PATIENTS TAKE CHARGE
How physicians can adapt to the empowerment trend

That's not correct...
Everyone on Facebook says this is the right treatment.
Google says...
I just need an antibiotic.
Why can't I have the drug I saw advertised on TV?
Why are you charging so much?
I don't want to do that.
Primary end point: A1C change from baseline at week 26

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>STEGLATRO 5 mg</th>
<th>STEGLATRO 15 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N</strong></td>
<td>152; BL=8.0%</td>
<td>155; BL=8.1%</td>
<td>152; BL=8.0%</td>
</tr>
<tr>
<td><strong>DIF. FROM PLACEBO, %</strong></td>
<td>-0.5 (P&lt;0.001)</td>
<td>-0.6 (P&lt;0.001)</td>
<td></td>
</tr>
</tbody>
</table>

* N includes all randomized and treated patients with a baseline measurement of the outcome variable. At week 26, the primary A1C end point was missing for 10%, 11%, and 7% of patients, and during the trial, rescue medication was initiated by 16%, 1%, and 2% of patients randomized to placebo, STEGLATRO 5 mg, and STEGLATRO 15 mg, respectively. Missing week 26 measurements were imputed using multiple imputation with a mean equal to the baseline value of the patient. Results include measurements collected after initiation of rescue medication. For those patients who did not receive rescue medication and had values measured at 26 weeks, the mean changes from baseline for A1C were –0.2%, –0.8%, and –0.9% for placebo, STEGLATRO 5 mg, and STEGLATRO 15 mg, respectively.

b Intent-to-treat analysis using ANCOVA adjusted for baseline value, prior antihyperglycemic medication, and baseline estimated glomerular filtration rate (eGFR).

ANCOVA=analysis of covariance; BL=baseline; LS=least squares.
Study design: 463 adults with type 2 diabetes, inadequately controlled (A1C between 7% and 10.5%) on metformin (≥1500 mg/day for 8 weeks) and sitagliptin 100 mg once daily participated in a randomized, double-blind, multicenter, 26-week, placebo-controlled study to evaluate the efficacy and safety of STEGLATRO. Study subjects were randomized to STEGLATRO 5 mg, STEGLATRO 15 mg, or placebo administered once daily in addition to continuation of background metformin and sitagliptin therapy. The primary efficacy end point was the change from baseline in A1C at week 26.

STEGLATRO is indicated as an adjunct to diet and exercise for appropriate adults with type 2 diabetes. STEGLATRO is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

SELECTED SAFETY INFORMATION

Contraindications: STEGLATRO is contraindicated in patients with severe renal impairment, end-stage renal disease, or on dialysis, and/or a history of a serious hypersensitivity reaction to ertugliflozin.

Hypotension: STEGLATRO causes intravascular volume contraction. Symptomatic hypotension may occur after initiating STEGLATRO, particularly in patients with impaired renal function (estimated glomerular filtration rate [eGFR] less than 60 mL/min/1.73 m²), elderly patients (≥65 years), patients with low systolic blood pressure, or patients on diuretics. Before initiating STEGLATRO, volume status should be assessed and corrected if indicated. Monitor for signs and symptoms after initiating therapy.

Ketoacidosis: Ketoacidosis, a serious life-threatening condition requiring urgent hospitalization, has been reported in patients with type 1 and type 2 diabetes receiving sodium glucose co-transporter 2 (SGLT2) inhibitors, including STEGLATRO. Some cases were fatal. Assess patients with signs and symptoms of metabolic acidosis for ketoacidosis, regardless of blood glucose level. If ketoacidosis is suspected, STEGLATRO should be discontinued, patients should be evaluated, and prompt treatment should be instituted. Before initiating STEGLATRO, consider risk factors for ketoacidosis, including pancreatic insulin deficiency from any cause, caloric restriction, and alcohol abuse. In patients treated with STEGLATRO, consider monitoring for ketoacidosis and temporarily discontinuing STEGLATRO in clinical situations known to predispose to ketoacidosis (eg, prolonged fasting due to acute illness or surgery).

Additional Selected Safety Information on next page.
Choose STEGLATRO™ (ertugliflozin) for appropriate adults with type 2 diabetes

STEGLATRO is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. STEGLATRO is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

SELECTED SAFETY INFORMATION (continued)

Acute Kidney Injury and Impairment in Renal Function: STEGLATRO causes intravascular volume contraction and can cause renal impairment. There have been postmarketing reports of acute kidney injury, some requiring hospitalization and dialysis, in patients receiving SGLT2 inhibitors. Before initiating STEGLATRO, consider factors that may predispose patients to acute kidney injury. Consider temporarily discontinuing STEGLATRO in any setting of reduced oral intake or fluid losses; monitor patients for signs and symptoms of acute kidney injury. If acute kidney injury occurs, discontinue STEGLATRO promptly and institute treatment.

STEGLATRO increases serum creatinine and decreases eGFR. Patients with moderate renal impairment (eGFR 30 to less than 60 mL/min/1.73 m²) may be more susceptible to these changes. Renal function abnormalities can occur after initiating STEGLATRO. Renal function should be evaluated prior to initiating STEGLATRO and periodically thereafter. Use of STEGLATRO is not recommended when eGFR is persistently between 30 and less than 60 mL/min/1.73 m² and is contraindicated in patients with an eGFR less than 30 mL/min/1.73 m².

Urosepsis and Pyelonephritis: There have been postmarketing reports of serious urinary tract infections, including urosepsis and pyelonephritis, requiring hospitalization in patients receiving SGLT2 inhibitors. Cases of pyelonephritis also have been reported in patients treated with STEGLATRO in clinical trials. Treatment with SGLT2 inhibitors increases the risk for urinary tract infections. Evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated.

Lower Limb Amputations: An increased risk for lower limb amputation has been observed in clinical studies with another SGLT2 inhibitor. Across seven Phase 3 clinical trials with STEGLATRO, nontraumatic lower limb amputations were reported in 1 (0.1%) patient in the comparator group, 3 (0.2%) patients in the STEGLATRO 5-mg group, and 8 (0.5%) patients in the STEGLATRO 15-mg group. A causal association between STEGLATRO and lower limb amputation has not been definitively established. Before initiating STEGLATRO, consider factors that may predispose patients to the need for amputations. Monitor patients and discontinue STEGLATRO if complications occur. Counsel patients about the importance of routine preventative foot care.

Hypoglycemia With Concomitant Use With Insulin and Insulin Secretagogues: Insulin and insulin secretagogues (e.g., sulfonylurea) are known to cause hypoglycemia. STEGLATRO may increase the risk of hypoglycemia when used in combination with insulin and/or an insulin secretagogue. Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with STEGLATRO.

Necrotizing Fasciitis of the Perineum (Fournier’s Gangrene): A rare but serious and life-threatening necrotizing infection requiring urgent surgical intervention has been reported in postmarketing surveillance in females and males with diabetes mellitus receiving SGLT2 inhibitors. Serious outcomes have included hospitalization, multiple surgeries, and death. Patients treated with STEGLATRO presenting with pain or tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise, should be assessed for necrotizing fasciitis. If suspected, start treatment immediately with broad-spectrum antibiotics and, if necessary, surgical debridement. Discontinue STEGLATRO, closely monitor blood glucose levels, and provide appropriate alternative therapy for glycemic control.

Genital Mycotic Infections: STEGLATRO increases the risk of genital mycotic infections. Patients who have a history of genital mycotic infections or who are uncircumcised are more likely to develop genital mycotic infections. Monitor and treat appropriately.

Increases in Low-Density Lipoprotein Cholesterol (LDL-C): Dose-related increases in LDL-C can occur with STEGLATRO. Monitor and treat as appropriate.

Macrovascular Outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with STEGLATRO.

The most common adverse reactions associated with STEGLATRO (≥5%) were female genital mycotic infections.

Please read the adjacent Brief Summary of the Prescribing Information.
INDICATIONS AND USAGE
STEGLATRO™ (ertugliflozin) 5 mg, 15 mg tablets

STEGLATRO™ is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use
- STEGLATRO is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

CONTRAINDICATIONS
- E’SEGRATRO is not recommended in patients with an eGFR of 30 mL/minute/1.73 m² to less than 60 mL/minute/1.73 m². No dose adjustment is needed in patients with mild renal impairment.

WARNINGS AND PRECAUTIONS
- Hypotension. STEGLATRO causes intravascular volume contraction. Therefore, symptomatic hypotension may occur after initiating STEGLATRO [see Adverse Reactions] particularly in patients with impaired renal function (eGFR less than 60 mL/min/1.73 m²) [see Use in Specific Populations]. Volume status should be assessed and corrected if indicated. Monitor for signs and symptoms of hypotension after initiating therapy.

- Ketoacidosis. Reports of ketoacidosis, a serious life-threatening condition requiring urgent hospitalization, have been identified in clinical trials and postmarketing surveillance in patients with type 1 and type 2 diabetes mellitus receiving sodium glucose co-transporter-2 (SGLT2) inhibitors and cases have been reported in STEGLATRO-treated patients in clinical trials. Across the clinical program, ketoacidosis was identified in 3 of 3,409 (0.1%) of STEGLATRO-treated patients and 0% of comparator-treated patients. Fatal cases of ketoacidosis have been reported in patients taking SGLT2 inhibitors. STEGLATRO is not indicated for the treatment of patients with type 1 diabetes mellitus [see Indications and Usage].

- Patients treated with STEGLATRO who present with signs and symptoms consistent with severe metabolic acidosis should be assessed for ketoacidosis regardless of presenting blood glucose levels, as ketoacidosis associated with STEGLATRO may be present even if blood glucose levels are less than 250 mg/dL. If ketoacidosis is suspected, STEGLATRO should be discontinued, patient should be evaluated, and prompt treatment should be instituted. Treatment of ketoacidosis may require insulin, fluid and carbohydrate replacement.

- Many of the reported cases, and particularly in patients with type 1 diabetes, the presence of ketoacidosis was not immediately recognized and institution of treatment was delayed because presenting blood glucose levels were below those typically expected for diabetic ketoacidosis (often less than 250 mg/dL). Signs and symptoms at presentation were consistent with dehydration and severe metabolic acidosis and included nausea, vomiting, abdominal pain, generalized malaise, and shortness of breath. In some but not all cases, factors predisposing to ketoacidosis such as insulin dose reduction, acute febrile illness, reduced caloric intake due to illness or surgery, pancreatic disorders suggesting insulin deficiency (e.g., type 1 diabetes, history of pancreatitis or pancreatic surgery), and alcohol abuse were identified.

- Before initiating STEGLATRO, consider factors in the patient history that may predispose to ketoacidosis, including pancreatic insulin deficiency from any cause, caloric restriction, and alcohol abuse. In patients treated with STEGLATRO consider monitoring for ketoacidosis and temporarily discontinuing STEGLATRO in clinical situations known to predispose to ketoacidosis (e.g., prolonged fasting due to acute illness or surgery).

- Acute Kidney Injury and Impairment in Renal Function. STEGLATRO causes intravascular volume contraction and can cause renal impairment (see Adverse Reactions). There have been postmarketing reports of acute kidney injury some requiring hospitalization and dialysis in patients receiving SGLT2 inhibitors.

Before initiating STEGLATRO, consider factors that may predispose patients to acute kidney injury including decompensated heart failure, chronic renal failure and concomitant medications (diuretics, ACE inhibitors, ARBs, NSAIDs). Consider temporarily discontinuing STEGLATRO in any setting of reduced oral intake (such as acute illness or fasting) or fluid losses (such as gastrointestinal illness or excessive heat exposure); monitor patients for signs and symptoms of acute kidney injury. If acute kidney injury occurs, discontinue STEGLATRO promptly and institute treatment.

- STEGLATRO increases serum creatinine and decreases eGFR. Patients with moderate renal impairment (eGFR 30 to less than 60 mL/min/1.73 m²) may be more susceptible to these changes. Renal function abnormalities can occur after initiating STEGLATRO [see Adverse Reactions]. Renal function should be evaluated prior to initiating STEGLATRO and periodically thereafter. Use of STEGLATRO is not recommended when eGFR is persistently between 30 and less than 60 mL/min/1.73 m² and is contraindicated in patients with on eGFR less than 30 mL/min/1.73 m² [see Dosage and Administration, Contraindications, and Use in Specific Populations].

