INDIANA ACADEMY OF
FAMILY PHYSICIANS

Quarterly Publication for Indiana's Family Physicians

Fall 2012

FRONTLINE PHYSICIAN

Clif Knight, MD, Candidate for AAFP Board of Directors

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2012 IAFP Annual Convention:

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Office of Inspector General 2012 Work Plan

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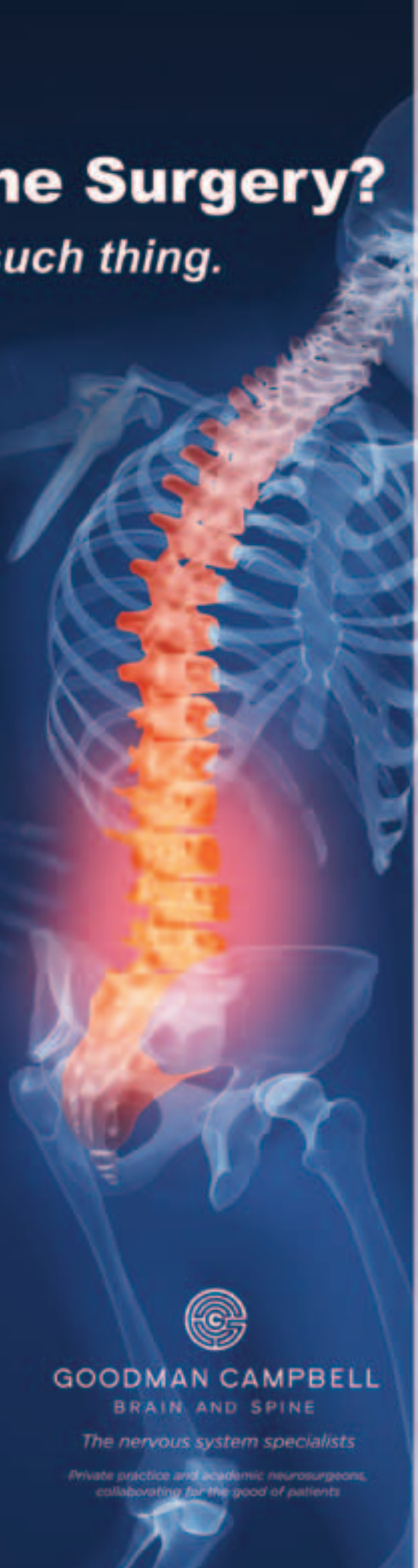
Simple Spine Surgery?

There's no such thing.



And yet, we hear it time and time again: I send my "simple spine" one place but my complex cases go to a neurosurgeon.

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FRONTLINE PHYSICIAN

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FrontLine Physician is the official magazine of the Indiana Academy of Family Physicians and is published quarterly.

Our Mission

The mission of the Indiana Academy of Family Physicians is to promote and advance family medicine in order to improve the health of Indiana.

Advocacy

Shaping health care policy in Indiana through interactions with government, the public, businesses, the health care industry and our patients

Membership

Serving as the essential resource for the professional success of the Family Physician workforce in Indiana

Education

We aim to be the provider of choice for family physician education in Indiana

Family Medicine: Exceptional Physicians, Exceptional Care

INDIANA ACADEMY OF FAMILY PHYSICIANS

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Risheet R. Patel, MD

Serving the IAFP

From your newly inaugurated president, welcome to the fall issue of the IAFP *FrontLine Physician*. It has been an exciting time for me personally and for the Academy as a whole. This past July, I had the privilege of being installed as the president of the IAFP. It has been an honor to be a member of the Executive Committee for the past three years, and I am thrilled to now serve as president. I'm certain this year will be full of excitement and challenges, and, through it all, I will serve the IAFP to my fullest abilities.

My inauguration was part of our Annual Scientific Assembly and Congress of Delegates. We hosted the event in Indianapolis for the first time in many years, and it was a resounding success. We presented a varied selection of CME topics and a SAM Study Group. The CME sessions sold out and were standing room only at times. Attendees were also treated to an intriguing Town Hall Dinner with Dr. Bob Phillips, the distinguished director of the Robert Graham Center.

Our Congress of Delegates was busy discussing a number of resolutions to help direct our Academy leadership. Resolutions were adopted on a range of topics from working on payment reform to restructuring the governance of our Academy. The weekend concluded with Family Medicine Day at Victory Field. We had more than 300 guests join us for a pre-game picnic followed by the Indianapolis Indians baseball. Overall, it was a very successful weekend, and we are already working on planning next year's meeting, which will again be in Indianapolis.

Finally, we are dedicating space in this issue to Dr. Clif Knight. As many of you know, he is running for a position on the AAFP Board of Directors. Dr. Knight has dedicated many years of service to the IAFP and the AAFP in a number of positions and is now ready to take that service to the next level. We wish him the best of luck in Philadelphia this October.

If I can be of any service to you over this year, please don't hesitate to e-mail me at risheetp@yahoo.com or contact the Academy office.

Thanks,

Risheet R. Patel, MD

Indiana's Mitchell Ellis Receives Special Recognition in the 2012 Tar Wars® Poster Contest

Congratulations to Mitchell Ellis, who was 2012's Indiana Tar Wars® poster contest winner. Mitchell and his family, along with IAFP staff member Missy Lewis, attended the annual Tar Wars® National Conference in Washington, D.C., sponsored by the American Academy of Family Physicians. This event is held each year in the summer. The Tar Wars® National Conference celebrates youth, creativity and being tobacco-free and is jam-packed with fun, excitement and learning opportunities for the entire family.

Mitchell received a prize packet that included a certificate of appreciation, a ribbon, a color copy of his poster and a special gift. His poster featured the slogan: **Racing Towards a Healthy Life: Be Smoke Free.**

The Tar Wars® National Conference is a once-in-a-lifetime opportunity for students to receive recognition for their tobacco-free efforts, voice their opinions about tobacco use to their congressional leaders, participate in tobacco-free workshops and meet other state winners who share their tobacco-free views.

The IAFP received this note of thanks from Mitchell after the conference:

Missy Lewis & Indiana Academy of Family Physicians:

Thank you for getting everything together for our Washington, D.C., trip. I had a really great time in Washington, D.C. I would not have been able to do this without your sponsorship. Thank you again for this opportunity.

Sincerely,

Mitchell Ellis

Mark Your Calendar

IAFP Events

IAFP Fall Conference
Saturday, October 27
Indianapolis

IAFP Board/Commission Cluster
Sunday, October 28
Indianapolis

AAFP Assembly

Congress of Delegates
Monday, October 15-Tuesday, October 16
Philadelphia, Pennsylvania

Scientific Assembly
Tuesday, October 16-Saturday, October 20
Philadelphia, Pennsylvania

2013

Emerald Isle CME and Golf Trip
Saturday, June 29-Saturday, July 6
Ireland, United Kingdom

2013 IAFP Annual Convention
Thursday, July 25-Sunday, July 28
Indianapolis

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It's Never Too Early to Plan to Serve as Physician of the Day

Don't be disappointed! Plan your POD shift now! In 2013, your Academy is responsible for providing episodic primary care services for Indiana's legislators and their staffs during the time the state legislature is in session. On days when the full House and Senate are in session the Physician of the Day is introduced on the floor of both houses. This interesting and fun program allows you to observe the legislative process firsthand, meet with your state legislators, and leave a great impression about family medicine on the General Assembly. Your day at the Statehouse will last from 8:30 a.m. to 4:30 p.m.

IAFP members can volunteer to spend one or more days at the Statehouse during the legislative session. We are currently scheduling physician volunteers for the months of February and April 2013. The program operates Mondays through Thursdays. If you are interested in serving as the Physician of the Day, please contact Chris Barry or Meredith Edwards at the IAFP office at 888.422.4237 (toll-free, in-state only) or 317.237.4237. THANK YOU!

THE STRENGTH IT TAKES

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Ireland LuxuryCoach Tour
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The IAFP is going to Ireland! Join us on a thrilling trip to the Emerald Isle in 2013. Not only will you see the sights and experience the culture of Ireland, but you'll also have time to play golf and earn CME credit.

More than 10 hours of prescribed CME credit will be offered:

- Practice Pearls for Treating Acne, Psoriasis, Eczema, and Skin Cancer
- Helping Your Patients Reduce the Chance of Stroke
- Adult Immunization Update
- Diabetic Peripheral Neuropathic Pain
- Current USPSTF Screening Recommendations for Selected Clinical Problems
- Physician Leadership Skills
- How Health Care Systems Are Changing

Saturday, June 29
Depart USA

Sunday, June 30
Dublin Sightseeing
Overnight in Dublin at the Burlington Hotel

Monday, July 1
Depart Dublin via motorcoach with guide
Clonmacnoise
Galway
Overnight at Hotel Meyrick in Galway

Tuesday, July 2
Visit Connemara Coast
Spiddal
Leenane and Kilary Harbour
Clifton
Overnight at Hotel Meyrick in Galway
Optional Golf at Connemara Golf Club

Wednesday, July 3
Travel through *the Burren*
Visit the incredible *Cliffs of Mohar*
Adare – Foynes – Killarney
Overnight at Killarney Plaza Hotel in Killarney
Optional Golf at Killarney Golf & Fishing Club

Thursday, July 4
Tour *The Ring of Kerry*
Free time to explore in Killarney
Overnight at Killarney Plaza Hotel in Killarney
Optional Golf at the Old Course at Ballybunion

Friday, July 5
Drive to County Cork
Tour Blarney Castle
Continue to Dublin
Overnight at the Burlington Hotel in Dublin

Saturday, July 6
Depart for USA

Find out more and start planning your trip today at http://specialeventcruises.com/iafp_golf.html.
For reservations and information, call Golf Travel ETC at 877-934-6531.

