use of a cardioselective beta-receptor blocker may be considered, bearing in mind that such medication can produce bronchospasm. There is insufficient evidence to determine if dialysis is beneficial for overdosage of DULERA. Cardiac monitoring is recommended in cases of overdosage.

Manufactured by 3M Health Care Ltd.,
Loughborough, United Kingdom.
Manufactured for Schering Corporation, a subsidiary of
MERCK & CO., INC.
Whitehouse Station, NJ 08889 USA.

6/10 **32704107T-JBS**

CMS Council looks to expand, engage new members

The CMS Council held its quarterly policy making meeting on Sept. 15, 2011.

Expand Council and engage new members

• THE COUNCIL COULD DOUBLE IN SIZE under Bylaws changes approved by 93% of voting councilors. The decision gives affiliated medical organizations a strong voice at Society meetings because it removes the majority membership requirement. In addition, all Cook County hospitals will be offered new positions on the CMS Council. Representatives from affilated organizations and hospitals will be selected based on their desire to serve.

• The CMS trial membership program remains in effect for another year. Those joining CMS through the program have the option of a phased-in membership dues structure. The extension gives CMS more time to demonstrate value and ease the transition towards full dues-paying membership.

Support for U.S. House bill to spur new antibiotic R&D

• A CMS resolution urges strong support for HR 2182, "Generating Antibiotic Incentives Now (GAIN) Act," national legislation aimed at stimulating antibiotic research and development. Adopted by the Council, the resolution requests adoption and action by ISMS and AMA.

Dr. Susan Kern (left), CMS Councilor, and Dr. Kamala Ghaey, CMS trustee, take notes during proceedings.

Changes to Samaritan Act boost CPR campaign

• Bystanders who give emergency CPR have new legal protection against civil damages under changes to the Good Samaritan Act that CMS and other groups strongly supported. Persons who render first aid must act in good faith, without compensation, and have met certain training standards, although certification is no longer required. Physician volunteers are needed to give "hands-only" CPR demonstrations throughout Cook County. **Interested physicians, residents, and students should fill out and return the form on the facing page.**

CMS President-elect Dr. Howard Axe addresses the Council.

Fall veto session

• Both the Illinois House and Senate passed a measure to extend the sun-setting Medical Practice Act until Dec. 31, 2012. As of press time, the bill was awaiting Governor Quinn's signature. In related news, ISMS convinced lawmakers to reject a proposal to double the physician relicensure fee and reduce the renewal cycle. To learn more, please see the ISMS Update section on page 26.

State insurance exchange

• In August, ISMS testified before a legislative committee implementing the state insurance exchange. The Society made the point that consumers should have a choice of health plans along with data on the different plan options. (State exchanges are required to be up and running by January 2013 to gain federal approval and begin selling insurance in 2014.) ISMS favors the establishment of an exchange through an existing state agency or as a public-private board, and opposes any price negotiation. An assessment on health plans could cover the yearly cost of running the exchange, estimated at $89 million.

PHYSICIANS--CAN YOU HELP?

Volunteers needed to spread word: "hands-only" CPR saves lives

MANY PEOPLE DIE NEEDLESSLY FROM SUDDEN CARDIAC ARREST. PLEASE CONSIDER GIVING A few hours of your time to train other health care providers and bystanders how to respond with life-saving CPR.

"Hands-only CPR" is as effective as mouth-to-mouth resuscitation, and is a life skill almost anyone can learn to perform in an emergency. It's as easy as calling 911, or applying the Heimlich maneuver.

Physicians, residents, and medical students—indeed, anyone with a basic life support provider card from the American Heart Association or Red Cross—is encouraged to get involved.

Teaching skills and a commitment to the Project SMILE (Saving More Illinois Lives through Education) format are essential. (Project SMILE was founded by CMS member Vemuri S. Murthy, MD. Dr. Murthy oversees all training and volunteer activities.)