- Urosepsis and Pyelonephritis. There have been postmarketing reports of serious urinary tract infections, including urosepsis and pyelonephritis, requiring hospitalization in patients receiving SGLT2 inhibitors. Cases of pyelonephritis also have been reported in STEGLATRO-treated patients in clinical trials. Treatment with SGLT2 inhibitors increases the risk for urinary tract infections. Evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated [see Adverse Reactions].

- Lower Limb Amputation. An increased risk for lower limb amputation (primarily of the toe) has been observed in clinical studies with another SGLT2 inhibitor. Across seven Phase 3 clinical trials in the STEGLATRO development program, non-traumatic lower limb amputations were reported in 1.0% of patients in the comparator group, 3.0% of patients in the STEGLATRO 5 mg group, and 8.0% of patients in the STEGLATRO 15 mg group. A causal association between STEGLATRO and lower limb amputation has not been definitively established.

- Before initiating STEGLATRO, consider factors in the patient history that may predispose them to the need for amputations, such as a history of prior amputation, peripheral vascular disease, neuropathy and diabetic foot ulcers. Counsel patients about the importance of routine preventative foot care.

- Monitor patients receiving STEGLATRO for signs and symptoms of infection including osteomyelitis, new pain or tenderness, sores or ulcers involving the lower limbs, and discontinue STEGLATRO if these complications occur.

- Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues. Insulin and insulin secretagogues (e.g., sulfonylureas) are known to cause hypoglycemia. STEGLATRO may increase the risk of hypoglycemia when used in combination with insulin and/or an insulin secretagogue [see Adverse Reactions]. Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with STEGLATRO.

- Necrotizing Fasciitis of the Perineum (Fournier’s Gangrene). Reports of necrotizing fasciitis of the perineum (Fournier’s gangrene), a rare but serious and life-threatening necrotizing infection requiring urgent surgical intervention, have been identified in postmarketing surveillance in patients with diabetes mellitus receiving SGLT2 inhibitors. Cases have been reported in females and males. Serious outcomes have included hospitalization, multiple surgeries, and death.

- Patients treated with STEGLATRO presenting with pain or tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise, should be assessed for necrotizing fasciitis. If suggestive of short treatment immediately with broad-spectrum antibiotics and, if necessary, surgical debridement. Discontinue STEGLATRO, closely monitor blood glucose levels, and provide appropriate alternative therapy for glycemic control.

- Genital Mycotic Infections. STEGLATRO increases the risk of genital mycotic infections. Patients who have a history of genital mycotic infections or who are uncircumcised are more likely to develop genital mycotic infections [see Adverse Reactions]. Monitor and treat as appropriate.

- Increases in Low-Density Lipoprotein Cholesterol (LDL-C). Rosuvastatin increases in LDL-C can occur with STEGLATRO [see Adverse Reactions]. Monitor and treat as appropriate.

- Macrovascular Outcomes. There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with STEGLATRO.

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.

- Pool of Placebo-Controlled Trials Evaluating STEGLATRO: 5 and 15 mg. The data in Table 1 are derived from a pool of three 26-week, placebo-controlled trials. STEGLATRO was used as monotherapy in one trial and as add-on therapy in two trials. These data reflect exposure of 1,029 patients to STEGLATRO with a mean exposure duration of approximately 25 weeks. Patients received STEGLATRO 5 mg (N=519), STEGLATRO 15 mg (N=510), or placebo (N=515) once daily. The mean age of the population was 57 years and 2% were older than 75 years of age. Fifty-three percent (53%) of the population was male and 73% were Caucasian, 15% were Asian, and 7% were Black or African American. At baseline the population had diabetes for an average of 7.5 years, had a mean HbA1c of 8.1%, and 19.4% had established microvascular complications of diabetes. Baseline renal function (mean eGFR 88.9 mL/min/1.73 m²) was normal or mildly impaired in 97% of patients and moderately impaired in 3% of patients.
These adverse reactions were not present at baseline, occurred more commonly on STEGLATRO than on placebo, and occurred in at least 2% of patients treated with either STEGLATRO 5 mg or STEGLATRO 15 mg.

Table 1: Adverse Reactions Reported in ≥2% of Patients with Type 2 Diabetes Mellitus Treated with STEGLATRO* and Greater than Placebo in Pooled Placebo-Controlled Clinical Studies of STEGLATRO Monotherapy or Combination Therapy

<table>
<thead>
<tr>
<th>Number (%) of Patients</th>
<th>Placebo N = 515</th>
<th>STEGLATRO 5 mg N = 519</th>
<th>STEGLATRO 15 mg N = 510</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female genital mycotic infections†</td>
<td>3.0%</td>
<td>9.1%</td>
<td>12.2%</td>
</tr>
<tr>
<td>Male genital mycotic infections†</td>
<td>0.4%</td>
<td>3.7%</td>
<td>4.2%</td>
</tr>
<tr>
<td>Urinary tract infections‡</td>
<td>3.9%</td>
<td>4.0%</td>
<td>4.1%</td>
</tr>
<tr>
<td>Headache</td>
<td>2.3%</td>
<td>3.5%</td>
<td>2.9%</td>
</tr>
<tr>
<td>Vaginal pruritus¶</td>
<td>0.4%</td>
<td>2.8%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Increased creatinine‡</td>
<td>1.0%</td>
<td>2.7%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Nephropathy</td>
<td>2.3%</td>
<td>2.5%</td>
<td>2.0%</td>
</tr>
<tr>
<td>Back pain</td>
<td>2.3%</td>
<td>1.7%</td>
<td>2.5%</td>
</tr>
<tr>
<td>Weight decreased</td>
<td>1.0%</td>
<td>1.2%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Thirst¶</td>
<td>0.6%</td>
<td>2.7%</td>
<td>1.4%</td>
</tr>
</tbody>
</table>

* The three placebo-controlled studies included one monotherapy trial and two add-on combination trials with metformin or with metformin and sitagliptin.
† Includes: genital candidiasis, genital infection fungal, vaginal infection, vulvitis, vulvovaginal candidiasis, vulvovaginal mycotic infection, and vulvovaginitis. Percentages calculated with the number of female patients in each group as denominator: placebo (N=235), STEGLATRO 5 mg (N=252), STEGLATRO 15 mg (N=245).
‡ Includes: balanitis candida, balanoposthitis, genital infection, and genital infection fungal. Percentages calculated with the number of male patients in each group as denominator: placebo (N=236), STEGLATRO 5 mg (N=267), STEGLATRO 15 mg (N=265).
¶ Includes: pruritus genitalis, pruritus vulvovaginalis.

Volume Depletion. STEGLATRO causes an osmotic diuresis, which may lead to intravascular volume contraction and adverse reactions related to volume depletion, particularly in patients with impaired renal function (eGFR less than 60 mL/min/1.73 m²). In patients with moderate renal impairment, adverse reactions related to volume depletion (e.g., dehydration, dizziness, nausea, syncope, hypotension, and orthostatic hypotension) were reported in 0%, 4.4%, and 1.9% of patients treated with placebo, STEGLATRO 5 mg, and STEGLATRO 15 mg, respectively. STEGLATRO may also increase the risk of hypotension in other patients at risk for volume contraction (see Use in Specific Populations).

Table 2: Changes from Baseline in Serum Creatinine and eGFR in the Pool of Three 26-Week Placebo-Controlled Studies, and a 26-Week Moderate Renal Impairment Study in Patients with Type 2 Diabetes Mellitus

<table>
<thead>
<tr>
<th>Baseline Mean</th>
<th>Placebo N=515</th>
<th>STEGLATRO 5 mg N=519</th>
<th>STEGLATRO 15 mg N=510</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creatinine (mg/dL)</td>
<td>0.83</td>
<td>0.82</td>
<td>0.82</td>
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<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>89.5</td>
<td>88.2</td>
<td>89.0</td>
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</table>

Week 6 Change

<table>
<thead>
<tr>
<th>Baseline Mean</th>
<th>Placebo N=515</th>
<th>STEGLATRO 5 mg N=519</th>
<th>STEGLATRO 15 mg N=510</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creatinine (mg/dL)</td>
<td>0.00</td>
<td>0.03</td>
<td>0.03</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>-0.3</td>
<td>-2.7</td>
<td>-3.1</td>
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</table>

Week 26 Change

<table>
<thead>
<tr>
<th>Baseline Mean</th>
<th>Placebo N=515</th>
<th>STEGLATRO 5 mg N=519</th>
<th>STEGLATRO 15 mg N=510</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creatinine (mg/dL)</td>
<td>-0.01</td>
<td>0.00</td>
<td>0.01</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>0.7</td>
<td>0.5</td>
<td>-0.6</td>
</tr>
</tbody>
</table>

Renal-related adverse reactions (e.g., acute kidney injury, renal impairment, acute peripheral failure) may occur in patients treated with STEGLATRO, particularly in patients with moderate renal impairment where the incidence of renal-related adverse reactions was 0.6%, 2.5%, and 1.3% in patients treated with placebo, STEGLATRO 5 mg, and STEGLATRO 15 mg, respectively.

Lower Limb Amputation. Across seven Phase 3 clinical trials in which STEGLATRO was studied as monotherapy and in combination with other antihyperglycemic agents, non-traumatic lower limb amputations occurred in 1 of 1,450 (0.1%) in the non-STEGLATRO group, 3 of 1,716 (0.2%) in the STEGLATRO 5 mg group, and 8 of 1,693 (0.5%) in the STEGLATRO 15 mg group.

Hypoglycemia. The incidence of hypoglycemia by study is shown in Table 3.

Table 3: Incidence of Overall and Severe Hypoglycemia in Placebo-Controlled Clinical Studies in Patients with Type 2 Diabetes Mellitus

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Placebo N=153</th>
<th>STEGLATRO 5 mg N=156</th>
<th>STEGLATRO 15 mg N=152</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall (N %)</td>
<td>1 (0.7)</td>
<td>4 (2.6)</td>
<td>4 (2.6)</td>
</tr>
<tr>
<td>Severe (N %)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>2 (1.3)</td>
</tr>
</tbody>
</table>

Add-on Combination Therapy with Metformin (26 weeks)

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Placebo N=209</th>
<th>STEGLATRO 5 mg N=207</th>
<th>STEGLATRO 15 mg N=205</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall (N %)</td>
<td>9 (4.3)</td>
<td>15 (7.2)</td>
<td>16 (7.8)</td>
</tr>
<tr>
<td>Severe (N %)</td>
<td>1 (0.5)</td>
<td>1 (0.5)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

Add-on Combination Therapy with Metformin and Sitagliptin (26 weeks)

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Placebo N=153</th>
<th>STEGLATRO 5 mg N=156</th>
<th>STEGLATRO 15 mg N=152</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall (N %)</td>
<td>5 (3.3)</td>
<td>7 (4.5)</td>
<td>3 (2.0)</td>
</tr>
<tr>
<td>Severe (N %)</td>
<td>1 (0.7)</td>
<td>1 (0.6)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

In Combination with Insulin and/or an Insulin Secretagogue in Patients with Moderate Renal Impairment

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Placebo N=133</th>
<th>STEGLATRO 5 mg N=148</th>
<th>STEGLATRO 15 mg N=143</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall (N %)</td>
<td>48 (36.1)</td>
<td>53 (38.5)</td>
<td>39 (27.3)</td>
</tr>
<tr>
<td>Severe (N %)</td>
<td>3 (2.3)</td>
<td>5 (3.4)</td>
<td>3 (2.1)</td>
</tr>
</tbody>
</table>

* Overall hypoglycemic events: plasma or capillary glucose of less than or equal to 70 mg/dL.
† Severe hypoglycemic events: required assistance, lost consciousness, or experienced a seizure regardless of blood glucose.
Genital Mycotic Infections. In the pool of three placebo-controlled clinical trials, the incidence of female genital mycotic infections (e.g., genital candidiasis, genital infection fungal, vaginal infections, vulvovaginal infections, vulvovaginal mycotic infection, vaginosis/vulvitis) occurred in 3%, 9.1%, and 12.2% of females treated with STEGALATRO™ (ertugliflozin) 5 mg, and STEGALATRO 15 mg, respectively (see Table 1). In females, discontinuation due to genital mycotic infections occurred in 0% and 0.6% of patients treated with placebo and STEGALATRO, respectively.