Formulary Update

onglyza
(saxagliptin) 5 mg tablets

kombiglyze XR
(saxagliptin and metformin HCl extended-release) tablets

Available on Formulary at Indiana Medicaid

For more information about these products, visit
www.onglyza-hcp.com or www.kombiglyzexr-hcp.com

Please read adjacent Brief Summary of US Full Prescribing Information for KOMBIGLYZE XR (saxagliptin and metformin HCl extended-release) (5/500•5/1000•2.5/1000 mg tablets), including **Boxed WARNING** about lactic acidosis.

Bristol-Myers Squibb

AstraZeneca

1743100

KOMBIGLYZE XR **℞ ONLY**

(saxagliptin and metformin HCl extended-release) tablets

Brief Summary of Prescribing Information. For complete prescribing information consult official package insert.

WARNING: LACTIC ACIDOSIS

Lactic acidosis is a rare, but serious, complication that can occur due to metformin accumulation. The risk increases with conditions such as sepsis, dehydration, excess alcohol intake, hepatic impairment, renal impairment, and acute congestive heart failure.

The onset of lactic acidosis is often subtle, accompanied only by nonspecific symptoms such as malaise, myalgias, respiratory distress, increasing somnolence, and nonspecific abdominal distress. Laboratory abnormalities include low pH, increased anion gap, and elevated blood lactate.

If acidosis is suspected, KOMBIGLYZE XR (saxagliptin and metformin HCl extended-release) should be discontinued and the patient hospitalized immediately. [See *Warnings and Precautions*.]

INDICATIONS AND USAGE

KOMBIGLYZE XR is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both saxagliptin and metformin is appropriate. [See *Clinical Studies* (14) in Full Prescribing Information.]

Important Limitations of Use

KOMBIGLYZE XR should not be used for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.

KOMBIGLYZE XR has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using KOMBIGLYZE XR. [See *Warnings and Precautions*.]

CONTRAINDICATIONS

KOMBIGLYZE XR is contraindicated in patients with:

- Renal impairment (e.g., serum creatinine levels ≥1.5 mg/dL for men, ≥1.4 mg/dL for women, or abnormal creatinine clearance which may also result from conditions such as cardiovascular collapse (shock), acute myocardial infarction, and septicemia.
- Hypersensitivity to metformin hydrochloride.
- Acute or chronic metabolic acidosis, including diabetic ketoacidosis. Diabetic ketoacidosis should be treated with insulin.
- History of a serious hypersensitivity reaction to KOMBIGLYZE XR or saxagliptin, such as anaphylaxis, angioedema, or exfoliative skin conditions. [See *Warnings and Precautions* and Adverse Reactions.]

WARNINGS AND PRECAUTIONS

Lactic Acidosis: Lactic acidosis is a rare, but serious, metabolic complication that can occur due to metformin accumulation during treatment with KOMBIGLYZE XR; when it occurs, it is fatal in approximately 50% of cases. Lactic acidosis may also occur in association with a number of pathophysiologic conditions, including diabetes mellitus, and whenever there is significant tissue hypoperfusion and hypoxemia. Lactic acidosis is characterized by elevated blood lactate levels (>5 mmol/L), decreased blood pH, electrolyte disturbances with an increased anion gap, and an increased lactate/pyruvate ratio. When metformin is implicated as the cause of lactic acidosis, metformin plasma levels >5 µg/mL are generally found.

The reported incidence of lactic acidosis in patients receiving metformin hydrochloride is very low (approximately 0.03 cases/1000 patient-years, with approximately 0.015 fatal cases/1000 patient-years). In more than 20,000 patient-years exposure to metformin in clinical trials, there were no reports of lactic acidosis. Reported cases have occurred primarily in diabetic patients with significant renal insufficiency, including both intrinsic renal disease and renal hypoperfusion, often in the setting of multiple concomitant medical/surgical problems and multiple concomitant medications. Patients with congestive heart failure requiring pharmacologic management, in particular those with unstable or acute congestive heart failure who are at risk of hypoperfusion and hypoxemia, are at increased risk of lactic acidosis. The risk of lactic acidosis increases with the degree of renal dysfunction and the patient's age. The risk of lactic acidosis may, therefore, be significantly decreased by regular monitoring of renal function in patients taking metformin and the use of the minimum effective dose of metformin. In particular, treatment of the elderly should be accompanied by careful monitoring of renal function. Metformin treatment should not be initiated in patients ≥80 years of age unless measurement of creatinine clearance demonstrates that renal function is not reduced, as these patients are more susceptible to developing lactic acidosis. In addition, metformin should be promptly withheld in the presence of any condition associated with hypoxemia, dehydration, or sepsis. Because impaired hepatic function may significantly limit the ability to clear lactate, metformin should generally be avoided in patients with clinical or laboratory evidence of hepatic disease. Patients should be cautioned against excessive alcohol intake when taking metformin since alcohol potentiates the effects of metformin hydrochloride on lactate metabolism. In addition, metformin should be temporarily discontinued prior to any intravascular radiocontrast study and for any surgical procedure [see *Warnings and Precautions*].

The onset of lactic acidosis often is subtle and accompanied only by nonspecific symptoms such as malaise, myalgias, respiratory distress, increasing somnolence, and nonspecific abdominal distress. There may be associated hypothermia, hypotension, and resistant bradyarrhythmias with more marked acidosis. The patient and the patient's physician must be aware of the possible importance of such symptoms and the patient should be instructed to notify the physician immediately if they occur [see *Warnings and Precautions*]. Metformin should be withdrawn until the situation is clarified. Serum electrolytes, ketones, blood glucose, and if indicated, blood pH, lactate levels, and even blood metformin levels may be useful. Once a patient is stabilized on any dose level of metformin, gastrointestinal symptoms, which are common during initiation of therapy, are unlikely to be drug related. Later occurrence of gastrointestinal symptoms could be due to lactic acidosis or other serious disease.

Levels of fasting venous plasma lactate above the upper limit of normal, but less than 5 mmol/L, in patients taking metformin do not necessarily indicate impending lactic acidosis and may be explainable by other mechanisms, such as poorly controlled diabetes or obesity, vigorous physical activity, or technical problems in sample handling. [See *Warnings and Precautions*.]

Lactic acidosis should be suspected in any diabetic patient with metabolic acidosis lacking evidence of ketoacidosis (ketonuria and ketonemia).

Lactic acidosis is a medical emergency that must be treated in a hospital setting. In a patient with lactic acidosis who is taking metformin, the drug should be discontinued immediately and general supportive measures promptly instituted. Because metformin hydrochloride is dialyzable (with a clearance of up to 170 mL/min under good hemodynamic conditions), prompt hemodialysis is recommended to correct the acidosis and remove the accumulated metformin. Such management often results in prompt reversal of symptoms and recovery [see *Contraindications* and *Warnings and Precautions*].

Pancreatitis: There have been postmarketing reports of acute pancreatitis in patients taking saxagliptin. After initiation of KOMBIGLYZE XR (saxagliptin and metformin HCl extended-release), patients should be observed carefully for signs and symptoms of pancreatitis. If pancreatitis is suspected, KOMBIGLYZE XR should promptly be discontinued and appropriate management should be initiated. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using KOMBIGLYZE XR.

Assessment of Renal Function: Metformin is substantially excreted by the kidney, and the risk of metformin accumulation and lactic acidosis increases with the degree of impairment of renal function. Therefore, KOMBIGLYZE XR is contraindicated in patients with renal impairment [see *Contraindications*].

Before initiation of KOMBIGLYZE XR, and at least annually thereafter, renal function should be assessed and verified as normal. In patients in whom development of renal impairment is anticipated (e.g., elderly), renal function should be assessed more frequently and KOMBIGLYZE XR discontinued if evidence of renal impairment is present.

Impaired Hepatic Function: Metformin use in patients with impaired hepatic function has been associated with some cases of lactic acidosis. Therefore, KOMBIGLYZE XR is not recommended in patients with hepatic impairment.

Vitamin B_{12} Concentrations: In controlled clinical trials of metformin of 29-week duration, a decrease to subnormal levels of previously normal serum vitamin B_{12} levels, without clinical manifestations, was observed in approximately 7% of patients. Such decrease, possibly due to interference with B_{12} absorption from the B_{12}-intrinsic factor complex, is, however, very rarely associated with anemia and appears to be rapidly reversible with discontinuation of metformin or vitamin B_{12} supplementation. Measurement of hematologic parameters on an annual basis is advised in patients on KOMBIGLYZE XR and any apparent abnormalities should be appropriately investigated and managed [see *Adverse Reactions*].

Certain individuals (those with inadequate vitamin B_{12} or calcium intake or absorption) appear to be predisposed to developing subnormal vitamin B_{12} levels. In these patients, routine serum vitamin B_{12} measurements at 2- to 3-year intervals may be useful.

Alcohol Intake: Alcohol potentiates the effect of metformin on lactate metabolism. Patients should be warned against excessive alcohol intake while receiving KOMBIGLYZE XR.

Surgical Procedures: Use of KOMBIGLYZE XR should be temporarily suspended for any surgical procedure (except minor procedures not associated with restricted intake of food and fluids) and should not be restarted until the patient's oral intake has resumed and renal function has been evaluated as normal.

Change in Clinical Status of Patients with Previously Controlled Type 2 Diabetes: A patient with type 2 diabetes previously well controlled on KOMBIGLYZE XR who develops laboratory abnormalities or clinical illness (especially vague and poorly defined illness) should be evaluated promptly for evidence of ketoacidosis or lactic acidosis. Evaluation should include serum electrolytes and ketones, blood glucose and, if indicated, blood pH, lactate, pyruvate, and metformin levels. If acidosis of either form occurs, KOMBIGLYZE XR must be stopped immediately and other appropriate corrective measures initiated.

Use with Medications Known to Cause Hypoglycemia

Saxagliptin — When saxagliptin was used in combination with a sulfonylurea or with insulin, medications known to cause hypoglycemia, the incidence of confirmed hypoglycemia was increased over that of placebo used in combination with a sulfonylurea or with insulin. [See *Adverse Reactions*.] Therefore, a lower dose of the insulin secretagogue or insulin may be required to minimize the risk of hypoglycemia when used in combination with KOMBIGLYZE XR. [See *Dosage and Administration* (2.3) in Full Prescribing Information.]