Volunteers will be trained in the Project SMILE format, either privately or in classes taught by coalition instructors. They will be asked to sign an agreement and assume responsibility for choosing the communities and locations for their presentations.

CMS will recognize each volunteer for his or her contributions during a quarterly Council Meeting or the yearly Annual Dinner Meeting.

Sign Up for Project SMILE:

To sign up, please fill out the form below and fax to: (312) 670-3646, or email information to rrubio@cmsdocs.org or to the Chicago Medical Society, 515 N. Dearborn St., Chicago, IL 60654.
For more information, call Ruby Bahena at (312) 670-2550, ext. 344.

Name: _____

Contact Info: _____

Related experience or certification: _____

CMS offers cornucopia of clinical, practice-based lectures

MEMBERS ENJOYED AN EXPANDED ARRAY of lectures and workshops this year, both virtual and on-site, as part of CMS' updated Midwest Clinical Conference Series.

Quarterly conferences addressed concepts in accountable care delivery, value-based payment, choosing an EMR, measuring patients' satisfaction, and implementing social media policies.

During a full-day EMR conference, CHITREC representatives were on hand to personally answer questions. A CMS dinner program gave participants direct access to reps from both CHITREC and athenahealth. Still other sessions addressed employment law and human resources policies. A parliamentary procedures skills workshop helped organizational leaders brush up on their speaking and debate skills.

On the clinical side, members earned up to seven hours of CME credit attending lectures on the multi-disciplinary approaches to breast care and end-of-life care.

Many participants said they appreciated having ample time to ask questions and to suggest future educational programs.

IMPLEMENTING HEALTH COURTS?

Medical liability reform still on ISMS' radar

SINCE THE DISASTROUS ILLINOIS SUPREME Court ruling in February 2010, ISMS has actively sought out alternative paths to medical liability reform.

For example, the Society vigorously supported a measure to reenact other provisions of the 2005 reform law, such as stronger affidavit of merit and expert witness standards, according to President Wayne V. Polek, MD, in comments before the Chicagoland Patient Safety Summit last Sept. 15-16.

Although the bill did not advance in the General Assembly, the proposed legislation also included improvements to the medical disciplinary process and expanded powers for the Medical Disciplinary Board and Division of Insurance.

ISMS has also pursued the implementation of health courts that could dramatically reduce the cost of defending lawsuits as well as the long adjudication and appeals process. In some models, the court would even pay for independent expert witnesses.

Operating outside the regular court system, specially trained health court judges would consult with neutral experts to make decisions. The standard of care would be based on the less strict "avoidability" standard rather than traditional negligence. Patients could still appeal and would not be forced into settlement if they do not agree to the terms, Dr. Polek noted.

Under the health court model, damages would be paid according to a predetermined schedule.

Dr. Polek encouraged physicians to read the Society's website "white paper" outlining the principles behind health courts which is available at **www.isms.org.**

Because the state already has two statutorily created special courts, mental health courts and drug courts, establishing a third court category under Illinois law offers a reasonable alternative, Dr. Polek stated.

Safe harbors

The safe harbor concept is another relatively new idea in the medical liability reform debate. The idea is based on the theory that complying with clinical guidelines would shield physicians from medical liability claims regardless of the patient's outcome, Dr. Polek stated.

Only one state has ever attempted to use them, but never found the right legal case to test the concept.

Evaluating the "Seven Pillars Approach"

The Society is looking at "The Seven Pillars Approach to Patient Safety" as an option to make health care delivery safer, more effective, and less costly. This novel means of addressing harm to patients was founded by CMS/ISMS member Timothy McDonald, MD, and was extensively reported on in *Chicago Medicine.*

A practicing anesthesiologist at UIC Medical Center, Dr. McDonald is chief safety and risk officer for health affairs and co-executive director of the university's Patient Safety Institute for Excellence. He is widely considered a pioneer in the patient safety movement. Dr. McDonald has presented to the ISMS Board and House, and gives presentations to physicians, administrative staff, and risk managers throughout the state.