In the same pool, male genital mycotic infections (e.g., balanitis candida, balanoposthitis, genital infection, genital infection fungal) occurred in 0.4%, 3.7%, and 4.2% of males treated with placebo, STEGALATRO 5 mg, and STEGALATRO 15 mg, respectively (see Table 1). Male genital mycotic infections occurred more commonly in uncircumcised males. In males, discontinuations due to genital mycotic infections occurred in 0% and 0.2% of patients treated with placebo and STEGALATRO, respectively. Phimosis was reported in 8 of 1729 (0.5%) male ertugliflozin-treated patients, of which four required circumcision.

Laboratory Tests.

Increases in Low-Density Lipoprotein Cholesterol (LDL-C). In the pool of three placebo-controlled trials, dose-related increases in LDL-C were observed in patients treated with STEGALATRO. Mean changes (percent changes) from baseline to Week 26 in LDL-C were placebo 0.21 g/dL (-1.4%), STEGALATRO 5 mg 0.46 g/dL (3.5%), and STEGALATRO 15 mg 0.48 g/dL (3.5%) with STEGALATRO 15 mg, respectively. The range of mean baseline LDL-C was 96.6 to 97.7 mg/dL across treatment groups (see Warnings and Precautions).

Increases in Hemoglobin. In the pool of three placebo-controlled trials, mean changes (percent changes) from baseline to Week 26 in hemoglobin were -0.21 g/dL (-1.4%) with placebo, 0.46 g/dL (3.5%) with STEGALATRO 5 mg, and 0.48 g/dL (3.5%) with STEGALATRO 15 mg. The range of mean baseline hemoglobin was 13.9 to 14.0 g/dL across treatment groups. At the end of treatment, 0.0%, 0.2%, and 0.4% of patients treated with placebo, STEGALATRO 5 mg, and STEGALATRO 15 mg, respectively, had a hemoglobin increase greater than 2 g/dL and above the upper limit of normal.

Increases in Serum Phosphate. In the pool of three placebo-controlled trials, mean changes (percent changes) from baseline in serum phosphate were 0.04 mg/dL (1.9%) with placebo, 0.21 mg/dL (6.8%) with STEGALATRO 5 mg, and 0.26 mg/dL (8.5%) with STEGALATRO 15 mg. The range of mean baseline serum phosphate was 3.53 to 3.54 mg/dL across treatment groups. In a clinical trial of patients with moderate renal impairment, mean changes (percent changes) from baseline at Week 26 in serum phosphate were 0.01 mg/dL (0.8%) with placebo, 0.29 mg/dL (9.7%) with STEGALATRO 5 mg, and 0.24 mg/dL (7.8%) with STEGALATRO 15 mg.

Drug Interactions.

Concomitant Use with Insulin and Insulin Secretagogues. STEGALATRO may increase the risk of hypoglycemia when used in combination with insulin and/or an insulin secretagogue (see Adverse Reactions). Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with STEGALATRO (see Warnings and Precautions).

Positive Urine Glucose Test. Monitoring glycosylated control with urine glucose tests is not recommended in patients taking SGLT2 inhibitors as SGLT2 inhibitors increase urinary glucose excretion and will lead to positive urine glucose tests. Use alternative methods to monitor glycosylated control.

Interference with 1,5-anhydroglucitol (1,5-AG) Assay. Monitoring glycosylated control with 1,5-AG assay is not recommended as measurements of 1,5-AG are unreliable in assessing glycosylated control in patients taking SGLT2 inhibitors. Use alternative methods to monitor glycosylated control.

USE IN SPECIFIC POPULATIONS.

Pregnancy.

Risk Summary. Based on animal data showing adverse renal effects, STEGALATRO is not recommended during the second and third trimesters of pregnancy. The limited available data with STEGALATRO in pregnant women are not sufficient to determine a drug-associated risk of adverse developmental outcomes. There are risks to the mother and fetus associated with poorly controlled diabetes in pregnancy (see Clinical Considerations).

In animal studies, adverse renal changes were observed in rats when ertugliflozin was administered during a period of renal development corresponding to the late second and third trimesters of human pregnancy. Doses approximately 13 times the maximum clinical dose caused renal pelvic and tubule dilatations and renal mineralization that were not fully reversible. There was no evidence of fetal harm in rats or rabbits at exposures of ertugliflozin approximately 300 times higher than the maximal clinical dose of 15 mg/day when administered during organogenesis (see Data).

The estimated background risk of major birth defects is 0.6-10% in women with pre-gestational diabetes with HbA1c >7 and has been reported to be as high as 20-25% in women with HbA1c <10. The estimated background risk of miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 24%-15% and 25%, respectively.

Clinical Considerations.

Disease-Associated Maternal and/or Embryo/Fetal Risk. Poorly-controlled diabetes in pregnancy increases the maternal risk for diabetic ketoacidosis, pre-eclampsia, spontaneous abortions, preterm delivery, stillbirth, and delivery complications. Poorly controlled diabetes increases the fetal risk for major birth defects, stillbirth, and macrosomia related morbidity.
Dealing with the stupid stuff

“...it sometimes seems like we go out of our way to create stupid stuff—stupid rules and regulations, unnecessary complexities, idiosyncrasies of insurance coverage that make it impossible to figure out what something actually costs.”

1. ICD-10 took a simple ear infection and turned it into acute suppurative otitis media without rupture, recurrence not specified, left. If you are bitten by a farm animal, is it necessary for our coding system to differentiate between a pig bite and a cow bite?

2. Prior authorization dances for tests we both know insurance is going to approve anyway. If my 80-year-old patient has a new onset severe headache without neurologic symptoms, I know and the insurance doctor knows that she’s going to qualify for an MRI. Why waste everyone’s time?

3. The list of 25 different ways the EHR lists 500 mg of metformin when I am trying to order it, virtually guaranteeing that I pick the wrong one.

4. Spending more time documenting what I did during a patient visit than actually caring for the patient.

5. Having insurance coverage for the preventive health service—screening mammogram, for example—but not for any of the diagnostic follow up testing when an abnormality is found. This discourages patients from completing their testing while leaving them worrying they have cancer.

Frustrations and challenges (“the stupid stuff”) are a major issue in most professions. However, in medicine, it sometimes seems like we go out of our way to create stupid stuff—stupid rules and regulations, unnecessary complexities, idiosyncrasies of insurance coverage that make it impossible to figure out what something actually costs, and an EHR that operates more like a Commodore 64 than an iPhone.

The number of things we do in the business of medicine that have no direct bearing on patient health or well-being is astounding. The first step in change is calling it what it is—stupid stuff.

Jennifer Frank, MD, is a family physician and physician leader in Northeastern Wisconsin and finds medicine still to be the best gig out there. Married with four kids, she is engaged in intensive study and pursuit of work-life balance.

“I refuse to accept that the patient-physician relationship is on life support.”
Remote monitoring surveys help patients avoid pain and the ED

Every day, Americans receive medical care in hospital EDs for preventable and non-emergency issues. Pain is one of the most common of those issues. In fact, a study in the Journal of Emergencies, Trauma and Shock found that at least 75 percent of patients present to the ED with a chief complaint related to pain. Despite the fact that pain can almost always be treated most effectively and cost efficiently outside of the ED, it sends patients across the U.S. to the emergency department regularly. When it is not managed effectively and efficiently, pain comes with a hefty price tag. The American Academy of Pain Medicine reports that, if you factor in the cost of care, medication, ED visits, hospitalizations, missed work and even decreased productivity tied to pain, the overall cost of pain amounts to at least $560-635 billion annually. Managing pain proactively, rather than in the ED, is necessary in order to drive down the high cost of treating it. Fortunately, there are steps healthcare providers and organizations can take—like using surveys to remotely monitor patients—to improve pain management and reign in healthcare costs.

Pain has many different causes; it can be a symptom of a chronic disease or its own unique chronic health concern. The Centers for Disease Control and Prevention estimates that 50 million Americans (or roughly 20 percent of the adult population in the U.S.) experience chronic pain.

Healthcare teams can best serve patients with both chronic conditions and chronic pain by remotely monitoring their health and proactively responding to issues. To monitor their patients, healthcare teams can use the patient engagement technology they currently use for appointment reminders to send patients invitations to complete online health monitoring surveys. Then, as patients respond, providers can use the information they capture to track health markers and determine when interventions are required.

To read more, visit bit.ly/remote-monitoring-patient-pain

Bloggers

“While concierge care has carved out its niche, DPC is more like a movement, with significant excitement among liberals and conservatives, young physicians and those (like me) nearing retirement, insured and uninsured, and people of all economic classes.”

—Rob Lamberts, MD, on the difference between concierge and direct primary care.

“The underlying problem is, we are being pulled in too many directions. We took oaths to put the needs of our patients above all else, but over time that priority has eroded in the face of economic drivers in healthcare and competitive realities.”

—Simon G. Talbot, MD, and Wendy Dean, MD, on the real problem facing doctors
Patients take charge

How physicians can adapt to the empowerment trend

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New rules on justifying body mass index coding

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Should your practice hire an IT staff or outsource the service?

LAST WORD

The risks of direct pay

What physicians need to know about the potential risks of direct primary care, writes Rob Lamberts, MD.

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Medical Economics

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The gentle power of MiraLAX® (PEG 3350) is prized by both doctors and patients.¹⁻³

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AGA=American Gastroenterological Association.

Primary care is dying because burdens are too great

After 21 years in primary care, I say: Let it die. The burden is too great, the liability preposterous, and the reward a corrupted, bastardized pittance of what we are worth. I think that if most “PCPs” knew what plumbers, insurance agents, builders, drug reps, and local government administrators made in salary, benefits, retirement, and paid holiday, they would quit and walk away. And do not forget the dentists—rich, no liability, and less education.

Thank God today’s students have the internet to search the real value of each subspecialty. There is the reason medical students won’t go into primary care. They know now what my generation did not: We are worth very little money. Our years of training, our years of experience in practice, our dedication to our patients, our long hours of work, and artificially supposed liability—all our personal sacrifice is worth next to nothing in 2019.

I say it is not worth fighting for—let the nurse practitioners have it. For treating us physicians so poorly at the hands of the health insurance companies, the Medicare/Medicaid monopoly, the filthy plaintiff’s attorneys, the greedy hospitals, and the subspecialty board organizations (see RUC corruption), this country will soon have no quality, home-grown primary care physicians.

Then the United States will experience the old adage: “Be careful what you wish for—you just might get it.”

Erik S. Richardson, MD
OXFORD, MISS.

Direct primary care can be revolutionary

Kudos to Rob Lamberts, MD, for explaining direct primary care [In his monthly columns on MedicalEconomics.com.] This is truly a revolutionary movement removing insurance companies, government, and hospitals from the doctor-patient relationship.

Not only will it lower costs and increase both doctor and patient satisfaction, but it will stimulate more idealistic medical students to desire to enter primary care.

George B. Elvove, MD
LIBERTYVILLE, ILL.

Write for us!

Medical Economics is looking for physician contributors to share their perspective with their peers on being a physician today, and can write compellingly about the challenges of practicing medicine.

Interested in writing? Email us at medec@ubm.com to learn more!
### Patients want financial services physicians don’t prioritize

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<th><strong>PATIENT</strong></th>
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**The billing and payment experience**

- **79%** of patients consider the billing/payment experience when choose a provider
- **Cost transparency**
  - **83%** of patients say proactive communication from physicians about the cost of treatment is very important
- **Flexible payments**
  - **70%** of patients want to be able to sign up for a payment plan online

**Source:** Patientco, “Patient Financial Experience Survey,” Jan. 2019

Only about **41%** of providers plan to invest in digital payment tools this year

Only about **8%** of providers list pre-treatment cost transparency as a top concern.

Only **20%** of providers use digital enrollment, focusing instead of in-person, staff-intensive payment plan enrollment (52%)

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“Patient loyalty depends on a better [financial] experience.”

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Olivier Le Moal /Stock.Adobe.com

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**MedicalEconomics.com**

**MEDICAL ECONOMICS I APRIL 10, 2019**
PATIENTS TAKE CHARGE

How physicians can adapt to the empowerment trend

by JEFFREY BENDIX Senior editor

In his 24 years of practice, family physician Rob Danoff, DO, has noticed a significant change in the way patients approach their medical care.

Early in his career, patients viewed him as their main source of information about their health problems and how to treat them. Now that’s no longer the case.

“I have multiple patients using internet resources to find out about their medical care, insurance co-pays, what is involved in procedures, what is involved in rehabilitation after procedures, the...

HIGHLIGHTS

The empowerment trend is driven by many factors: the cost of healthcare and patient desire to have their physicians be partners, not authority figures.