Metformin hydrochloride — Hypoglycemia does not occur in patients receiving metformin alone under usual circumstances of use, but could occur when caloric intake is deficient, when strenuous exercise is not compensated by caloric supplementation, or during concomitant use with other glucose-lowering agents (such as sulfonylureas and insulin) or ethanol. Elderly, debilitated, or malnourished patients and those with adrenal or pituitary insufficiency or alcohol intoxication are particularly susceptible to hypoglycemic effects. Hypoglycemia may be difficult to recognize in the elderly and in people who are taking beta-adrenergic blocking drugs.

Concomitant Medications Affecting Renal Function or Metformin Disposition: Concomitant medication(s) that may affect renal function or result in significant hemodynamic change or may interfere with the disposition of metformin, such as cationic drugs that are eliminated by renal tubular secretion [see *Drug Interactions*], should be used with caution.

Radiologic Studies with Intravascular Iodinated Contrast Materials: Intravascular contrast studies with iodinated materials can lead to acute alteration of renal function and have been associated with lactic acidosis in patients receiving metformin. Therefore, in patients in whom any such study is planned, KOMBIGLYZE XR should be temporarily discontinued at the time of or prior to the procedure, and withheld for 48 hours subsequent to the procedure and reinstituted only after renal function has been re-evaluated and found to be normal.

Hypoxic States: Cardiovascular collapse (shock), acute congestive heart failure, acute myocardial infarction, and other conditions characterized by hypoxemia have been associated with lactic acidosis and may also cause prerenal azotemia. When such events occur in patients on KOMBIGLYZE XR therapy, the drug should be promptly discontinued.

Hypersensitivity Reactions: There have been postmarketing reports of serious hypersensitivity reactions in patients treated with saxagliptin. These reactions include anaphylaxis, angioedema, and exfoliative skin conditions. Onset of these reactions occurred within the first 3 months after initiation of treatment with saxagliptin, with some reports occurring after the first dose. If a serious hypersensitivity reaction is suspected, discontinue KOMBIGLYZE XR, assess for other potential causes for the event, and institute alternative treatment for diabetes. [See *Adverse Reactions*.]

Use caution in a patient with a history of angioedema to another dipeptidyl peptidase-4 (DPP-4) inhibitor because it is unknown whether such patients will be predisposed to angioedema with KOMBIGLYZE XR.

Macrovascular Outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with KOMBIGLYZE XR (saxagliptin and metformin HCl extended-release) or any other antidiabetic drug.

ADVERSE REACTIONS

Clinical Trials Experience: 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.

Monotherapy and Add-On Combination Therapy

Metformin hydrochloride — In placebo-controlled monotherapy trials of metformin extended-release, diarrhea and nausea/vomiting were reported in >5% of metformin-treated patients and more commonly than in placebo-treated patients (9.6% versus 2.6% for diarrhea and 6.3% versus 1.3% for nausea/vomiting). Diarrhea led to discontinuation of study medication in 0.6% of the patients treated with metformin extended-release.

Saxagliptin — In two placebo-controlled monotherapy trials of 24-week duration, patients were treated with saxagliptin 2.5 mg daily, saxagliptin 5 mg daily, and placebo. Three 24-week, placebo-controlled, add-on combination therapy trials were also conducted: one with metformin immediate-release, one with a thiazolidinedione (pioglitazone or rosiglitazone), and one with glyburide. In these three trials, patients were randomized to add-on therapy with saxagliptin 2.5 mg daily, saxagliptin 5 mg daily, or placebo. A saxagliptin 10 mg treatment arm was included in one of the monotherapy trials and in the add-on combination trial with metformin immediate-release.

In a prespecified pooled analysis of the 24-week data (regardless of glycemic rescue) from the two monotherapy trials, the add-on to metformin immediate-release trial, the add-on to thiazolidinedione (TZD) trial, and the add-on to glyburide trial, the overall incidence of adverse events in patients treated with saxagliptin 2.5 mg and saxagliptin 5 mg was similar to placebo (72.0% and 72.2% versus 70.6%, respectively). Discontinuation of therapy due to adverse events occurred in 2.2%, 3.3%, and 1.8% of patients receiving saxagliptin 2.5 mg, saxagliptin 5 mg, and placebo, respectively. The most common adverse events (reported in at least 2 patients treated with saxagliptin 2.5 mg or at least 2 patients treated with saxagliptin 5 mg) associated with premature discontinuation of therapy included lymphopenia (0.1% and 0.5% versus 0%, respectively), rash (0.2% and 0.3% versus 0.3%), blood creatinine increased (0.3% and 0% versus 0%), and blood creatine phosphokinase increased (0.1% and 0.2% versus 0%). The adverse reactions in this pooled analysis reported (regardless of investigator assessment of causality) in >5% of patients treated with saxagliptin 5 mg, and more commonly than in patients treated with placebo are shown in Table 1.

Table 1: Adverse Reactions (Regardless of Investigator Assessment of Causality) in Placebo-Controlled Trials* Reported in ≥5% of Patients Treated with Saxagliptin 5 mg and More Commonly than in Patients Treated with Placebo

	Number (%) of Patients	
	Saxagliptin 5 mg N=862	Placebo N=799
Upper respiratory tract infection	69 (7.7)	51 (7.6)
Urinary tract infection	50 (5.8)	49 (6.1)
Headache	37 (4.3)	47 (5.9)

* The 5 placebo-controlled trials include two monotherapy trials and one add-on combination therapy trial with each of the following: metformin, thiazolidinedione, or glyburide. Table shows 24-week data regardless of glycemic rescue.

In patients treated with saxagliptin 2.5 mg, headache (6.5%) was the only adverse reaction reported at a rate ≥5% and more commonly than in patients treated with placebo.

In this pooled analysis, adverse reactions that were reported in ≥2% of patients treated with saxagliptin 2.5 mg or saxagliptin 5 mg and ≥1% more frequently compared to placebo included: sinusitis (2.9% and 2.8% versus 1.8%, respectively), abdominal pain (2.4% and 1.7% versus 0.5%), gastroenteritis (1.9% and 2.3% versus 0.9%), and vomiting (2.2% and 2.3% versus 1.3%).

The incidence rate of fractures was 1.0 and 0.6 per 100 patient-years, respectively, for saxagliptin (pooled analysis of 2.5 mg, 5 mg, and 10 mg) and placebo. The incidence rate of fracture events in patients who received saxagliptin did not increase over time. Causality has not been established and nonclinical studies have not demonstrated adverse effects of saxagliptin on bone.

An event of thrombocytopenia, consistent with a diagnosis of idiopathic thrombocytopenic purpura, was observed in the clinical program. The relationship of this event to saxagliptin is not known.

Use in Combination with Insulin

In the add-on to insulin trial [see *Clinical Studies* (14.4) in Full Prescribing Information], the incidence of adverse events, including serious adverse events and discontinuations due to adverse events, was similar between saxagliptin and placebo, except for confirmed hypoglycemia (see **Hypoglycemia** subsection).

Adverse Reactions Associated with Saxagliptin Coadministered with Metformin Immediate-Release in Treatment-Naive Patients with Type 2 Diabetes

Table 2 shows the adverse reactions reported (regardless of investigator assessment of causality) in ≥5% of patients participating in an additional 24-week, active-controlled trial of coadministered saxagliptin and metformin in treatment-naive patients.

Table 2: Coadministration of Saxagliptin and Metformin Immediate-Release in Treatment-Naive Patients: Adverse Reactions Reported (Regardless of Investigator Assessment of Causality) in ≥5% of Patients Treated with Combination Therapy of Saxagliptin 5 mg Plus Metformin Immediate-Release (and More Commonly than in Patients Treated with Metformin Immediate-Release Alone)

	Number (%) of Patients	
	Saxagliptin 5 mg + Metformin* N=320	Placebo + Metformin* N=329
Headache	24 (7.5)	17 (5.2)
Nasopharyngitis	22 (6.9)	13 (4.0)

* Metformin immediate-release was initiated at a starting dose of 500 mg daily and titrated up to a maximum of 2000 mg daily.

In patients treated with the combination of saxagliptin and metformin immediate-release, either as saxagliptin add-on to metformin immediate-release therapy or as coadministration in treatment-naive patients, diarrhea was the only gastrointestinal-related event that occurred with an incidence

≥5% in any treatment group in both studies. In the saxagliptin add-on to metformin immediate-release trial, the incidence of diarrhea was 9.9%, 5.8%, and 11.2% in the saxagliptin 2.5 mg, 5 mg, and placebo groups, respectively. When saxagliptin and metformin immediate-release were coadministered in treatment-naive patients, the incidence of diarrhea was 6.9% in the saxagliptin 5 mg + metformin immediate-release group and 7.3% in the placebo + metformin immediate-release group.

Hypoglycemia

In the saxagliptin clinical trials, adverse reactions of hypoglycemia were based on all reports of hypoglycemia. A concurrent glucose measurement was not required or was normal in some patients. Therefore, it is not possible to conclusively determine that all these reports reflect true hypoglycemia.

The incidence of reported hypoglycemia for saxagliptin 2.5 mg and saxagliptin 5 mg versus placebo given as monotherapy was 4.0% and 5.6% versus 4.1%, respectively. In the add-on to metformin immediate-release trial, the incidence of reported hypoglycemia was 7.8% with saxagliptin 2.5 mg, 5.8% with saxagliptin 5 mg, and 5.0% with placebo. When saxagliptin and metformin immediate-release were coadministered in treatment-naive patients, the incidence of reported hypoglycemia was 3.4% in patients given saxagliptin 5 mg + metformin immediate-release and 4.0% in patients given placebo + metformin immediate-release.