Problem Solvers

Leading Chicago Area Employment Law: Management Lawyers

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Jeralyn H. Baran	Chuhak & Tecson PC	Chicago	312.444.9300
R. Theodore Clark, Jr.	Clark Baird Smith LLP	Rosemont	847.378.7700
James S. Barber	Clausen Miller PC	Chicago	312.606.7712
Cheryl Blackwell Bryson	Duane Morris LLP	Chicago	312.499.6708
Jon Zimring	Duane Morris LLP	Chicago	312.499.6753
Peter A. Silverman	Figliulo & Silverman PC	Chicago	312.251.5275
George J. Matkov, Jr.	Ford & Harrison LLP	Chicago	312.332.0777
James C. Franczek, Jr.	Franczek Radelet PC	Chicago	312.786.6110
Ronald J. Hein, Jr.	Franczek Radelet PC	Chicago	312.786.6150
Lisa A. McGarrity	Franczek Radelet PC	Chicago	312.786.6136
David P. Radelet	Franczek Radelet PC	Chicago	312.786.6190
Andrea R. Waintroob	Franczek Radelet PC	Chicago	312.786.6170
James J. Zuehl	Franczek Radelet PC	Chicago	312.786.6155
William N. Krucks	Freeborn & Peters LLP	Chicago	312.360.6504
David N. Michael	Gould & Ratner LLP	Chicago	312.236.3003
Paul J. Cherner	Hinshaw & Culbertson LLP	Chicago	312.704.3220
Michael J. Leech	Hinshaw & Culbertson LLP	Chicago	312.704.3133
Tom H. Luetkemeyer	Hinshaw & Culbertson LLP	Chicago	312.704.3056
Thomas Y. Mandler	Hinshaw & Culbertson LLP	Chicago	312.704.3456
Daniel K. Ryan	Hinshaw & Culbertson LLP	Chicago	312.704.3248
James P. Daley	K&L Gates LLP	Chicago	312.807.4224
Robert H. Brown	Laner Muchin Dombrow Becker Levin and Tominberg Ltd	Chicago	312.467.9800
Violet M. Clark	Laner Muchin Dombrow Becker Levin and Tominberg Ltd	Chicago	312.467.9800
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ISMS protects physicians from $300 fee increase

ISMS MEMBERS LIKE YOU KNOW THAT WE are dedicated to saving you money and representing you in Springfield. Often those two goals go hand-in-hand--and the 2011 veto session of the Illinois General Assembly was just such an occasion.

The *Illinois Medical Practice Act* was scheduled to expire at the end of November. This law governs the practice of medicine in Illinois, setting out criteria for licensure and standards for discipline. In the past it has been set to expire every ten years, but recently the legislature has only been willing to renew it for a year or two at a time, opening up a "Pandora's box" of opportunities for legislators, regulators, and other interests to try to change how you practice medicine.

During this year's renewal negotiations, the Illinois Department of Financial and Professional Regulation (IDFPR) tried to ***double*** the fee you pay to renew your medical license, from $300 to $600. These licensure fees are designated for IDFPR's Medical Disciplinary Fund, but in recent years the General Assembly has been in the bad habit of sweeping the Medical Disciplinary Fund into the state's General Revenue Fund, sapping needed resources from IDFPR. In light of these sweeps, an increase in medical licensure fees would amount to a "tax increase" on Illinois physicians, and ISMS was not going to stand for it.

Through months of negotiations, our legislative advocacy team stood their ground on this issue. When the time came to vote on the bill, the Illinois Senate and House agreed with us, unanimously passing a renewal bill that included **no fee increase for Illinois physicians**.