The drawback of patients taking more responsibility for their care is that the information they find on their own sometimes is misleading or wrong.

That’s not correct...

Everyone on Facebook says this is the right treatment.

Google says...

Why can’t I have the drug I saw advertised on TV?

I just need an antibiotic.

Why are you charging so much?

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Patients take charge

quality of the doctor, and the hospital facilities,” he says.

Danoff, the director of the family residency program at Jefferson Health’s Sidney Kimmel College of Medicine in suburban Philadelphia, is hardly unique when it comes to patients who’ve done extensive homework about their health problems and how they might be treated. Doctors and healthcare experts say growing numbers of patients are becoming empowered—a term the World Health Organization defines as “a process through which people gain greater control over decisions and actions affecting their health.”

On an everyday level, an empowered patient is one who searches for health and wellness information on their own rather

Portrait of an empowered patient

by JEFFREY BENDIX Senior editor

D oug Lindsay may well be the ultimate example of an empowered patient. Twenty years ago Lindsay, a resident of St. Louis, found his life turned upside down when he began experiencing a series of debilitating conditions including tachycardia, painful muscle cramps, and vertigo. He was forced to drop out of college, and wound up spending the next 11 years essentially bedridden for all but a couple of hours each day.

None of the doctors he consulted could explain his condition or how to cure it. So Lindsay decided to take matters into his own hands. “I realized if I just kept asking doctors what was wrong I might never get an answer,” he says. “So I pivoted and began tackling my problem as a scientist. I decided I would partner with the doctors, but take the lead in finding answers.”

Lindsay immersed himself in texts on physiology, endocrinology, and general medicine. Through his studies, he theorized the existence of a class of disorders involving dysfunction of the autonomic nervous system, which controls functions such as breathing and heart rate. He discussed his findings with his doctors, who were highly skeptical at first. “They said problems like this don’t exist,” he recalls.

Undaunted, Lindsay continued his research. He bought his first computer, enabling him to access articles through Medline and explore websites such as the National Organization for Rare Disorders for additional information. He prepared a paper outlining his theory at an international medical conference, and found a collaborator who ran an academic laboratory researching autonomic dysfunction.

“One he’d run the testing [on me] and had objective data, it was much harder for people to dismiss,” he says. And while it took 14 years and two surgeries, today he leads something close to a normal life, having developed a career as a lecturer, blogger, and what he calls “personal medical consultant” to people with rare or complex diseases and conditions.

“I have some limitations, but I’m no longer homebound,” he says. “I can travel and give speeches and go to the grocery store any time I want, which feels pretty good.”

While Lindsay’s experience is unusual, he thinks it holds lessons for doctors dealing with patients who are seeking greater control over their healthcare—starting with a willingness to treat the patient as a partner.

“If the doctor has a sign saying something like ‘your Google search is not the same as my medical degree’ they should take it down,” he says. “I think doctors need to regard empowered patients with the mindset that they have someone they can partner with.”

Even a patient who comes to an appointment with wrong information represents an opportunity if the doctor takes the time to listen carefully, Lindsay says. “The chance is there for the doctor to put aside the patient’s incorrect explanation of their symptom and say ‘tell me more about that sore on your leg,’” he says. “When we get back to things where the patient is the expert, which is making observations about their own body or feelings, it gives the doctor a chance to start from some place solid.”

Still, Lindsay says, the chance that a patient will misdiagnose their problem is outweighed by the benefits of shrinking what he terms “the knowledge gap” between doctors and patients.

“The existence of the Googles and the WebMDs represents a special opportunity for both sides because patients have access to more information and doctors can guide them through it,” he says. “You have two people working together instead of one being in the hands of the other. That can lead to much better outcomes than we ever had before.”
than waiting to get it from their doctor, then partners with their doctor in deciding the care they need, who should provide it, and where, explains Jan Oldenburg, a patient engagement consultant, blogger, and author of Participatory Healthcare: A Person-Centered Approach to Healthcare Transformation.

"Empowered patients are very clear that they have the ultimate responsibility for their own health and that the ultimate decision-making is in their hands," Oldenburg explains. "They view doctors as advisers and resources rather than all-knowing authority figures."

THE ROOTS OF PATIENT EMPOWERMENT

Experts point to a variety of factors coming together in the last few years to foster the empowerment trend, starting with the ready availability of health and medical information via the internet, but also including the popularity of social media and ubiquity direct-to-consumer pharmaceutical advertising.

"We’ve seen a real explosion in the kind of information that ordinary people can get access to about their own health and from sources like medical journals and results of clinical trials," Oldenburg says. "That means patients today can go pretty deep into their health issues and quickly get to a position where they’re at least asking questions that might lead their doctors to do additional research."

Oldenburg cites the example of a patient profiled in her book, who suffers from lupus. "She told me, ‘my doctors may have an MD degree but I’ve got a PhD in lupus. I’ve lived with this condition and understand it in a deep way that can inform how we think about treatments.’"

In addition, the internet has made it easier for people to find advice and support from people with similar health challenges through message boards, groups on social media, and organizations such as PatientsLikeMe and the Society for Participatory Medicine.

"Whereas traditionally patients turned to big organizations like the American Heart Association for information, now there are a lot more informal ways to connect with other patients and learn from them,” notes Emmy Ganos, PhD, a program officer with the Robert Wood Johnson Foundation.

Such networks can be especially helpful to people with rare diseases and conditions. “Those patients often know a lot about their medical issues and can teach each other things that their doctors may not know, like a home remedy or type of exercise that works well,” Ganos says.

RATING THE PROVIDERS

Growing numbers of patients are also using the internet to research and comment on the quality of individual doctors, practices and hospitals. A study published in the March 2019 issue of Health Affairs found that in 2015, 27 percent of respondents to a longitudinal survey consulted online rankings or reviews of doctors, compared with 17 percent who did so in 2012.

Another development fueling patient empowerment, experts say, is financial: as a result of rising copays and deductibles, and the growing popularity of high-deductible insurance plans, patients often face substantial payments even for routine tests and procedures and generic medications.

"It used to be that if you got really sick, you could be on the hook for huge amounts,” Ganos says. "Now it’s common to find that even if you’re relatively healthy or have a pretty well-controlled chronic condition, you could still be paying thousands of dollars out of your own pocket.”

The upshot is that patients are far more attentive to costs than they used to be. “You find more people are willing to ask, ‘is this [procedure or test] really necessary?’ or, ‘maybe I can find an alternative that works better for my budget,” she says.

Danoff says cost concerns drive many of his retired patients, who often live on fixed incomes, to do their own research before coming to see him—despite having grown up at a time when unquestioning acceptance of doctors’ recommendations was the norm.

“They’re looking at different costs of care and options for different medications based on their copays and overall household budgets, as well as things like a facility’s location and ease of access,” he says. “That’s a big change even from five or 10 years ago.”

THE LARGER CONTEXT

Along with money and access to information, Ganos says, patient empowerment is consistent with other trends in American

“...It’s about taking the time to explain to patients that I’m suggesting a treatment or medication based on my years of schooling and my 23 years in practice. That’s what develops the sense of trust you need in the doctor-patient relationship.”

—DAMON RASKIN, MD, INTERNIST, PACIFIC PALISADES, CALIF.
society. Among them is distrust of authority, an attitude that first took root among baby boomers and has continued with younger generations. Tied in with that is a growing desire among Americans of all ages to take charge of all facets of their lives, including healthcare.

“The idea of a paternalistic medical culture doesn’t fit as well with people’s views of their lives as it did in the past,” Ganos says. “Patients understand that they know things that doctors don’t know about their lives and their health and have an expectation that they need to take an active role in their own healthcare.”

The fact that patients now have access to much of the same medical information as their doctors, and that more of them regard their doctors as partners rather than all-knowing authority figures has been difficult for some doctors to accept.

“When you have patients asking whether what you’re recommending is really the best treatment, bringing in their own information, it can feel threatening,” Oldenburg says. Paul Wicks, PhD, vice president for innovation at PatientsLikeMe.com, a website geared to patients with rare and/or chronic diseases, says he hears anecdotal reports of doctors offended by patients using medical terminology, asking to try alternative medications to those their doctor has prescribed, or otherwise questioning the doctor’s advice. “A small number of physicians have been rude, or in rare cases fired the patient for attempting to use Dr. Google,” he says.

The physician-patient relationship has changed. Physicians must change with it.  

I refuse to accept that the patient-physician relationship is on life-support.

With the exception of areas of innovation such as direct primary care, it is yet to be discerned what number of different team members that a patient will accept before the sanctity of the individual relationship is lost.

Healthcare systems have done a poor job of communicating expectations and rationale for new pathways to care. The role of technology within the patient-physicians dynamic remains in flux, ill-defined, and inconsistent. Both patients and physicians are left with underlying confusion and uncertainty as they attempt to apply antiquated frameworks to navigate the modern healthcare environment.

Technology has revolutionized how patients interact with their own health as well as the structure of individual episodes of care. Clinicians access up-to-date resources at the click of a mouse. Computers and cell phones distract eyes and ears, often making listening a luxury for both parties. I am astounded by the number of patients who express guilt and sheepish admissions that they have researched their symptoms online.

I regularly encourage my patients...
HOW DOCTORS SEE IT

Most doctors, however, say they welcome patients taking a more active approach to their healthcare. “I have long believed that knowledge is power, and people should be learning as much as they can about their current conditions and health generally,” says Leonard Reeves, MD, FAAFP, a family physician and associate dean of the Northwest Campus of the Medical College of Georgia in Rome, Ga.

Reeves left private practice about five years ago, but continues to see patients at a free clinic in Rome. He encourages those he treats to learn all they can about their health problems because it can spark a conversation that yields meaningful information.

“There’s only so much you can learn from lab tests and blood draws” he says. “At some point you’ve got to listen to the patient’s fears and concerns because it may be something totally different from their chief complaint,” he says.

Administrators and physicians at The Permanente Medical Group, the country’s largest medical group, see patient empowerment as vital to shared decision-making, which in turn leads to better outcomes, says Patricia Conolly, MD, executive vice president of information technology and an associate executive director of Permanente.

“Often there’s more than one way to address an issue or problem a patient is experiencing, and there’s mounting evidence that if the patient is part of making the decision, their adherence to

Ultimately, I refuse to accept that the patient-physician relationship is on life support. Rather, it is possible to reframe the core structural elements of trust, access and continuity that allow the relationship to be successful and meaningful. For example, to many, the notion of continuity means seeing a given physician at every visit and that they be omnipresent in care delivery. A modern notion of continuity speaks to a cohesive team that delivers comprehensive care under the leadership of a physician. Access must be reconsidered within the contexts of telemedicine and the potential of artificial intelligence to augment encounters with the healthcare team.

I still carry my uncle’s black leather handbag from the 1950s as I make my own modern house calls, though I now have the benefit of filling the bag with a point-of-care ultrasound, digital stethoscope and iPad. Perhaps this is an ideal image for how we should approach the modern patient-physician relationship, honoring the roots of the profession, while employing the benefit of new technologies and methods for team-based delivery of care.

It is the responsibility of both health delivery systems and physicians to share transparently a coherent vision of evolving practice and relationships, and to assure that this new vision achieves quality patient care. The physician-patient relationship must still provide the cohesion necessary for the patient to maintain trust, access and continuity that form the bedrock of the best patient—and physician—experience.

Aaron George, DO, is a family physician practicing in his hometown of Chambersburg, Penn. He was an Andlinger fellow in health policy with the Center for Public Health in Vienna, Austria, and has been awarded both the Bristol-Myers Squibb award for excellence in graduate medical education, as well as recently named one of the 40 under 40 physicians by the Pennsylvania Medical Society.
Patients take charge

“Empowered patients are very clear that they have the ultimate responsibility for their own health and that the ultimate decision-making is in their hands. They view doctors as advisers and resources rather than all-knowing authority figures.”

— JAN OLDENBURG, PATIENT ENGAGEMENT CONSULTANT AND AUTHOR

“Empowered patients are very clear that they have the ultimate responsibility for their own health and that the ultimate decision-making is in their hands. They view doctors as advisers and resources rather than all-knowing authority figures.”

17 whatever the recommendation is will be greater,” Conolly says.

Damon Raskin, MD, an internist in Pacific Palisades, Calif., has seen that dynamic play out in his practice. Patients who inform themselves about their health are more likely to adhere to a medication regimen and follow his advice, he says, particularly when it comes to treating chronic diseases such as diabetes or conditions like high cholesterol.