In the active-controlled trial comparing add-on therapy with saxagliptin 5 mg to glipizide in patients inadequately controlled on metformin alone, the incidence of reported hypoglycemia was 3% (19 events in 13 patients) with saxagliptin 5 mg versus 36.3% (750 events in 156 patients) with glipizide. Confirmed symptomatic hypoglycemia (accompanying fingerstick blood glucose ≤50 mg/dL) was reported in none of the saxagliptin-treated patients and in 35 glipizide-treated patients (8.1%) (p<0.0001).

In the add-on to insulin trial, the overall incidence of reported hypoglycemia was 18.4% for saxagliptin 5 mg and 19.9% for placebo. However, the incidence of confirmed symptomatic hypoglycemia (accompanying fingerstick blood glucose ≤50 mg/dL) was higher with saxagliptin 5 mg (5.3%) versus placebo (3.3%). Among the patients using insulin in combination with metformin, the incidence of confirmed symptomatic hypoglycemia was 4.8% with saxagliptin versus 1.9% with placebo [see *Warnings and Precautions*].

Hypersensitivity Reactions

Saxagliptin — Hypersensitivity-related events, such as urticaria and facial edema in the 5-study pooled analysis up to Week 24 were reported in 1.5%, 1.5%, and 0.4% of patients who received saxagliptin 2.5 mg, saxagliptin 5 mg, and placebo, respectively. None of these events in patients who received saxagliptin required hospitalization or were reported as life-threatening by the investigators. One saxagliptin-treated patient in this pooled analysis discontinued due to generalized urticaria and facial edema.

Infections

Saxagliptin — In the unblinded, controlled, clinical trial database for saxagliptin to date, there have been 6 (0.12%) reports of tuberculosis among the 4959 saxagliptin-treated patients (1.1 per 1000 patient-years) compared to no reports of tuberculosis among the 2868 comparator-treated patients. Two of these six cases were confirmed with laboratory testing. The remaining cases had limited information or had presumptive diagnoses of tuberculosis. None of the six cases occurred in the United States or in Western Europe. One case occurred in Canada in a patient originally from Indonesia who had recently visited Indonesia. The duration of treatment with saxagliptin until report of tuberculosis ranged from 144 to 929 days. Post-treatment lymphocyte counts were consistently within the reference range for four cases. One patient had lymphopenia prior to initiation of saxagliptin that remained stable throughout saxagliptin treatment. The final patient had an isolated lymphocyte count below normal approximately four months prior to the report of tuberculosis. There have been no spontaneous reports of tuberculosis associated with saxagliptin use. Causality has not been established and there are too few cases to date to determine whether tuberculosis is related to saxagliptin use.

There has been one case of a potential opportunistic infection in the unblinded, controlled clinical trial database to date in a saxagliptin-treated patient who developed suspected foodborne fatal salmonella sepsis after approximately 600 days of saxagliptin therapy. There have been no spontaneous reports of opportunistic infections associated with saxagliptin use.

Vital Signs

Saxagliptin — No clinically meaningful changes in vital signs have been observed in patients treated with saxagliptin alone or in combination with metformin.

Laboratory Tests

Absolute Lymphocyte Counts

Saxagliptin — There was a dose-related mean decrease in absolute lymphocyte count observed with saxagliptin. From a baseline mean absolute lymphocyte count of approximately 2200 cells/microL, mean decreases of approximately 100 and 120 cells/microL with saxagliptin 5 mg and 10 mg, respectively, relative to placebo were observed at 24 weeks in a pooled analysis of five placebo-controlled clinical studies. Similar effects were observed when saxagliptin 5 mg and metformin were coadministered in treatment-naive patients compared to placebo and metformin. There was no difference observed for saxagliptin 2.5 mg relative to placebo. The proportion of patients who were reported to have a lymphocyte count ≤750 cells/microL was 0.5%, 1.5%, 1.4%, and 0.4% in the saxagliptin 2.5 mg, 5 mg, 10 mg, and placebo groups, respectively. In most patients, recurrence was not observed with repeated exposure to saxagliptin although some patients had recurrent decreases upon rechallenge that led to discontinuation of saxagliptin. The decreases in lymphocyte count were not associated with clinically relevant adverse reactions.

The clinical significance of this decrease in lymphocyte count relative to placebo is not known. When clinically indicated, such as in settings of unusual or prolonged infection, lymphocyte count should be measured. The effect of saxagliptin on lymphocyte counts in patients with lymphocyte abnormalities (e.g., human immunodeficiency virus) is unknown.

Platelets

Saxagliptin — Saxagliptin did not demonstrate a clinically meaningful or consistent effect on platelet count in the six, double-blind, controlled clinical safety and efficacy trials.

Vitamin B_{12} Concentrations

Metformin hydrochloride — Metformin may lower serum vitamin B_{12} concentrations. Measurement of hematologic parameters on an annual basis is advised in patients on KOMBIGLYZE XR (saxagliptin and metformin HCl extended-release) and any apparent abnormalities should be appropriately investigated and managed. [See *Warnings and Precautions*.]

Postmarketing Experience: Additional adverse reactions have been identified during postapproval use of saxagliptin. Because these reactions are reported voluntarily from a population of uncertain size, it is generally not possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

- Hypersensitivity reactions including anaphylaxis, angioedema, and exfoliative skin conditions. [See *Contraindications* and *Warnings and Precautions*.]
- Acute pancreatitis. [See *Indications and Usage* and *Warnings and Precautions*.]

DRUG INTERACTIONS

Strong Inhibitors of CYP3A4/5 Enzymes

Saxagliptin — Ketoconazole significantly increased saxagliptin exposure. Similar significant increases in plasma concentrations of saxagliptin are anticipated with other strong CYP3A4/5 inhibitors (e.g., atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, ritonavir, saquinavir, and telithromycin). The dose of saxagliptin should be limited to 2.5 mg when coadministered with a strong CYP3A4/5 inhibitor. [See *Dosage and Administration (2.2)* and *Clinical Pharmacology (12.3)* in Full Prescribing Information.]

Cationic Drugs

Metformin hydrochloride — Cationic drugs (e.g., amiloride, digoxin, morphine, procainamide, quinidine, quinine, ranitidine, triamterene, trimethoprim, or vancomycin) that are eliminated by renal tubular secretion theoretically have the potential for interaction with metformin by competing for common renal tubular transport systems. Such interaction between metformin and oral cimetidine has been observed in healthy volunteers. Although such interactions remain theoretical (except for cimetidine), careful patient monitoring and dose adjustment of KOMBIGLYZE XR (saxagliptin and metformin HCl extended-release) and/or the interfering drug is recommended in patients who are taking cationic medications that are excreted via the proximal renal tubular secretory system.

Use with Other Drugs

Metformin hydrochloride — Some medications can predispose to hyperglycemia and may lead to loss of glycemic control. These medications include the thiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blockers, and isoniazid. When such drugs are administered to a patient receiving KOMBIGLYZE XR, the patient should be closely observed for loss of glycemic control. When such drugs are withdrawn from a patient receiving KOMBIGLYZE XR, the patient should be observed closely for hypoglycemia.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category B — There are no adequate and well-controlled studies in pregnant women with KOMBIGLYZE XR or its individual components. Because animal reproduction studies are not always predictive of human response, KOMBIGLYZE XR, like other antidiabetic medications, should be used during pregnancy only if clearly needed.

Coadministration of saxagliptin and metformin, to pregnant rats and rabbits during the period of organogenesis, was neither embryolethal nor teratogenic in either species when tested at doses yielding systemic exposures (AUC) up to 100 and 10 times the maximum recommended human doses (MRHD; saxagliptin 5 mg and metformin 2000 mg), respectively, in rats; and 249 and 1.1 times the MRHDs in rabbits. In rats, minor developmental toxicity was limited to an increased incidence of wavy ribs; associated maternal toxicity was limited to weight decrements of 11% to 17% over the course of the study, and related reductions in maternal food consumption. In rabbits, coadministration was poorly tolerated in a subset of mothers (12 of 30), resulting in death, moribundity, or abortion. However, among surviving mothers with evaluable litters, maternal toxicity was limited to marginal reductions in body weight over the course of gestation days 21 to 29; and associated developmental toxicity in these litters was limited to fetal body weight decrements of 7%, and a low incidence of delayed ossification of the fetal hyoid.

Saxagliptin — Saxagliptin was not teratogenic at any dose tested when administered to pregnant rats and rabbits during periods of organogenesis. Incomplete ossification of the pelvis, a form of developmental delay, occurred in rats at a dose of 240 mg/kg, or approximately 1503 and 66 times human exposure to saxagliptin and the active metabolite, respectively, at the MRHD of 5 mg. Maternal toxicity and reduced fetal body weights were observed at 7986 and 328 times the human exposure at the MRHD for saxagliptin and the active metabolite, respectively. Minor skeletal variations in rabbits occurred at a maternally toxic dose of 200 mg/kg, or approximately 1432 and 992 times the MRHD.

Saxagliptin administered to female rats from gestation day 6 to lactation day 20 resulted in decreased body weights in male and female offspring only at maternally toxic doses (exposures ≥1629 and 53 times saxagliptin and its active metabolite at the MRHD). No functional or behavioral toxicity was observed in offspring of rats administered saxagliptin at any dose.

Saxagliptin crosses the placenta into the fetus following dosing in pregnant rats.

Metformin hydrochloride — Metformin was not teratogenic in rats and rabbits at doses up to 600 mg/kg/day. This represents an exposure of about 2 and 6 times the maximum recommended human daily dose of 2000 mg based on body surface area comparisons for rats and rabbits, respectively. Determination of fetal concentrations demonstrated a partial placental barrier to metformin.

Nursing Mothers: No studies in lactating animals have been conducted with the combined components of KOMBIGLYZE XR. In studies performed with the individual components, both saxagliptin and metformin are secreted in the milk of lactating rats. It is not known whether saxagliptin or metformin are secreted in human milk. Because many drugs are secreted in human milk, caution should be exercised when KOMBIGLYZE XR is administered to a nursing woman.