This latest extension of the *Medical Practice Act* only lasts until Dec. 31, 2012, so it is likely that we will have to fight this and other battles again in the near future. In addition, a state in dire fiscal straits, upheaval in our nation's health care system, allied health professionals seeking ever-greater expansions in their scope of practice, and a host of other issues are likely to present significant challenges to Illinois physicians in 2012 and beyond.

The moral of the story: ISMS' legislative advocacy is more valuable than ever to Illinois physicians. Don't forget to spread the word to your colleagues, who may take for granted the hard work that you help support. Thank you for your membership, and for helping ISMS fight for you!

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- **Illinois Department of Professional Regulation Hearings/Investigations**

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For Additional Information and an Initial Consultation
Contact Robert L. Nora at:

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10 S. LaSalle Street
Suite 2500
Chicago, Illinois 60603
312.650.7900
rnora@ntllplaw.com
www.noratanzillo.com

CALENDAR OF EVENTS

January 18

CMS Executive Committee Meeting
8:00 a.m.
CMS Building

January 28

Polish-American Medical Society Annual Gala
Ritz Carlton Hotel
Chicago

February 4

ISMS Board of Trustees Meeting
9:00 a.m.
ISMS Headquarters

February 13-15

AMA National Advocacy Conference
Washington, DC

February 15

CMS Executive Committee Meeting
8:00 a.m.
CMS Building

February 15

CMS Board of Trustees Meeting
9:00 a.m.
CMS Building

February 21

CMS Council Meeting
6:00 p.m.
Maggiano's Banquets
Chicago

2012 OSHA Workshops on Bloodborne Pathogens & Beyond:

What Healthcare Professionals Need to Know Before OSHA is at the Door

WHO SHOULD ATTEND? Physicians, Nurses, Physician Assistants, and Office Managers.

LEARNING STRATEGIES: All workshops are taught by specialists in exposure control. The course is designed for clinicians and their staff.

At the conclusion of this activity, participants should be able to:

- **Implement a training program for healthcare employees that may be exposed to bloodborne pathogens.**
- **Identify appropriate personal protective equipment (PPE).**
- **Develop an emergency response plan.**
- **Create a written exposure control plan for healthcare workers assigned as first-aid providers.**
- **Develop a strategy to prevent the spread of pandemic flu within their practice.**

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2-HOUR OSHA WORKSHOP--
DATES & LOCATIONS:

- **Saturday, March 24: DoubleTree by Hilton Hotel (Oak Brook) 10 a.m. – 12N**
- **Wednesday, April 11: Chicago Medical Society Bldg. (Downtown Chicago) 10 a.m. -12N**
- **Friday, May 11: Advocate Lutheran Gen. Hospital (Park Ridge) 2 p.m. -4 p.m.**
- **Wednesday, June 6: Advocate Christ Medical Center (Oak Lawn) 2 p.m.- 4 p.m.**
- **Wednesday, July 18: Chicago Medical Society Blg. (Downtown Chicago) 10 a.m.-12N**
- **Wednesday, August 8: (Webinar) 10 a.m. -12N**
- **Friday, September 7: DoubleTree by Hilton Hotel (Oak Brook) 9:30 a.m. -11:30 a.m.**
- **Friday, October 5: Advocate Christ Medical Center (Oak Lawn) 10 a.m. -12N**
- **Friday, November 2: Advocate Lutheran Gen. Hospital (Park Ridge) 2 p.m. -4 p.m.**

For location, CME information, directions, fees and online registration visit: www.cmsdocs.org.
Registration Questions? Call : 312-670-2550 x338.

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NO SMALL ACHIEVEMENT: LEARNING THE BUSINESS OF MEDICINE

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SOLUTION: Dr. Navalgund had the Cash Flow Conversation with his PNC Healthcare Business Banker, who put his industry knowledge to work. Together, they tailored a set of solutions to strengthen his cash flow: loans for real estate and equipment along with a line of credit to grow his practice, plus remote deposit to help speed up receivables.

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