“I have some patients who don’t believe that lowering cholesterol is going to reduce their risk of heart disease, so if they become informed about it, that can help with adherence to taking a statin,” he says.

EMPOWERMENT DOWNSIDES
The drawback of patients taking more responsibility for their care is that the information they find on their own sometimes is misleading, incomplete, or simply wrong.

“Sometimes a patient will come in saying, ‘I need this test,’ or ‘I want to be on such-and-such antibiotic,’ and I have to say, ‘but that antibiotic isn’t good for your particular condition,’ or ‘did you know it will interact negatively with one of your other medications?’” Danoff says. He urges patients who research online to look only at sites with a .edu or .gov in their web address, where the information is generally evidence-based and up-to-date.

Similarly, Danoff urges caution when patients say they don’t want to be treated by a certain specialist or admitted to a particular hospital because of a negative rating or comment on the web.

“I have to remind them that they’re reading one website or one comment and it may not be representative, the person may have had an ax to grind, so they should try to get information from different sources for a more accurate picture,” he says.

Raskin, too, is skeptical about the value of provider and facility ratings. “If patients don’t want to see me because they saw a negative comment online about my billing department, that’s their choice. But those patients who meet me and we develop a relationship, they’re usually quite satisfied with me and my office,” he says.

For Reeves, a danger of patients seeking out information online is that what they find may turn out to be a sales pitch disguised as objective information. “You can usually ferret out some of these more questionable websites simply by seeing what they have to sell,” he says. “I tell my patients, ‘if it claims to cure more than three things stay away from it, because it’s not going to do that.’”

In those cases, doctors have to spend already-scarce appointment time explaining why the patient’s information is wrong or inappropriate, thereby exacerbating the enormous time pressures they already face.

The response many doctors adopt is to rigorously prioritize, says Wicks.

“When a patient comes in with hundreds of pages of internet printouts saying, ‘I found this miracle cure, what do you think?’ [these] doctors will say, ‘We don’t have time to go through all of this, what can I do for you at this appointment?’”

Wicks explains, adding that it’s important to do so in a respectful way, such as offering to look at the information if the patient will send links to the websites where they found it.

Still, many doctors prefer a patient who come in even with bad information to one who is entirely passive in the relationship.

“My view is the more information the patient has, the better,” says Kaiser Permanente’s Conolly. “It makes it easier to have a conversation, but more importantly, it tells us they’ve been thinking about their problem, and that’s a big part of eliciting a thorough and appropriate history. My nightmare is the patient who responds to questions with one-syllable answers.”

Ultimately, doctors say, harnessing patient empowerment in a way that helps the patient requires the classic traits of good doctor-patient relationships: trust, communication, and patience.

“It’s about taking the time to explain to patients that I’m suggesting a treatment or medication based on my years of schooling and my 23 years in practice,” says Raskin. “That’s what develops the sense of trust you need in the doctor-patient relationship.”

Conolly acknowledges that winning the trust of an empowered patient sometimes requires extra effort on the doctor’s part, but says that few doctors will object to the effort if it results in better patient care. “And after these conversations lots of patients will say ‘thank you,’ and that feels pretty good. It’s why we became doctors.”

MEDICAL ECONOMICS • APRIL 10, 2019

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How physicians can get off the corporate treadmill

There’s a quiet revolution taking place in healthcare. The dramatic swing of the pendulum over the last 20 years—away from private independent physicians, towards being employees of big corporate healthcare organizations—has not, by any means, been a smooth transition for the nation’s physicians. A quick glance at any healthcare news site will show the growing unease among practicing doctors. They are increasingly looking for ways off of the corporate treadmill, frustrated by the dramatic loss of autonomy and control that they have experienced.

Two examples of healthcare models that are rapidly gaining popularity are direct primary care (DPC) and concierge medicine. Both eliminate the need for insurance and the regulatory middle man and significantly reduce bureaucratic burdens. Watch that space.

Physicians also are moving away from corporate medicine by taking advantage of the supply-demand mismatch that exists in most medical specialties, and independently contracting with healthcare facilities to provide services.

Traditionally, this type of work was done under temporary or “locum” contracts and mostly by doctors at the end of their careers, as a way of “cutting back” on clinical work. But with the surge in healthcare demand over the last few years, savvy physicians can arrange this work on a regular basis for themselves (in many parts of the country and very close to home, too), and are doing so much earlier in their medical careers.

After only one or two years of post-practice residency, an avalanche of physicians are realizing that long-term job satisfaction is almost impossible with the inevitable constant administrative clashes involved in a corporate-type healthcare environment.

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**Coding Insights**

**New 2019 regulations for BMI coding**

**Q:** Can an ICD-10-CM body mass index (BMI) code be used as a stand-alone code? If not, what does the documentation need to include to justify the use of a BMI code?

**A:** The 2019 ICD-10-CM Official Guidelines state that you cannot use a BMI code alone (these are found in ICD-10-CM code category Z68.-). BMI codes should only be assigned when the associated diagnosis (such as overweight or obesity) meets the definition of a reportable diagnosis.

Keep in mind that BMI codes were never intended to be used as standalone codes; they were always meant to be accompanied by a corresponding diagnosis code. In previous years, the guidelines read, “As with all other secondary diagnosis codes, the BMI codes should only be assigned when they meet the definition of a reportable diagnosis.” However, there was a long-standing issue of Coding Clinic published in 2011 that stated:

> “Individuals who are overweight, obese or morbidly obese are at an increased risk for certain medical conditions when compared to persons of normal weight. Therefore, these conditions are always clinically significant and reportable when documented by the provider. In addition, the body mass index (BMI) code meets the requirement for clinical significance when obesity is documented.”

This 2011 direction appears to no longer be valid. The Coding Clinic published in the fourth quarter of 2018 specifically states that the provider must provide documentation of a clinical condition such as obesity or overweight to justify the reporting of a code for BMI.

So this begs the question of what diagnoses, such as sleep apnea, diabetes, or hypertension, could make the use of a BMI code relevant. The same Coding Clinic article does not identify the conditions that can be considered associated with a BMI. So my best advice to show that BMI is clinically relevant is to ensure that the documentation clearly links the condition to BMI.

For patients with provider documentation identifying “morbid” obesity, the code E66.01 (morbid [severe] obesity due to excess calories) can be assigned even if the BMI is not greater than 40, per the Coding Clinic. This guidance is important since there are some situations where a patient can have severe or morbid obesity with a BMI of 35-39.9 due to co-existing comorbid conditions.

As noted in the 2019 ICD-10-CM Official Guidelines, Section I.A.19, “The assignment of a diagnosis code is based on the provider’s diagnostic statement that the condition exists. The provider’s statement that the patient has a particular condition is sufficient. Code assignment is not based on clinical criteria used by the provider to establish the diagnosis.”

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How to integrate health apps at the point of care

by LISA A. ERAMO, MA  Contributing author

Integrating an app with your EHR may present revenue opportunities—particularly those apps that measure physiologic data and are FDA-approved.

They track caloric intake, sleep, and daily steps. They educate patients about their conditions and medications. They coach patients to self-manage their anxiety, depression, diabetes, and pain ... and so much more. We’re talking about the thousands of consumer health apps available on app stores today.

Experts agree that these apps foster consumer empowerment that may even translate to better outcomes and lower costs, both of which can help physicians gain points under the Merit-based Incentive Payment System (MIPS). Some apps—those that capture physiologic data—may also help physicians generate revenue for reviewing the data that’s captured.

Another reason to keep these apps on the radar? Consumers want them. A September 2018 report from the consulting firm PwC found that 54 percent of surveyed consumers would be open to trying an FDA-approved digital app or online tool to treat their medical condition.

This raises an important question: Should physicians recommend these apps to their patients, particularly in an era of value-based reimbursement?

Definitely, says Niko Skievaski, co-founder and president of Redox, a healthcare data standardization company in Madison, Wisc. “Providers need to be the ones saying that one app is better for patients than another in the same way they’d say one medication is better than another,” he adds. “They need to think about apps as therapeutic interventions.”

Frederic S. Goldstein, president and founder of Accountable Health, LLC, a population health management company in Jacksonville, Fla. agrees. “The time between office visits is where the action happens,” he says, adding that many consumer health and wellness apps help fill these gaps using reminders, prompts, and coaching. “These are all intervention efforts to potentially correct a behavior before it gets bad enough to require treatment.”

Consumer health and wellness apps are also important because they enable data-informed conversations between patients and physicians, says Jan Oldenburg, principal at Participatory Health, a patient engagement consulting company in Richmond, Va. “This data can help physicians and patients make more of an impact during the limited time they have during face-to-face visits,” she adds.

PHYSICIAN ADOPTION ON THE RISE

Given the benefits, are physicians starting to recommend these apps at the point of care? Yes, according to the PwC report. Fifty-six percent of physicians said they’ve initiated discussion about an app or digital program during a conversation with a patient. Twenty-six percent said a patient initiated the discussion.

More physicians don’t initiate these conversations because the quality of the apps
Technology

Varying tremendously, says Iauheni Solad, MD, internist and medical director of digital health and telemedicine at Yale New Haven Health System in New Haven, Conn. "We want to make sure that when clinicians recommend these apps during the clinical encounter, they have a clear understanding of the app's effectiveness," he says. "Physicians should avoid apps with low-quality content and inappropriate data handling, and we need to guide them in making this choice," he adds.

Yale New Haven pays for access to a digital platform that allows physicians to prescribe apps that have been clinically validated and assessed for their value to the patient. Patients receive a text message with a URL link to download the app. The platform also includes a physician-facing dashboard that aggregates data from all apps into a single view for each patient, making it easier to manage individuals using different apps to manage multiple chronic conditions.

However, this type of platform may be cost-prohibitive for small independent practices, meaning these physicians often must sort through the endless sea of apps on their own trying to identify which ones are clinically effective and worthwhile. There are also other challenges, most notably that many apps are not integrated with EHRs, meaning it may be difficult to glean useful information from the data that’s collected.

Using and Recommending Consumer Health Apps

Fortunately, there are several steps physicians can take to make the task of selecting, recommending, and using apps at the point of care less daunting. Consider these seven steps.

1/ Narrow the list of potential apps.

Experts share these questions to consider:

- What behavior do you want to change?
  Are there any apps that can help? For example, do you have a lot of patients with diabetes who need help managing their diet, exercise, or medications? There are many apps available to help patients with each of these tasks, one of which is provided by the American Diabetes Association. Other associations may provide similar apps targeting a chronic condition.

- What information do you typically ask patients to track and share? Is there an app that captures this information digitally?

- What MIPS quality measures do you report? What quality metrics are included in your value-based payer contracts? What apps are available to target these conditions?

- What apps are your colleagues and larger health systems using? Have any of these apps helped patients achieve better outcomes?

2/ Assess the efficacy of the app.

Did the app developer solicit physician input, and can you rely on the accuracy of the content? Physicians should download the app first to get a sense of whether it’s clinically sound and something patients will use, says Ashish Atreja, MD, MPH, FACP, chief strategy officer at Rx.Health, a platform for prescribing curated apps and digital therapeutics. Is it easy to set up an account? And read user feedback and reviews. Do patients find the app valuable, and does it help them improve their health?

Using wellness apps

“There are unfortunately malicious entities out there who are putting applications together just to collect name, date of birth, and other information. These details are pretty valuable on the black market.”

— STEVEN E. WALDRENN, MD, MS, VICE PRESIDENT AND CHIEF MEDICAL INFORMATICS OFFICER, AMERICAN ACADEMY OF FAMILY PHYSICIANS
While you’re protecting your patients

Who’s protecting your practice?

ISMIE offers medical professional liability insurance to healthcare professionals in a variety of practice settings. From physicians and allied health providers to administrators, we thrive at bringing solutions that address the unpredictability of practicing medicine. ISMIE offers a policyholder-led claims process and risk management resources that protect your practice. Contact your broker partner today to discuss your specific coverage options, or visit www.ismie.com/growth to learn more.
Using wellness apps

5 reasons to consider recommending a consumer health app to your patients

- Assess patient adherence to treatment plans and track medication compliance.
- Enable patient-provider communication via secure messaging.
- Encourage patients to self-monitor their health and raise awareness of lifestyle choices.
- Provide patient education about medical conditions, drugs, and more.
- Track medical and biometric data (some of which is directly connected to medical devices such as blood pressure monitors, blood sugar monitors, wearable ECG monitors, and pulse oximeters) for clinical decision support.