Pediatric Use: Safety and effectiveness of KOMBIGLYZE XR in pediatric patients have not been established.

Geriatric Use: *KOMBIGLYZE XR* — Elderly patients are more likely to have decreased renal function. Because metformin is contraindicated in patients with renal impairment, carefully monitor renal function in the elderly and use KOMBIGLYZE XR with caution as age increases. [See *Warnings and Precautions* and *Clinical Pharmacology (12.3)* in Full Prescribing Information.]

Saxagliptin — In the six, double-blind, controlled clinical safety and efficacy trials of saxagliptin, 634 (15.3%) of the 4148 randomized patients were 65 years and over, and 59 (1.4%) patients were 75 years and over. No overall differences in safety or effectiveness were observed between patients ≥65 years old and the younger patients. While this clinical experience has not identified differences in responses between the elderly and younger patients, greater sensitivity of some older individuals cannot be ruled out.

Metformin hydrochloride — Controlled clinical studies of metformin did not include sufficient numbers of elderly patients to determine whether they respond differently from younger patients, although other reported clinical experience has not identified differences in responses between the elderly and young patients. Metformin is known to be substantially excreted by the kidney. Because the risk of lactic acidosis with metformin is greater in patients with impaired renal function, KOMBIGLYZE XR (saxagliptin and metformin HCl extended-release) should only be used in patients with normal renal function. The initial and maintenance dosing of metformin should be conservative in patients with advanced age due to the potential for decreased renal function in this population. Any dose adjustment should be based on a careful assessment of renal function. [See *Contraindications*, *Warnings and Precautions*, and *Clinical Pharmacology (12.3)* in Full Prescribing Information.]

OVERDOSAGE

Saxagliptin — In a controlled clinical trial, once-daily, orally-administered saxagliptin in healthy subjects at doses up to 400 mg daily for 2 weeks (80 times the MRHD) had no dose-related clinical adverse reactions and no clinically meaningful effect on QTc interval or heart rate.

In the event of an overdose, appropriate supportive treatment should be initiated as dictated by the patient's clinical status. Saxagliptin and its active metabolite are removed by hemodialysis (23% of dose over 4 hours).

Metformin hydrochloride — Overdose of metformin hydrochloride has occurred, including ingestion of amounts greater than 50 grams. Hypoglycemia was reported in approximately 10% of cases, but no causal association with metformin hydrochloride has been established. Lactic acidosis has been reported in approximately 32% of metformin overdose cases [see *Warnings and Precautions*]. Metformin is dialyzable with a clearance of up to 170 mL/min under good hemodynamic conditions. Therefore, hemodialysis may be useful for removal of accumulated drug from patients in whom metformin overdosage is suspected.

PATIENT COUNSELING INFORMATION

See FDA-approved Medication Guide in Full Prescribing Information.

Instructions

Patients should be informed of the potential risks and benefits of KOMBIGLYZE XR and of alternative modes of therapy. Patients should also be informed about the importance of adherence to dietary instructions, regular physical activity, periodic blood glucose monitoring and A1C testing, recognition and management of hypoglycemia and hyperglycemia, and assessment of diabetes complications. During periods of stress such as fever, trauma, infection, or surgery, medication requirements may change and patients should be advised to seek medical advice promptly.

The risks of lactic acidosis due to the metformin component, its symptoms and conditions that predispose to its development, as noted in *Warnings and Precautions (5.1)*, should be explained to patients. Patients should be advised to discontinue KOMBIGLYZE XR immediately and to promptly notify their healthcare provider if unexplained hyperventilation, myalgia, malaise, unusual somnolence, dizziness, slow or irregular heart beat, sensation of feeling cold (especially in the extremities), or other nonspecific symptoms occur. Gastrointestinal symptoms are common during initiation of metformin treatment and may occur during initiation of KOMBIGLYZE XR therapy; however, patients should consult their physician if they develop unexplained symptoms. Although gastrointestinal symptoms that occur after stabilization are unlikely to be drug related, such an occurrence of symptoms should be evaluated to determine if it may be due to lactic acidosis or other serious disease.

Patients should be counseled against excessive alcohol intake while receiving KOMBIGLYZE XR.

Patients should be informed about the importance of regular testing of renal function and hematological parameters when receiving treatment with KOMBIGLYZE XR.

Patients should be informed that acute pancreatitis has been reported during postmarketing use of saxagliptin. Before initiating KOMBIGLYZE XR, patients should be questioned about other risk factors for pancreatitis, such as a history of pancreatitis, alcoholism, gallstones, or hypertriglyceridemia. Patients should also be informed that persistent severe abdominal pain, sometimes radiating to the back, which may or may not be accompanied by vomiting, is the hallmark symptom of acute pancreatitis. Patients should be instructed to promptly discontinue KOMBIGLYZE XR and contact their physician if persistent severe abdominal pain occurs [see *Warnings and Precautions*].

Patients should be informed that the incidence of hypoglycemia may be increased when KOMBIGLYZE XR is added to an insulin secretagogue (e.g., sulfonylurea) or insulin.

Patients should be informed that serious allergic (hypersensitivity) reactions, such as angioedema, anaphylaxis, and exfoliative skin conditions, have been reported during postmarketing use of saxagliptin. If symptoms of these allergic reactions (such as rash, skin flaking or peeling, urticaria, swelling of the skin, or swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing) occur, patients must stop taking KOMBIGLYZE XR and seek medical advice promptly.

Patients should be informed that KOMBIGLYZE XR must be swallowed whole and not crushed or chewed, and that the inactive ingredients may occasionally be eliminated in the feces as a soft mass that may resemble the original tablet.

Patients should be informed that if they miss a dose of KOMBIGLYZE XR, they should take the next dose as prescribed, unless otherwise instructed by their healthcare provider. Patients should be instructed not to take an extra dose the next day.

Healthcare providers should instruct their patients to read the Medication Guide before starting KOMBIGLYZE XR therapy and to reread it each time the prescription is renewed. Patients should be instructed to inform their healthcare provider if they develop any unusual symptom or if any existing symptom persists or worsens.

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AAFP Balances Critical Need for Effective Pain Management, Realities of Opioid Abuse

Academy Position Paper Opposes Mandated CME, Other Barriers for Prescribers

In a recently released paper, the AAFP has made it clear that the Academy opposes mandated CME as a prerequisite to DEA registration or licensure to prescribe opioid analgesics.

In an Aug. 1 position paper, "Pain Management and Opioid Abuse," the Academy states that mandated CME could limit patient access to legitimate pain management needs. "Family physicians and other primary care clinicians play a vital role in effective pain management, including the prescribing of opioid analgesics. The creation of additional prescribing barriers for primary care physicians would limit patient access when there is a legitimate need for pain relief," the Academy said in a related news release.

"As such, the AAFP opposes any action that limits patients' access to physician-prescribed pharmaceuticals, and opposes any actions by pharmaceutical companies, public or private health insurers, legislation, the FDA or any other agency, which may have the effect of limiting by specialty the use of any pharmaceutical product."

These statements reiterate two existing AAFP policies, one of which opposes any action limiting patient access to physician-prescribed pharmaceuticals, and the other of which "opposes legislation or executive action that would require mandatory education of family physicians as a condition for prescribing specific drugs, such as opioids."

The Academy outlined several other major points in the paper, including its view that the chief goal of pain management should be to improve and maintain patients' ability to function. The AAFP also urged family physicians to individualize therapy based on review of the potential risks and benefits to each patient, possible drug side effects, and a functional assessment of the patient, and to monitor ongoing therapy accordingly.

In addition, the Academy:

- Supports development of evidence-based physician education to ensure the safest and most effective use of long-acting and extended-release opioids and to reduce the problem of opioid abuse;
- Urges all states to obtain physician input when considering pain management regulation and legislation, as well as implement prescription drug monitoring programs and the interstate exchange of registry information as called for under the National All Schedules Prescription Electronic Reporting (NASPER) Act of 2005; and
- Strongly advocates increased national funding to support research into evidence-based strategies for optimal pain management and incorporation of those strategies into the patient-centered medical home model.

Many states already are working to control the problem of opioid misuse by, for example, adopting model medical board prescribing policies, instituting prescription monitoring programs and developing guidelines about documentation requirements. According to the AAFP, 37 out of 50 states have implemented, or are in the process of implementing, prescription drug monitoring programs that use NASPER grant funding. In addition, various professional organizations either have or are developing prescribing guidelines for physicians treating patients with chronic noncancer pain.

In the position paper, the Academy also cited the FDA's recently issued risk evaluation and mitigation strategy for extended-release and long-acting opioids, saying it will continue to work with the FDA and others on projects such as the FDA's Safe Use Initiative to "ensure policies are in place to allow effective and safe opioid prescribing by family physicians for patients in their pain management programs."

Originally published in AAFP News Now*, Aug. 2, 2012,*

ENDING CHILDHOOD OBESITY WITHIN A GENERATION

We support school-based nutrition and physical fitness initiatives, such as Fuel Up to Play 60, that help achieve these guiding principles:

1. Increase access to and consumption of affordable and appealing fruits, vegetables, whole grains, low-fat dairy products and lean meats in and out of school.

2. Stimulate children and youth to be more physically active for 60 minutes every day in and out of school.

3. Boost resources (financial/rewards/incentives/ training/technical assistance) to schools in order to improve physical fitness and nutrition programs.

4. Educate and motivate children and youth to eat the recommended daily servings of nutrient-rich foods and beverages.

5. Empower children and youth to take action at their school and at home to develop their own pathways to better fitness and nutrition for life.

Action for Healthy Kids®

AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN

eat right. American Dietetic Association
The world's largest organization of food and nutrition professionals.

USDA

FUEL UP to Play 60

NHMA National Hispanic Medical Association

NMA National Medical Association

SCHOOL NUTRITION ASSOCIATION

2012 IAFP Annual Convention: *Review and Photographs*

Outstanding Resident of the Year Erica Huddleston, MD, and her family attended our 2012 Annual President's Banquet.

IAFP members from across the state gathered in Indianapolis in July to attend the **2012 IAFP Annual Convention**. It was the first time in many years that we had held the meeting in Indianapolis, and this new centralized location resulted in significantly higher attendance figures. Attendees and their families enjoyed meeting in Indianapolis' thriving downtown area, with easy access to local attractions, museums, shopping and dining.

We offered more opportunities to earn **CME credit** this year, with more than 25 Prescribed AAFP CME credits available. Clinical topics and practice management sessions were included on the program, and all CME plans were based on previous attendee evaluations and IAFP member CME Needs Assessments.

We also featured an **MC-FP SAM Study Group** on cerebrovascular disease, which again proved so popular that it sold out early. Our facilitator, **Curt Ward, MD**, led participants through each of the 60 questions in the ABFM's Self-Assessment Module and oversaw interactive discussion among participants.

Many members attended the **All-Member Congress of Delegates** to have their votes and voices in IAFP business matters. Our **Town Hall Dinner** was a valuable opportunity to hear new policy topics from the thought leaders of Indiana and the nation. This year, we welcomed **Bob Phillips, MD**, the distinguished director of the Robert Graham Center, to discuss the neces-

sary changes the current graduate medical education funding system requires to support primary care.

Our **Annual President's Banquet and Installation of Officers,** followed by **All-Member Family Party**, was an exciting event for the whole family. An elegant dinner was held to honor our incoming and outgoing president and the contributors to our *Family Practice Stories Book*. Later in the evening, children joined their parents for a dessert buffet and dancing, with entertainment by the Marlins. We also honored **Erica R. Huddleston, MD**, who was selected as the recipient of this year's Outstanding Resident award. Dr. Huddleston has been selected as chief resident at Community Health Network Family Medicine Residency Program in Indianapolis.

Students, residents and residency faculty members were invited to a "Preparing for the Match" panel, followed by a special Congress of Delegates Orientation. The session ended with a reception — a great chance for students to learn more about our residencies. Immediately following the close of the Scientific Assembly, we held a **picnic at Victory Field**, where we cheered on the Indianapolis Indians.

IAFP First Vice President David Schultz, MD; his wife, Kendra; and their son, Jonathan

Larry Allen, MD, and Risheet Patel, MD, in conversation at the Congress of Delegates

JW Malenkos, MD; Samir Ginde, MD; and Nathan Mcloed, MD, at the President's Banquet

Juan Carlos Venis and Jason White, IAFP student leaders

See lots more photos on our Facebook page: www.facebook.com/inafp!

Our **Exhibit Show** offered an opportunity to learn about the newest clinical advances and practice management tips and services. A huge thank-you to the following companies that were in attendance:

Abbott
Achieve EHR
American Express
American Health Network
Astellas Pharma US, Inc.
ATI Physical Therapy
Balance MD
Boehringer Ingelheim Pharmaceuticals
Bristol-Myers Squibb
Care Improvement Plus
Community Health Network
Covidien
EmCare
Esacote North America
Essential Molecular/PGX Laboratories
Goodman Campbell Brain and Spine
Grifols, Inc.
Health Diagnostic Laboratory, Inc.
Indiana Academy of Family Physicians
Indiana Army National Guard
Indiana Spine Group
Inquest Health System
iSalus Healthcare
Kowa Pharmaceuticals America
MD Wise
Medical Protective
Medstar Laboratory, Inc.
Merck & Co., Inc.
Michael H. Fritsch, MD – Otology
MMIC
Northwest Radiology Network
OrthoIndy
ProAssurance
Purdue Pharma L.P.
Reid Hospital
Sanofi Pasteur
South Bend Medical Foundation
St. Vincent

- Peyton Manning Children's Hospital at St. Vincent
- St. Vincent Bariatric Center of Excellence
- St. Vincent Cancer Care
- St. Vincent Critical Care Transport
- St. Vincent Heart Center of Indiana
- St. Vincent Women's Maternal Fetal and Neonatal Services
- St. Vincent Medical Group
- St. Vincent Medical Imaging
- St. Vincent Neuroscience Institute
- St. Vincent One Call Transfer
- VeinSolutions, a member of St. Vincent Medical Group
- St. Mary's Hospital, Evansville, Indiana

SuccessEHS
Teva Respiratory
U.S. Air Force
Urology of Indiana
Vein Clinics of America
ViroPharma, Inc.
We Care TLC

Newly installed IAFP President Risheet Patel, MD, attends the President's Banquet with his family and girlfriend Aimee Sirois, MD.

Thank you to our CME moderators:

- Fred Ridge, MD
- Risheet Patel, MD
- Teresa Lovins, MD
- Tom Kintanar, MD
- Daniel Walters, MD

Thank you also to Deanna Willis, MD, and Ken Elek, MD, who opened the program for us.

The Indiana Academy of Family Physicians gratefully acknowledges the following companies/organizations for providing educational support and/or grants for the 2012 IAFP Annual Convention:

- American Board of Family Medicine
- American Academy of Family Physicians, supported by an educational grant from Endo Pharmaceuticals, Inc., Jansen Pharmaceuticals, Inc., administered by Janssen Scientific Affairs, LLC, and Purdue Pharma, L.P.
- California Academy of Family Physicians, supported by an educational grant from Bristol-Myers Squibb and Pfizer
- CorVasc MDs
- Eli Lilly & Co.
- Hall Render Killian Heath & Lyman
- Indiana University School of Medicine
- iSalus, Inc.
- Managed Health Services
- Newby Consulting
- Outcomes Managed Educational Workshops (OMEW)
- WellPoint, Inc.

Thank you to the following companies who supported our Annual Convention through sponsorships of materials and/or special events:

- CS2Day
- Goodman Campbell Brain and Spine
- Indina University School of Medicine
- iSalus Healthcare
- Balance MD
- Lutheran Medical Group

"Seriously Inspired"

by Tiffany Meador, MD

After returning from Kansas City, the conference theme still resonates in my mind, and I am left "Seriously Inspired." Inspired to advocate for the broadened scope of practice, for Medicaid reimbursement and for continued graduate medical education funding. Inspired to pursue research grants, fellowship opportunities and international electives. Inspired to further serve my patients, my community and my fellow colleagues.

The 2012 National Conference of Family Medicine Residents was a unique opportunity to meet residents, students and physicians from across the nation who are like-minded in their passion for family medicine. I am honored to have served as the Indiana Chapter delegate at the resident Congress of Delegates. In addition to browsing the endless rows of booths in the exhibit hall, I participated in resolution-writing, candidate elections and voting on key resolutions that may go on to influence AAFP policy.

Resolution Writing

After learning that resolutions are the conduit for creating AAFP policy, I was inspired to write a resolution requesting that the AAFP explore opportunities for residents and students to be representatives on the board of the Center for International Health Initiatives (CIHI). CIHI is an advisory board that, among other things, hosts the annual Global Health Workshop, which will be in Minneapolis later this year. Considering that more family medicine residents and residency programs are showing an interest in Global Health, and students who participate in international electives are more likely to go into primary care specialties, resident and student representatives could offer meaningful insight to the Board's activities as well as experience significant educational value and leadership opportunities.

Resolutions

The following are just a sample of the resolutions that were adopted this year and will be referred by the AAFP Board of Directors to the appropriate Academy entity. This group then reviews the resolution and determines if further action is appropriate and if policy should be developed relating to the topic of the resolution.

RESOLVED:

1. That the AAFP create policy regarding use of social media by its member physicians.
2. That the AAFP support civil marriage for same-gender couples to contribute to overall health and longevity, improved family stability and to benefit children of gay, lesbian, bisexual, transgender (GLBT) families.
3. That the AAFP amend their policy on Ethics and Advanced Planning for End-of-Life Care to state "Family physicians should continue to support the medical, psychological and spiritual needs of dying patients and their families by initiating Advanced Directive discussions and end-of-life planning during times of health."
4. That the AAFP strongly endorse its support for universal access to contraceptives.
5. That the AAFP support reasonable accommodation for medical students and residents who are breastfeeding.

It was a great honor to serve as the Indiana Chapter delegate to the 2012 National Conference. I hope my fellow residents are as inspired as I am to continue the pursuit of excellence in family medicine.

***Tiffany Meador, MD**, is a family medicine resident (PGY-2) at St. Vincent Family Medicine Residency Program in Indianapolis, and the IAFP's resident delegate to the AAFP. After attending the AAFP's 2012 National Conference of Family Medicine Residents, Dr. Meador sent us this report about her experiences.*

Clif Knight, MD, Candidate for AAFP

The IAFP's current president, Risheet Patel, MD, recently interviewed Dr. Knight. This interview gives insight into Dr. Knight's goals, priorities and experience as he begins his campaign for the AAFP Board of Directors.

Why are you running for the AAFP Board of Directors?
I've served state and national academies in some capacity ever since I was a medical student almost 30 years ago. It has been incredibly challenging but equally educational and satisfying. The opportunity to serve our membership on the AAFP Board of Directors is incredibly appealing to me. The Academy makes a difference in the professional and personal lives of our members and a positive impact on the patients and communities that they serve everyday. I would consider it a privilege to serve on the AAFP Board, knowing that I am able to influence the strategic direction of the organization and positively influence the lives of our members and their patients.

If elected, what would some of your goals and priorities be during your term?
As a member of the Board, I would strive to make sure that the limited resources of our Academy are being focused on those areas that mean the most to our members. Having served on the Commission on Membership and Member Services, I am familiar with our member satisfaction surveys and the resulting priorities identified by those surveys. Now more than ever, we need to be deliberate about using the data from our membership surveys to prioritize our resources for meeting the needs of our members and the patients and communities they serve. We must always have that check step — making sure that when we utilize resources, we are answering the needs of our membership and effectively meeting our members' expectations.