“A lot of these app developers are small companies looking to gain traction,” says Skievaski. “They’re very approachable. Email them or call them, and ask them to convince you that it’s going to work for your patients.” He also suggests that physicians look to see whether any medical journals have published clinical studies about the app, he adds.

Studies published in medical journals hold more weight than those published by the app developers themselves, says Atreja. That’s because developer-sponsored studies rarely use randomized controlled trials, and tend to focus on small sample sizes of individuals who are already healthy, he says. A January 2019 study published in *Health Affairs* found this to be true as well.

3/ **Determine whether the app will integrate with your EHR.**

Integration allows providers to make use of continuous monitoring and predictive analytics, says Solad. Although EHR vendors are increasingly working with app developers to enable interfaces that allow for seamless data transmission, the majority of apps currently do not integrate, he adds. However, if a physician is passionate about using a particular app, Solad suggests asking the developer whether it would consider working with the EHR vendor to enable integration. Developers may be willing to do so if it means they can expand their user base, Soldad says.

Integration may also present revenue opportunities for certain apps—particularly those that measure physiologic data and are FDA-approved. When using these apps, providers may be able to report CPT code 99091, for which Medicare pays approximately $59. However, providers should find out whether their local Medicare and Medicaid administrative contractors and commercial payers will pay this code for the review of consumer app-derived physiologic data before they try to bill it, says Michael Warner, DO, CPC, a national advisory board member of AAPC, a training and credentialing organization for the business of healthcare in Salt Lake City, Utah. CPT code 99091 is reportable once per patient every 30 days provided that the physician reviews appropriate data every 30 days and spends at least 30 minutes reviewing, interpreting, and responding to the data, says Warner.

Even if the app doesn’t have an interface with your EHR, it may have a dashboard that aggregates and presents the data in a meaningful way—and this may be as useful as integration in some cases, says Oldenburg.

“In fact, it’s really important that the app aggregates information and presents trends visually because it helps both patients and physicians see trends and harvest learnings,” she adds.

Physicians should also keep in mind that not every app may be well-suited for integration, says Steven E. Waldren, MD, MS, vice
president and chief medical informatics officer at the American Academy of Family Physicians. For example, physicians may want to integrate an app that’s tied to an FDA-approved glucometer but not necessarily one that simply tracks exercise. Glucometer readings can inform medical decision-making when tied to specific alerts for data that falls outside of set parameters, he adds. Exercise data, on the other hand, wouldn’t necessarily trigger a clinical intervention.

4/ Determine whether there’s a cost for using the app.
Keep in mind that patient adoption may be lower for apps that aren’t free to use, says Atreja.

5/ Review the developer’s data handling policy.
Does it even have a policy? “There are unfortunately malicious entities out there who are putting applications together just to collect name, date of birth, and other information,” says Waldren. “These details are pretty valuable on the black market.” Look for answers to these questions: What data can the app access after patients download it? Some apps may be able to access phone and email contacts, call logs, calendar data, data about the device’s location, and more. What will the developer do with that data? This information can often be found in the “app permissions” under the details, or in the apps privacy policies.

6/ Engage patients to use the apps.
Oldenburg suggests starting with a handful of patients who already use apps. “Tell them, ‘I’m using this app, and I’d love to see what you think of it. I’d like you to send me a note in a couple of weeks to let me know how it’s going,’” she says. As these individuals see positive results, share their stories with other patients to motivate them, she adds.

Ask medical assistants to help patients download the app while they’re still in the care setting, says Skievaski. This helps ensure follow through, and it demonstrates that the physician values the app because they’re willing to devote resources to help ensure patients’ success.

7/ Integrate the app into the clinical workflow.
There are several ways in which physicians can integrate a consumer health app into their workflow. If the app doesn’t already integrate with the EHR, consider asking patients to simply open the app on their mobile device at the time of the visit, says Solad. A nurse or medical assistant can review the most recent data (or look at the dashboard if the app includes one) before the physician enters the exam room and then enter that data into the EHR, says Atreja. Another idea is to review the data when care coordinators contact patients receiving chronic care management services.

THINK OUTSIDE THE BOX
Although validation is important, it shouldn’t necessarily preclude physicians from trying the app with their patients to achieve better outcomes, she adds. “You don’t need to be super scientific,” she says. Start recommending an app, and then track the results of the people who are using the app versus those who aren’t. Are you starting to see some results?”

Remember to gather feedback from patients. Do patients like the app? Do they use it consistently? Does it help them manage their condition? “The app development community is very iterative,” says Skievaski. “It releases something and then relies on feedback from users and providers. This is where physicians can actually make a difference so these products provide value back to patients.”

How apps can save money
The use of digital health apps in five patient populations (diabetes prevention, diabetes, asthma, cardiac rehabilitation, and pulmonary rehabilitation) could save the U.S. healthcare system an estimated $7 billion annually, according to recent report published by IQVIA, a biopharmaceutical development company.
An overwhelming number of new medical technologies promises to improve diagnostics and increase efficiencies in healthcare—and we’ll start to see these improvements as soon as this year. Patients are advocating for themselves more vocally as the standard of care shifts toward a more person-centered model and the expectations of convenience and access to information is more critical than ever. Changes in medical (or insurance) coverage and legislation have pressed physicians to be more strategic about how they can provide optimal care.

This is not the time for fighting change, but it is an opportunity for clinicians to implement these changes in a way that will benefit, not burden, both themselves and their patients.

1. The rise of the machines

Artificial intelligence (AI) technologies should give us great hope for the near future. The technology will enhance, not replace, human efforts. AI promises to alleviate repetitive burdens and provide more accurate tools, so that the medical community can offer better care. AI’s explosion onto the funding/startup scene is both indicative of its potential and the reason less tech-savvy people feel overwhelmed.

Growth in the AI health market is expected to reach $6.6 billion by 2021. While early adoption can be an advantage, we as clinicians must educate ourselves so as to truly leverage AI’s potential. On a day-to-day basis, look to AI tools for automating routine processes and providing more intuitive interfaces for your EHRs and other online tasks.

At a higher level, AI algorithms can analyze that EHR data to identify risk predictors and recommend targeted treatments. Pathology results—relied upon for 70 percent of healthcare decisions—can be more precise under the guidance of AI.

That same level of accuracy will be used for earlier cancer detection and more efficient pharmaceutical discoveries. For due diligence, look beyond the jargon and ask, “How will we see the benefits of this technology today?”

2. A virtual takeover

Telehealth solutions have not been compelling enough to warrant mass adoption due to either needless complexity or the lack of value-add to patients and physicians. But the same philosophies that have governed the patient-first approach to care have now been applied to technology design, resulting in an infinite number of possibilities for connecting patients and clinicians remotely.

These virtual visits (two-way video calls) best serve level 1-3 patients and those requiring refills and follow-ups, freeing up office time for patients with different/urgent needs. The rise of video calls means doctors can spend more time providing face-to-face care instead of playing phone tag.

A new Medicare code for “Brief Communication Technology-Based Service” will reimburse doctors for virtual care, which opens the door for new revenue while reducing time wasted on administrative tasks. Now as accessible as any consumer app, telehealth will enable doctors to maximize their billable time and offer better continuity of care.

We’re poised for a future that showcases a drive for better, more personal access to care and the embracing of technology to deliver it through consolidated databases. It’s an exciting time to be a physician—and to reconnect with our roots. Why did you become a physician? Likely so that you can help people—and a return to more personal care-leveraging technology will help you do just that.

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Samant Virk, MD, is the CEO and founder of MediSprout. Send your technology questions to medec@ubm.com.
Six tips to getting paid for CPT modifiers

PT modifiers help payers understand all of the distinct services and procedures physicians perform. As the scope of practice for today’s internists continues to expand, these modifiers are also increasingly required to ensure accurate payment, says Toni Elhoms, CCS, CRC, CPC, director of coding and compliance at RT Welter & Associates Inc., a healthcare consulting company in Arvada, Colo.

For example, say an internist performs an annual wellness exam and addresses a skin lesion during the same visit. If the physician doesn’t append modifier -25 (significant, separately identifiable evaluation and management service by the same physician on the same day of the procedure or other service) to the evaluation and management (E/M) service for the lesion, most payers will disregard the E/M service and only pay for the annual wellness exam, says Elhoms.

Appending a modifier when it isn’t warranted can also be costly. For example, an internist owns their own radiology equipment. If they append modifier -26 (professional component only) to each radiology service, they actually miss out on revenue, depending on the service, says Elhoms. For example, when appending modifier -26 to the CPT code for chest x-ray, single view (71045), physicians could lose approximately $13 for every test performed.

Elhoms cites the case of an internal medicine practice with its own radiology equipment that saw an immediate 60 percent increase in reimbursement simply by removing this modifier from the radiology CPT codes it reported.

On the other hand, when a physician incorrectly appends a modifier and subsequently receives payment, they could be subject to a post-payment audit. “I’ve seen so many recoupments regarding inappropriate use of modifier -25 that have put private practice physicians out of business,” says Elhoms. “There’s a false sense of security when it’s paid. Recoupment requests can come out of nowhere.”

Elhoms knows of one family medicine practice that couldn’t recover from a $250,000 recoupment after a payer audited the practice’s use of modifier -25 on E/M office visit codes when providers rendered osteopathic manipulation treatment (OMT) during the same encounter.

The payer alleged that the documentation didn’t support a significant and separately identifiable service, and the payer felt
the OMT was part of the typical work associated with the E/M code and shouldn’t have been paid separately, she says.

Is there anything physicians can do to collect the payment they deserve while also avoiding compliance risk? Here are six tips experts recommend:

1/ Know your payer policies.
Just because one payer accepts a modifier doesn’t mean all will, says Michael Miscoe, JD, founding partner of Miscoe Health Law LLC in Central City, Pa. For example, one payer might accept modifier -25 in all instances consistent with the CPT definition of “significant, separately identifiable” while another might not permit it at all for certain services (e.g., when a physician reports an E/M code in addition to a code for a pain management injection).

Take the time to identify the modifiers each payer does—and doesn’t—recognize. “Check each payer’s medical policies for service-specific as well as general policies regarding separate reporting,” says Miscoe.

2/ Hire a certified coder.
“Ideally, you would have at least one person in-house who can assist with modifiers and be proactive about monitoring denials and providing education,” says Elhoms. Another option: Keep a trusted compliance consultant on standby as questions arise, she adds.

3/ Focus on clinical documentation.
For example, when physicians report modifier -25, their documentation must support the history, exam, and medical decision-making for two separate services, says Elhoms.

Think of each service as a separate encounter even though they’re rendered during the same visit, she adds. For modifier -59 (distinct procedural service), documentation must support a different session, different procedure or surgery, different site or organ system, separate incision/excision, separate lesion, or separate injury (or area of injury in extensive injuries) not ordinarily encountered or performed on the same day by the same individual.

4/ Take a closer look at your billing system.
Does your vendor incorporate National Correct Coding Initiative (NCCI) edits and update these edits quarterly? If so, are you certain that each payer has adopted those edits in its reimbursement policies? Do templates or billing automation encourage modifiers when they aren’t warranted or omit modifiers that are required?

5/ Append each modifier to the correct code.
For example, modifier -59 should accompany a procedure or service code but not an office visit E/M code. Always refer to the NCCI procedure-to-procedure edits or specific payer bundling rules when determining what procedure or service code should include this modifier.

Example: When reporting an excisional biopsy and lesion destruction, append modifier -59 to the code for the lesion destruction. When removing an intrauterine device and inserting a Nexplanon during an office visit, append modifier -59 to the code for the IU removal. Modifier -25, on the other hand, is always appended to an E/M office visit code when supported by the circumstances of the encounter, says Elhoms.

6/ Know what to do if you run into payment problems.
Consider the following advice:

Balance bill the patient. While most payer contracts don’t permit this, a physician who is not under contract with a commercial payer may have the option to do so if all other state statutory advance notice requirements are met. Physicians are not permitted to balance bill patients with Medicare, and some states are enacting statutes to limit exposure of patients to either non-covered service costs or disallowed amounts for services that are covered, says Miscoe.

Fight the denial. If the payer hasn’t published a policy on modifier usage, physicians may be able to successfully appeal the denial by citing standard industry guidance (e.g., CPT definitions of various modifiers, the NCCI Policy Manual for Medicare Services, or even medical policies of other major commercial payers), says Miscoe.

Negotiate your payer contracts. Ask payers to accept modifiers in all or certain circumstances, says Elhoms.