What are some of the leadership strengths that you will take to the AAFP Board of Directors?
The diversity of experiences that I've had will contribute to this leadership role — rural practice, the academic environment and now a system leadership role. I have developed a thorough understanding of education principles and the importance of legislative advocacy and have been involved as a student, a resident and a new physician. I am very deliberate about being open-minded, listening to differing opinions, and trying to make decisions based on both evidence and experience. A willingness to innovate and try things differently is a great strength of mine. And I'm very optimistic and very passionate about the core principles of family medicine.


Collaborating with other health care advocates during the Indiana General Assembly


Clif and his family enjoy sightseeing in London, England.

You've mentioned the need to focus on the priorities of the overall membership. Can you expand on this?
Every organization has limited resources. What you have to be careful of is not giving into the temptation of pursuing your own pet projects or favorites of individual members. That's where it takes a strong team to be able to work together, challenge each other and go back to those guiding principles. As a membership organization, we exist to serve our members. We need to feel confident that we can collegially and professionally challenge each other as we make difficult decisions on not just which programs to pursue but also which programs may need to be discontinued. That's a difficult conversation, but you have to take the personalities out and look at it from an organizational standpoint and what is best for our members and their patients.

Are there examples of when you've had to do something at the state chapter or with work responsibilities that may have helped with that?
At the state chapter, we've had to make decisions that have changed the makeup of our districts and the logistics of our congress. These changes may have been unsettling for a few, but as a group we came together and made decisions from an organizational standpoint that made our Academy more focused, efficient and effective.

You are on the Board of Trustees for a new medical school here in Indiana. What have you gained from this experience?

Board of Directors

I'm on the Board of Trustees of Marian University, which is developing a new college of osteopathic medicine. Because it is a new school, we have had the opportunity to develop the leadership and curriculum in a way that gives students an early appreciation for the importance of primary care. This experience has helped me better understand what needs to be done across the country as we are trying to make changes in medical school structures and curriculum that will more appropriately enhance and spotlight the importance of family medicine and primary care.

Can you describe your work experience?

Post-residency, I joined a three-physician family medicine practice in a small rural town about 45 miles from the nearest hospital. We did inpatient and prenatal care, covered a significant nursing home population and did a wide variety of procedures. After a few years, I had an opportunity to begin teaching in the residency that I trained in. I was full-time faculty for 15 years, including five years as program director. I was also the medical director of a 100-bed extended-care facility during part of my time at the residency program. About five years ago, I became vice president of medical affairs for two acute-care hospitals before becoming chief medical officer and vice president of medical and academic affairs for Community Health Network in Indianapolis.

And what do you do in your current position?

I facilitate quality improvement and support our approximately 2,000 physician medical staff. With the roll out of electronic health records (EHR) throughout all of our facilities, I work from the standpoint of how our physician population interacts with the EHR and how they work as part of the teams caring for patients. We have recently expanded our residency program by affiliating with an osteopathic hospital and are in the process of gaining the accreditation needed to build additional residency programs. I am responsible for making sure that we have the resources to allow medical students and residents to have excellent educational and clinical opportunities. I continue to see patients on a limited but regular basis. The majority of my patients are folks that I have taken care of for 20 or more years and have established relationships with.

What experience do you have at the AAFP state and national level?

I've been blessed to have served in a wide variety of leadership roles within our state chapter, dating back to medical school, including president and chairman of the Board. I have served as chair of our Foundation Board of Trustees, Commission on Legislation and our Political Action Com-

Continued on page 26

Report from the 2012 IAFP Congress of Delegates

The IAFP Congress of Delegates, which is open to all members, met on July 27 and 28 in conjunction with the IAFP Annual Convention. This year, the Congress heard a total of 11 resolutions and two recommendations — all sent in from IAFP members.

One of the Congress' main tasks in 2012 was to vet potential changes to the IAFP's governance (see Mandate #2). The IAFP's Taskforce on Leadership sent to the Congress a resolution on how to streamline the IAFP board structure. The Taskforce on Leadership's resolution passed the Congress with a number of amendments. Next, the IAFP Bylaws Committee will have approximately 11 months to work on converting the resolution into a bylaws amendment. The amendment will be presented to the 2013 Congress of Delegates. If passed, the IAFP governance structure will be updated.

The Congress also considered eliminating IAFP local dues. The Congress agreed to end the $15 local dues charge and subsequently increase member state dues by $15. The move will keep the IAFP accounting cleaner and should end the confusion that an extra dues schedule causes. Local activities (like region meetings) will continue to be funded under a line item in the IAFP budget.

All items passed by the IAFP Congress are referred to as mandates. A full list of IAFP mandates are included in this article. During the next year the IAFP Commissions and Committees will take action on the mandates, including forwarding resolutions onto the AAFP Congress of Delegates, which takes place in October in Philadelphia, Pennsylvania.

For a full accounting of the 2012 Congress, visit http://www.in-afp.org/allmembercongressofdelegatessummary/ and click on "2012 Congress of Delegates Transactions."

IAFP 2012 Mandates

Item #1: IAFP Region Dues
Assigned to: *Executive Committee*

RESOLVED, that the Indiana Academy of Family Physicians eliminate the region (local) dues of $15; and be it further

RESOLVED, that the Indiana Academy of Family Physicians increase its state chapter dues by $15, and be it further

RESOLVED, that the Indiana Academy of Family Physicians have a line item in its annual budget for region activities.

Item #2: IAFP Governance
Assigned to: *Bylaws Committee*

RESOLVED, that the Bylaws and appropriate Rules and Regulations of the IAFP be changed to reflect the changes in governance structure outlined in Attachment A.

Attachment A
Executive Committee Membership: President, President-Elect, Immediate Past President, Treasurer, Board Chair (if filled by an individual other than one of the aforementioned officers) and Speaker (non-voting member).

Election Process: The President-Elect is elected by the Congress of Delegates yearly at the Annual Meeting for a one-year term with automatic advancement to President (also a one-year term). Physician members eligible for election to President-Elect include any member not otherwise excluded by term limits and who has spent at least one three-year cycle on the Board of Directors. The President-Elect will be elected by a simple majority of the Congress of Delegates each year. Candidates for President-Elect may announce their candidacy at any time after the Congress of Delegates which immediately precedes the meeting in which they hope to be elected. Treasurer follows existing process for Treasurer selection.

Terms of office: After serving as Immediate Past President, members must wait two years before running for a Board of Directors at large seat. The Speaker and Vice-Speaker may fulfill 2 consecutive three-year terms, and then must wait 2 years before seeking another term.

Scope of work: Meet as needed to oversee Board processes and provide staff oversight. Oversee internal conflict and any actions against members, leadership, or the organization of a sensitive or confidential nature. Perform the annual review of the EVP.

Board of Directors

Membership: Executive Committee, both AAFP Delegates, and six at-large directors. The student and resident regions are each expected to designate a voting member to attend all meetings of the board of directors. In instances where AAFP Delegates cannot attend, their AAFP Alternate Delegate can vote in their place. The Speaker of the Congress shall be a voting member to the Board of Directors. In instances when the Speaker cannot attend a Board meeting, the Vice Speaker should vote in the Speaker's place. The Bylaws committee will consider the need for alternate directors.

Election Process: The at-large members of the Board of Directors will serve in three-year staggered terms with a yearly election of two new at-large members held by the Congress of Delegates. At-large members of the Board may serve up to 2 consecutive terms (with formal re-election required) and then must sit out at least 1 year before again pursuing re-election to the Board.

Scope of work: Meet quarterly to accomplish the work of the IAFP Congress of Delegates and oversee the activities of the organization as outlined in the IAFP Bylaws and Rules and Regulations. The Board of Directors shall assign from among its members a liaison to each of the standing commissions/committees of the IAFP.

Congress of Delegates

Membership: Unchanged from current of All Member Congress of Delegates set up. Election Process: Unchanged from current All Member Congress of Delegates process.

Scope of work: Town hall meetings, open to full IAFP membership, either in person or by electronic means will provide opportunities for ongoing dialogue between the IAFP Board of Directors and a wide scope of members. These meetings will be called as specific issues of importance or urgency arise throughout the year. The members present at the Congress of Delegates at the Annual Convention may be called upon to respond to queries for information or action to assist the Board of Directors up until the following Annual Meeting.

Commissions and Committees: No change is anticipated to the current commission and committee structure. Responsibility and frequency of meetings for commissions and committees will potentially increase. Physician members may serve in an unlimited capacity on IAFP Commissions and Committees.

Nominating Committee: The Nominating committee's scope will be increased to identifying demographics that need to be included on the board, and identifying and recruiting executive committee and board members for election by the Congress.

AAFP Delegation: No process changes

Region Governance: There shall no longer be elected a Director or Alternate Director in title from any region nor regular or required region meetings.

Region structure: This will remain unchanged.

Student and Resident Governance: The student and resident regions will be allowed to choose the process by which they choose their representatives to the Board of Directors.

Transition plan: Upon passage, this resolution will be referred to the bylaws committee, which will be asked to return with updated bylaws for consideration by the

Congress in 2013. Upon passage of those bylaws, the new governance structure will go into effect immediately. The Bylaws Committee will be developing a plan for the exact nature of the transition. The currently slated 1st Vice President (who was elected as 2nd Vice President in 2012) will assume a one-year At-Large Board member position. Positions will be refilled in the process outlined in the Board of Directors Election Process above.

Vacancies: In the event of a vacancy in the Board of Directors or Executive Committee, the Executive Committee will work with the Congress of Delegates to fill such positions expeditiously and with a fair election process.

In absentia: In the event that a nominee for any position exists but is unable to attend the meeting at which they would attempt to be elected, they may still run assuming they have submitted such a request in writing prior to the start of that year's Congress of Delegates. After the initial call for nominees at the Congress of Delegates, no further nominees, in person or in writing, will be accepted.

Deficiencies: Should there be found any deficiencies in the plan as outlined above during the transition period, the Board of Directors is authorized to make such changes as necessary to remedy the situation. Should any substantive changes be required, these must be presented for a vote of the Congress of Delegates.

Item #3: AAFP Corporate Dues
Assigned to: *AAFP Delegates*

RESOLVED, that the IAFP send a resolution to the AAFP Congress of Delegates asking the AAFP to study the creation of a new class of "corporate dues" wherein entities paying dues for a large number of physicians can pay at a lower rate.

RESOLVED, that the resolution not be sent to the AAFP Congress of Delegates should we find that the AAFP is already considering a new class of corporate dues.

Item #4: Identification of Credentials
Assigned to: *Commission on Legislation and Governmental Affairs*

RECOMMENDATION: The reference committee recommends that the resolution be referred to the IAFP Commission on Legislation for action. RESOLVED, that the IAFP support legislation or regulation requesting that all nurse practitioners and physician assistants identify themselves with their full and proper credentials (Physician Assistant, Doctor of Nursing Practice, Nurse Practitioner) when meeting a patient or family caring for a patient for the first time and give these patients or family member the name of their collaborating or supervising physician.

Item #5: Prior Authorization and Pharmacy Benefit Managers
Assigned to: *Commission on Health Care Services*

RESOLVED, the IAFP will discuss with pharmaceutical benefit managers requesting that when a prescribed medication is denied, the pharmaceutical benefit manager provides in the first communication what other therapeutic options are covered.

Item #6: Indoor Tanning
Assigned to: *Commission on Health Care Services and Commission on Legislation and Governmental Affairs*

RESOLVED, that the IAFP support better education of all citizens of Indiana related to the risks of indoor tanning.

Item #7: Health Care Workforce Center
Assigned to: Executive Committee

RECOMMENDATION: The IAFP leadership and staff will work with the Indiana Area Health Education Center (AHEC), and other key stakeholders from around the state, to evaluate, develop, and promote, including


2012's Congress of Delegates gets underway.

lobbying as necessary, the establishment of a health care workforce center for Indiana.

Item #8: Gathering Support for PCMH Payment by Payors
Assigned to: *Executive Committee*

RECOMMENDATION: The IAFP leadership and staff will work with co-sponsors of a resolution to the Indiana State Medical Association (ISMA) to endorse a resolution asking the ISMA to be more active in promoting the patient centered medical home, including appropriate increased payment for services provided with payors active in Indiana.

Item #9: Methadone Clinics and INSPECT
Assigned to: *Commission on Legislation and Governmental Affairs*

RESOLVED, that the IAFP support legislation or regulation that requires methadone clinics to submit INSPECT reports the same as pharmacies currently do.

Item #10: Training or Licensure for Prescribing Narcotic Painkillers
Assigned to: *Commission on Education and Commission on Health Care Services*

RESOLVED, that the IAFP regularly report to its members regarding the AAFP investigation of possible voluntary training, mandatory training, or specific licensure for physicians to prescribe narcotic painkillers.

Office of Inspector General 2012 Work Plan

by Joy Newby, LPN, CPC, PCS, Newby Consulting, Inc.

At the end of each fiscal year, the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) publishes its Work Plan. This article provides brief descriptions of new and ongoing reviews and activities that OIG plans to pursue with respect to HHS programs and operations for the next fiscal year. In this newsletter, Newby Consulting, Inc. (NCI) selected three reviews and activities the OIG plans to pursue that affect all physicians.

The OIG's work plan includes several reviews related to evaluation and management (E/M) codes. One review has been completed, and a report has been issued. Other reports regarding E/M services are expected later this year.

Evaluation and Management Services: Trends in Coding of Claims

The OIG will review evaluation and management (E/M) claims to identify trends in the coding of E/M services from 2000 to 2009. They will also identify providers that exhibited questionable billing for E/M services in 2009. Medicare paid $32 billion for E/M services in 2009, representing 19 percent of all Medicare Part B payments. Providers are responsible for ensuring that the codes they submit accurately reflect the services they provide (CMS' *Medicare Claims Processing Manual*, Pub. No. 100-04, Ch. 12, § 30.6.1). E/M codes represent the type, setting and complexity of services provided and the patient status, such as new or established (OEI; 04-10-00180; expected issue date: FY 2012; work in progress).

On May 5, 2012, the OIG issued the first in a series of reports discussing the utilization of evaluation and management (E/M) services. The report, "Coding Trends of Medicare Evaluation and Management Services," notes the number of E/M services billed increased by 13 percent.

The report notes that established patient office visits represented the largest amount of Medicare payments for E/M services in 2010. While 99213 was billed most often during the 10-year period, the OIG noted a shift in billing from the three lower-level E/M codes to the two higher-level codes. Combined, physicians increased their billing of the two highest level E/M codes (99214 and 99215) by 17 percent between 2001 and 2010.

Based on the OIG's findings, the Centers for Medicare & Medicaid Services (CMS) is developing and issuing comparative billing reports (CBR) aimed at 5,000 physicians across the country who have consistently billed for high-level E/M codes. The report is not intended to be punitive or an indication of fraud. CMS will be proactive by providing information about the physicians' coding and billing practices. According to CMS, this should help providers identify potential errors in billing practices and make changes to help prevent improper billing and payment in the future.

Comparative Billing Reports

Under CMS contracts, comparative billing reports are produced by SafeGuard Services LLC and distributed by Livanta LLC. The reports provide comparative data on how an individual physician varies from other physicians in the same specialty by looking at utilization patterns. The billing data in the report includes a comparison of the physician's own billing pattern with the state and national average billing patterns for the physician's specialty.

These reports explain that CMS hopes the physician will find the "educational tool" helpful in "identifying opportunities for improvement." Further, CMS "believes the information can assist the physician in performing a self-audit to assess conformity with Medicare billing guidelines." A sample CBR can be found on Safeguard Services' website at http://www.safeguard-servicesllc.com/cbr/documents/CBR016_Evaluation_Management_Services_sample.pdf.

Some Part A/B Medicare Administrative Contractors (MAC) issue their own CBRs. The reports include an explanation of why the physician received the CBR. As an example, one MAC includes the following warning in a CBR related to E/M coding:

…upcoding and under coding are viewed as errors by Medicare. If your billing pattern significantly varies from that of your peers, as shown in the graph above, please review your coding and billing of this category of E/M services for accuracy. If error rates do not decrease, Medicare may have to perform additional edits/audits or provider specific reviews to lower the error rate.

Although we were not able to obtain family practice's utilization of E/M codes on the state level, we were able to locate the most recent data for family practice's national utilization of E/M codes (dates of service January 1, 2011, through June 30, 2011)

New Patient E/M Codes	National Utilization
99201	1.23%
99202	15.60%
99203	46.51%
99204	30.16%
99205	6.51%

Established Patient	E/M Codes National Utilization
99211	3.72%
99212	4.30%
99213	48.19%
99214	40.23%
99215	3.56%

on Palmetto GBA Medicare's website. Additional specialties are also available on the following website: http://www.palmettogba.com/Palmetto/Providers.Nsf/files/6-2011_NC_EM_Comparison_Report.pdf/$File/6-2011_NC_EM_Comparison_Report.pdf.

Palmetto's data did not include family practice's national distribution for established patient E/M codes. Although not as current, we found national data for calendar year 2010 on the CMS website. Using this data, we calculated family practice's national utilization of established patient E/M codes. Additional information for family practice and other specialties can be found on the CMS website at http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareFeeforSvcPartsAB/downloads//EMSpecialty2010.pdf?agree=yes&next=Accept.

Compare your utilization of E/M codes with the national statistics. This will assist you in determining what codes to focus on when you perform your coding and documentation review.

Evaluation and Management Services: Potentially Inappropriate Payments

The OIG will assess the extent to which CMS made potentially inappropriate payments for E/M services and the consistency of E/M medical review determinations. This assessment will also review multiple E/M services for the same providers and beneficiaries to identify electronic health records (EHR) documentation practices associated with potentially improper payments. Medicare contractors have noted an increased frequency of medical records with identical documentation across services. Medicare requires providers to select the code for the service based upon the content of the service and have documentation to support the level of service reported (CMS' *Medicare Claims Processing Manual*, Pub. No. 100-04, Ch. 12, § 30.6.1) (OEI; 04-10-00181; 04-10-00182; expected issue date: FY 2013; work in progress).

Later in 2012, the OIG expects to issue two additional reports on E/M codes. One will determine the appropriateness of Medicare payments for E/M services. The other will assess the extent of documentation vulnerabilities in E/M services using electronic health record systems.

Documentation Versus Medical Necessity

There are two sets of documentation guidelines for evaluation and management services, 1995 and 1997. CMS has instructed its contractors to use the guidelines that are most advantageous to the physicians. The only significant difference between the 1995 and 1997 guidelines is in the examination components. The exam component in the 1995 guidelines is based on organ systems and body areas. *The 1995 Documentation Guidelines for Evaluation and Management Services* are available on the CMS website at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/95Docguidelines.pdf

To read the rest of this article, please visit www.in-afp.org and click on Education & Practice Management > Coding and Billing Updates.

"Clif Knight, MD, for AAFP Board of Directors," continued from page 21.

mittee. I was a member of the AAFP New Physicians Committee and represented the AAFP at the Young Physicians Section of the AMA. I later served on the AAFP Commission on Membership and Member Services, which resulted in the opportunity to chair the special constituencies subcommittee. Currently, I serve on the AAFP Commission on Quality and Practice, and I and have served in the AAFP Congress of Delegates for the last 12 years.

What are some of the biggest challenges you feel family physicians are facing in today's environment?

I think the current, and huge, environment of change is the greatest challenge to family physicians today. Changes to the way we are reimbursed, the rapid increase in new technology, the continued flux of health care reform, system changes such as the statewide health care insurance exchanges, the heightened shortage of primary care physicians, etc., all can be overwhelming for our membership, and as an Academy, we must provide support and services that empower family physicians to turn these changes into a benefit rather than a hindrance. We need to help support our members and give them confidence that they are in an enhanced position of influence that they have potentially not had before.

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