Taking proactive steps to ensure compliant use of modifiers pays dividends in the long run, says Elhoms.
ProAssurance has been monitoring risk and protecting healthcare industry professionals for more than 40 years, with key specialists on duty to diagnose complex risk exposures.

Work with a team that understands the importance of delivering flexible healthcare professional liability solutions.
Position your newly hired clinician for success

Whether you’re hiring a physician or a non-physician provider, odds are you’ll spend a great deal of time and money attracting the right clinician candidate to your practice. Effective on-boarding can help ensure your new hire knows what is expected and become productive more quickly. Yet despite the high stakes involved, getting new hires off to a good start often gets much less attention than recruiting does.

Protect that big recruitment investment by getting your new clinicians off to a strong start. Here are some quick tips for how to do it.

Be realistic about ramp-up time.
It’s natural to be excited about the productivity a new clinician can bring to your organization. It will take a while, though, for your new hire to realize their full capacity.

Plan more accurately for the ramp-up by considering the individual’s training and prior experiences. A nurse practitioner (NP) or physician assistant (PA) may need a lot of training and oversight for many months, especially if they’ve just graduated or are coming from a different specialty.

Even experienced providers will need time to get acclimated to your systems, protocols, and workflows. And if you expect a newly hired physician to attract new patients, keep in mind that building a network also takes time.

Provide clear expectations.
The first step to avoid such costly misunderstandings is to be as clear as possible about what you expect. Invest time to document a full year’s productivity goals in advance of your new hire’s arrival—then share the specifics once he/she starts.

Productivity may be the most important area where misunderstandings can occur, but it’s not the only one. You may also be making workflow and work style assumptions that don’t align with your new hire’s.

For example, do you consider it “standard” that charts be completed within a certain timeframe? Will you be disappointed if your new physician does not personally meet with primary care doctors or present at local hospitals? Are NPs and PAs expected to network with their peers in your local area? Are there unwritten rules for how to work with staff?

Try to be as specific as possible about all of the things that could undermine your new hire’s ability to fit in and thrive—don’t just assume they already know.

Be prepared to give specific, objective feedback as your clinician gains experience, too. For example, make sure your physicians have access to reports detailing their productivity, new patient visits, and other key metrics.

Give them administrative support.
Every workplace has everyday “stuff” that new employees have to learn: how to use company email, where the bathroom is, where to park, how and when salaries are delivered. Preparing a document that covers all of these sorts of basics, then sending it to all new employees before they start, can them feel welcome and ready for work.

Learning new software can make getting up to speed harder for new physicians, NPs, and PAs. Staff can help by making access to system training available and helping new providers learn your practice’s clinical and billing documentation policies.

Your practice management team can also help new physicians bring revenue in faster by getting started on credentialing as soon as possible. The complete process might take months—so starting well ahead of the physician’s first day of work is a good idea. Make sure your team has already planned for the documents and data they’ll need from the physician to complete the process.

Laurie Morgan is partner and senior consultant in Capko & Morgan. Send your practice management questions to medec@ubm.com.
Martha Pietruszewski is at the age where friends are taking the leap from being on their parents’ healthcare insurance plan to having their own insurance. Consequently, they’re turning to her for advice as a peer mentor and strategist for millennial women.

Pietruszewski says she isn’t sure who’s at fault, but the millennials she’s spoken with aren’t prepared to make decisions about their insurance plans. “It’s really stressful for them,” she says. “There’s a big [knowledge] gap.”

During the recent open enrollment season, the 24-year-old was fielding all kinds of questions from her robust network of Instagram followers about which options they should choose and how exactly deductibles work. Coaching others through the health insurance transition, a rite of passage of sorts, is just one of many obstacles she helps them navigate.

Now that she’s sorted out her own health insurance plan, she hopes to act as a life coach for her peers by sharing what she’s encountered along the way.

Many millennials have been on their parents’ health insurance plans since birth. Thus having their own insurance plan marks the first time they are responsible for their own health. Millennials are also navigating insurance terminology, managing their deductibles, and learning about in-network care.

That’s on top of student loans, first jobs, moving out, and maybe even new cars. Something’s got to give, so some millennials might let primary care slip at a time when they still feel healthy and invincible.

If the statistics bear out, millennials probably won’t choose a primary care physician once they’ve switched to their own plan. A recent poll by the Kaiser Family Foundation shows that millennials are less likely than preceding generations to have a primary care doctor. The poll found that 45 percent of 1,200 random individuals ages 18 to 29 said they did not have a primary care doctor. That’s much greater than other population groups: 28 percent for those ages 30 to 49 and 12 percent for those 65 and older.

“Millennials are busy and cash-strapped, so they go where care is cheap, effective, and easy,” says Susanne Madden, MBA, CEO of the Verden Group, a consulting firm for healthcare providers.

And as Pietruszewski points out, millennials might not have had easy access to a primary care doctor if covered by their parent’s insurance through age 26. That’s because in-network care through parents doesn’t always translate to children living in a different state.

Rather than bother to look for a doctor, some millennials self-diagnose. As the Kaiser study pointed out, they also aren’t as apt to schedule that annual physical as other generations.

Doctors, in an attempt to capture this demographic at a time when habits are being formed and chronic conditions can be caught and treated early, are looking to make everything from scheduling appointments to asking questions both quicker and
**Operations**

Millennial patients

easier for patients.

“We’re all in 2019 now and relying on smartphones,” Madden says. “The difference is that the older generations are a lot more tolerant of not having that technology. Millennials, because they’re the connected generation, they’ve directed that change. There really is a groundswell demanding this, but millennials are just leading the charge.”

**GREAT EXPECTATIONS**

In 2017, Pietruszewski jumped around among five doctors trying to find a solution for a hormonal imbalance. She started by searching online and reading reviews for in-network doctors. Pietruszewski says she kept switching because doctors didn’t listen to her or gave what seemed like a one-size-fits-all answer.

Eventually she settled on a physician she found through a referral. She appreciated that the doctor reviewed all of her symptoms to get to the root cause of her problem. The doctor didn’t have the ability to schedule appointments online. She admits she doesn’t like talking on the phone but says that didn’t deter her from making the call.

Millennials want to be seen quickly, and they want to get to the root of their problems—fast. In the past, Madden says, patients waited to be seen by their primary care doctor first and then wait for an appointment for a specialist their primary care doctor referred them to. Nowadays, many health insurance plans don’t require patients to see a primary care physician in order to access care from a specialist.

That means patients, including millennials, can go directly to a specialist for a problem they’ve self-diagnosed. Alternatively, they can bypass primary care and go straight to urgent care. Madden says they’re also more likely to find online communities and seek advice from others with their chronic illness.

“They use Dr. Google first and read about what others have to say,” she says. “And they crowdsource. Reviews are king. Millennials tend to care less about where doctors did their residency and much more about what other people had to say about the practice or physician.”

**THE DOCTOR WILL SEE YOU RIGHT NOW**

Mott Blair, MD, was born and raised in Wallace, N.C., a rural community about 40 minutes north of Wilmington. He began working at his father’s practice before eventually taking over. He’s known his patients for decades, and he’s now treating the grandchildren of his father’s patients.

While North Carolina’s population is booming, the residents in his community mostly grew up there and stayed. As a result, nearly one-third of his patients are millennials. While they might be unique in that they haven’t fled to a major city after school, their needs and expectations are on par for their demographic.

“We’ve implemented a lot of strategies to address and embrace this generation,” Blair says. Chief among them is open access appointments. Blair keeps about one-third of his daily appointment spots open for last-minute visits.

“Millennials want to be seen right then and there. They don’t want to wait a week,” he says. He also uses the online patient portal platform MyChart.

Another major component of his patient strategy has been virtual visits. Blair says he’s embraced this technology because the practice covers 29 counties in North Carolina that are rural and whose residents live far apart. Virtual visits became crucial during the recent hurricane when patients had trouble navigating flood waters for their appointments.

Next up: implementing a new scheduling software that will allow patients to book their own appointments online.

**CHANGING MINDS WHILE HEALING HEARTS**

Pietruszewski likes the primary care doctor she’s been seeing since she was born, but she’s not going to bother him for something...
Millennial patients

“We have to reduce fragmentation of care if we’re ever going to have that kind of patient-centered care. If you have a football team, you better have a good quarterback, someone to coordinate the play.”

— MOTT BLAIR, MD, FAMILY PHYSICIAN, WALLACE, N.C.

like a common cold. She says his time is too important to be spent telling her to rest and drink plenty of fluids. She’ll see a healthcare provider if her cold lingers, but if she does she might head to the urgent care for a quick visit.

Just as millennials have forced primary care practices to cater to their expectations, doctors are now looking to convince millennials of the need for a primary care doctor, someone who will take responsibility for the big picture of their health. And even those colds, too.

Primary care physicians still serve as an entry point into the healthcare system and a main point of contact for patients since specialists, urgent cares, and hospitals always ask for a primary care physician. They typically refer patients back to their primary care physician for follow-up, too.

“We have to reduce fragmentation of care if we’re ever going to have that kind of patient-centered care,” Blair says. “If you have a football team, you better have a good quarterback, someone to coordinate the play.”

The patient-centered medical home concept (PCMH) is one that physicians, including Blair, are promoting within their practices. The goal is to rein in patients who hop from specialist to urgent care to a second specialist while self-diagnosing and treating a potentially more serious problem. This could also be a way that physicians can convince millennials to return to primary care.

Madden says that while the concept is relatively new—the term was coined in the 1970s and ’80s but the National Committee for Quality Assurance began pushing for it in 2008—the model is one that older generations already follow, as many of them grew up with different attitudes about physicians.

The bonus of the PCMH concept is that care delivered in this kind of setting usually coincides with better use of patients’ insurance and can reduce out-of-pocket costs. If millennials can find a good PCMH, they’ll have much better health outcomes and a much different relationship with their doctor, Madden says.

Madden adds that part of the problem is millennials are typically at the peak of their health and don’t have many chronic conditions. Until they’ve reached a stage in life where they need more care, they won’t likely see the benefit of a PCMH until they’re using one to its full potential.

The good news is that Madden finds that patients in their 20s and 30s are very conscious of their health. They exercise more and eat better compared to older generations. They see activities like stress reduction and meditation as forms of self-care.

In addition, they’re encouraging others to adopt good habits by sharing what they’re doing on social media. There are plenty of posts about their fitness challenges and trending diets. There are endless hashtags highlighting self-care routines that include everything from a good face mask to a trip to the dentist.

Rather than wait until it’s too late to convince millennials of the need for a primary care physician, it’s important that healthcare providers embrace the technology younger patients are demanding now so as to bring them into the fold and provide the tools for when they need care later in life.

“We know there is a lot of benefit inherent in having someone coordinate care,” Madden says. “That helps with efficiency of care, effectiveness, and outcome.”

Editor’s note: This article was first published in our sister publication, Physicians Practice.
Ease patients’ financial pain points through billing transparency

As more costs for care and treatment shift to patients, they’re becoming more discerning about where they go to receive care. That is new territory for healthcare providers, who aren’t used to having to compete for business by appealing to savvy consumers.

Without the experience of retail marketing, physicians and health systems have found it difficult to attract and keep patients within the new healthcare economy. In an Experian Health consumer study, researchers found that the most significant pain points for patients lie in the financial aspects of their care.

To create the type of experiences your patients will enjoy and tell the world about, you’ll need to address these pain points in a way that puts their needs first. Here are three healthcare providers should address:

1/ Inaccurate estimates about the cost of care. Healthcare billing is complicated by nature, especially as insurance policies, medical suppliers, and partnering organizations constantly evolve. It’s easier for hospitals to speculate what a patient might have to pay than to break down exactly what factors into those costs. But it’s extremely frustrating for patients to receive bills far higher than they expected.

The discrepancy between the bill and the expectation leads to sinking customer satisfaction and more unpaid bills. Healthcare providers need to set more accurate expectations by providing transparent price estimates, including how much the patient’s insurance company will cover and how much the patient will pay.

2/ Patients are unable to compare prices among providers. As organizations make pricing easier to understand, patients will use this information to compare treatment prices of local hospitals and providers. Organizations will need to keep their consumer-centric focus to stay relevant. If you ignore transparency or if the costs you project are difficult to understand, you could be left out of the comparison altogether.

Instead, make those comparisons a part of the conversation. If a trusted clinic offers MRIs for thousands of dollars less, work with the patient to ensure the imaging is high-quality enough instead of shunning the idea. Focusing on patients as consumers means taking every aspect of their well-being into account, including what’s financially best for them.

3/ Patients are not allowed to make payment choices. Having the freedom to choose and the information necessary to do so wisely notably enhances patient satisfaction. It also helps patients to understand their bills from the very beginning, which is critical in appealing to them as consumers. No matter how good their care was, patients still report negative experiences if they’re frustrated about their bills.

The solutions

Being transparent helps clarify the bill, and patient-facing technologies, such as online patient portals, makes payment more convenient. There’s no confusion about where to send the payments, and billing through a portal can be consolidated into a single payment or payment plan that patients can access almost anywhere. Online portals can also incorporate credit data into the patient billing process. Credit data offers insight into each patient’s propensity to pay and financial disposition. This information allows organizations to identify the best financial pathway (payment plans, assistance, deposits, etc.) for the patient at the time of service, or even before.

Patient self-service products anticipate how best to help each patient by creating a proactive and compassionate mobile-first experience that empowers people to apply for financial assistance, activate payment plans, review insurance benefits, and estimate their cost of care.

Now that consumers are paying more for their healthcare out of their own pockets, they’re not willing to accept pain points from healthcare providers. Stand apart by being exactly what patients expect: an organization that caters to them as though their business matters.

Paul Hoffman is vice president of product development at Experian Health. Send your financial questions to medec@ubm.com
A closer look at employer-sponsored healthcare

A guide for physicians on what employers are facing in the healthcare market—and how they’re regaining control

by KAREN APPOLD  Contributing author

Employers have become frustrated with year-over-year healthcare cost increases that are three to four times the inflation rate while their employees realize poor health outcomes. Poor outcomes lead to high disability rates and low productivity, adding insult to injury.

At the same time, many U.S. employers are competing globally against companies with lower healthcare costs and higher productivity.

“The situation has reached such a crisis that big changes are imperative—the status quo is unacceptable,” says Dave Ratcliffe, principal, health & productivity consulting at Buck, a human resources and benefits consulting, administration, and technology services firm.

Lori Block, MBA, principal, industry insights leader at Buck, identifies five key areas of employer frustration:

- **Lack of competition.** Consolidated medical and pharmacy benefit manager vendor markets means less competition, resulting in higher prices for employers.
- **Quantity vs. quality.** Providers are incented to perform more services rather than improving the quality of care and achieving better outcomes.
- **Unpredictable risk exposure.** Most large employers self-insure their health benefits programs, thereby bearing all of the risk of cost escalation.
- **Pharmaceutical profits vs. patient outcomes.** The current prescription drug supply chain model lacks transparency and the many layers of manufacturers, wholesalers, and distributors are reaping profit at the expense of employers and patients.
- **Market resistance to change.** Employers perceive that doctors, hospitals, pharmaceutical companies, insurers, and even brokers are mostly vested in the status quo, making change slow and difficult.

“On top of all of this, employees are similarly frustrated as their share of the costs continue to rise, wiping out any salary increases and leading to job dissatisfaction,” Ratcliffe says.

Another key frustration is that employers have become subject to a myriad of complex regulatory requirements, most notably those stemming from the ACA. “Many employers were forced to spend thousands of dollars on consultants to help them comply with its reporting requirements,” says Judy

HIGHLIGHTS

- Healthcare costs consistently have risen faster than inflation, leading employers to look for new ways to bring them under control.
- Many employers are finding ways to tailor their health benefit plans to the individual needs of their employees.
“Coupled with core health insurance, voluntary benefits offer employees choice and control based on their personal health needs. This ensures that everyone in a company has access to adequate coverage, and provides an additional financial safety net.”

— KIM A. BUCKEY, DIRECTPATH, LLC

Boyette, JD, senior partner in the employee benefits practice group at the California law firm Hanson Bridgett.

Employers also maintain that they aren’t getting good value for what they spend on healthcare. In 1988, employer healthcare spending was about 6% of total wages, compared with the current level of 12%.

“Business leaders have less money to put in their employees’ pockets because they are spending more on health insurance than ever before,” says Benjamin Isgur, health research institute leader with the consulting firm PwC.

ADVANTAGES OF EMPLOYER INVOLVEMENT

Since healthcare costs will most likely continue to rise, and healthcare benefits remain important in attracting and retaining top talent, many employers are exploring how to become more involved in their healthcare program design, including adopting wellness programs and interacting more directly on health issues, such as providing on-site healthcare clinics, Boyette says.

With so much of their money going toward healthcare costs, employers want to know that they are getting a return on their investment. For example, if an employer can pay a little more to make it easy for employees to access preventative care and other wellness programs, like smoking cessation, exercise, or nutrition classes, employers may see greater involvement in healthcare as a way to have more control over the outcomes of their larger expenditures for healthcare coverage.

HOW EMPLOYER-SPONSORED HEALTHCARE IS EVOLVING

Employers are becoming more responsive to the differing needs and priorities of their workforce’s different generations by offering a broader range of benefits options and examining strategies to most effectively communicate those options, says Kim A. Buckey, vice president of client services for DirectPath, LLC, a company that helps employees become better healthcare consumers.

More employers are offering or expanding voluntary benefits options, such as critical illness, hospital indemnity, or cancer insurance.

“Coupled with core health insurance, voluntary benefits offer employees choice and control based on their personal health needs. This ensures that everyone in a company has access to adequate coverage, and provides an additional financial safety net,” Buckey says.

Buckey sees employers providing another important safety net through tax-advantaged reimbursement programs such as health savings and flexible spending accounts, or health reimbursement arrangements. These options provide additional funds to cover health ex-

Healthcare coverage: an integral component of employee compensation

Research from Accenture found that 76% of workers see health insurance as a primary or important factor for continuing to work at their current employer. Furthermore, 15% said they would leave their job immediately if health insurance were eliminated, and that number rose to 31% within 12 months. Turnover isn’t the only issue: 32% of respondents said they would be less motivated to work hard, and 21% said they would be absent from work more often.
employers reduce their health insurance spend.

**REVOLUTIONIZING MEDICAL CARE DELIVERY**

As the healthcare landscape evolves, employers must track how they’re delivering medical care. Accenture estimates that up to half of all large U.S. employers will offer on-site medical clinics by the end of 2019. Already, one-third of large U.S. employers currently offer their own primary care clinic on or near their worksite. This surge in internal health clinics is driven by a sharp increase in firms’ direct and indirect medical costs.

Kaveh Safavi, MD, JD, senior managing director for Accenture’s healthcare business, has found that consumers desire more personalized care, leading employers to find ways for their employees to pick and choose their care options.

One way employers are doing this is by going outside of traditional health plans and using third-party companies that provide customizable health plans.

As the desire for more digital tools increases, employers are implementing technology into their respective clinics. Most employer-sponsored health clinics have high usage of digital health services such as online access to laboratory results (68%), online appointment scheduling (68%), secure patient-provider communication (55%), and e-prescribing (53%).

“The early returns registered by employers offering on-site clinics will likely spur adoption among smaller businesses,” Safavi says. Of those employers measuring returns on their employee health clinics, more than half report a return on investment of at least 50%.

Employers are also increasing the use of telemedicine. In 2018, 55% of employers offered telemedicine as part of at least one of their healthcare services and on-site clinics, Buckey says. Furthermore, employers have begun negotiating directly with providers to offer care at reduced prices, such as General Motors’ recent arrangement with Henry Ford Health System in Michigan.

**MITIGATING COSTS**

For the last 10 years or so, the most prevalent strategy employers have used to mitigate costs has been to increase employee out-of-pocket expenses. But according to Ratcliffe, that approach only redistributes costs without actually lowering them. Now, however, “Employers are now taking more aggressive actions, and are actively pursuing market innovations that will transform healthcare delivery,” he says.

But solutions are not one-size-fits-all. “The most successful employers will start with a gap analysis to determine current and emerging supply and demand opportunities based on their unique locations and employee make-up,” Ratcliffe says. Then,

**“The most successful employers will start with a gap analysis to determine current and emerging supply and demand opportunities based on their unique locations and employee make-up.”**

— DAVE RATCLIFFE, PRINCIPAL, HEALTH & PRODUCTIVITY CONSULTING, BUCK

**Employer healthcare spending reaches record high**

For many employers, the cost of healthcare for employees is one of their largest operating expenses. According to the Henry J. Kaiser Family Foundation 2018 Employer Health Benefits Survey, the average annual premiums for employer-sponsored health insurance in 2018 were $6,896 for single coverage and $19,616 for family coverage and the average premium for family coverage increased 20% since 2013 and 55% since 2008. On average, covered workers contribute 18% of the premium for single coverage and 29% of the premium for family coverage.
Trends

Employer-sponsored healthcare

their impetus to change and opportunity for savings will be evaluated relative to the disruption and effort required to implement the changes.

Here are seven actions employers have taken to mitigate costs:

1/ Including access to non-emergency care through clinics in supermarkets and retail stores or independent urgent care centers in order to reduce use of expensive emergency department services, Boyette says.

2/ Introducing tiered networks, and steering employees to providers that have been determined by health plans to be more cost effective, Boyette says.

3/ Paying for health plan participants to travel to other states or countries in order to have certain procedures (e.g., knee replacements) done at hospitals or by certain doctors who have reported high-quality results at a significantly lower price, Boyette says.

4/ Offering employees and retirees funds and access to coverage through a private healthcare exchange—a type of online store, or health insurance marketplace where employees or retirees purchase health insurance and other benefits, typically using these funds, Boyette says.

5/ Providing bundled services. Some employers, like Walmart, are contracting with highly-rated providers for an all-in price for certain procedures (e.g., knee or hip replacement surgery), says Jaja Okigwe, MBA, CEO of First Choice Health, a health benefits administration provider.

These approaches cover pre- and post-surgical appointments as well as the actual surgery.

6/ Self-funding. Sixty percent of all employers today are self-funded, which means they purchase claims processing and administration from a traditional insurer or independent administrator, but pay for the cost of medical claims themselves, Okigwe says.

Under a self-funded arrangement the employer, rather than an insurance carrier, assumes the financial risk for providing healthcare benefits to employees. “Since the employer bears the risk, they may be more motivated to become more involved in order to drive as much efficiency as possible to lower risk and cost,” Boyette says.

7/ Actively engaging with employees to develop healthcare plans. “Employers are increasingly seeking and acting on employee-generated requirements for health and wellness programs and are looking to a range of providers outside of health plans to access health and wellness services that cater to their needs,” Safavi says.

LEADERS IN HEALTHCARE INNOVATION

With employees paying more for healthcare than ever—the annual premium for employer-sponsored family healthcare coverage reached $19,616 in 2018—employers and employees alike are desperate for ways to control healthcare spending.

Haven, the joint venture among Amazon, J.P. Morgan, and Berkshire Hathaway put the healthcare industry on notice that employers are no longer willing to accept the status quo. The combined entity will initially target administrative costs and improper healthcare use in an effort to reduce costs, improve satisfaction, and realize better outcomes for employees of those three companies.

“Eventually, their innovations will be shared with other employers, which could cause a ripple effect through the healthcare delivery system,” Buckey says. “The venture is a signal to the market that it needs to evolve or traditional players will lose favor to more innovative industry entrants committed to delivering transparency and much needed change.”

Editor’s note: This article was first published in our partner publication, Managed Healthcare Executive.
The rising price of insulin
How can physicians help their patients?

by JORDAN ROSENFELD Contributing author

Insulin, the life-saving medication that the more than 30.3 million Americans with diabetes require to live, is getting dramatically more expensive every year.

According to a report from a working group at the American Diabetes Association (ADA), the list price of insulin has nearly tripled since 2002 and the average price of insulin has increased by 64 percent since January 2014.

Some patients have to make hard choices between paying for their medicine or other basic life necessities, such as food and electricity, or are even rationing their insulin, a dangerous practice that can lead to death.

What is driving this exorbitant spike in cost for a drug that has remained largely unchanged since its discovery in the early 1920s? And what can physicians do to help their patients obtain the insulin they need?

Deane Waldman, MD, MBA, distinguished senior fellow in healthcare at the Texas Public Policy Foundation in Austin, Texas, says simply caring for patients is muddled by third-party entities, including the government, health insurers and pharmacy benefits managers (PBMs).

This works against physicians being able to offer their patients the best care possible, because physicians are forced to prescribe from what are often limited medications available through a patient’s insurers and pharmacies.

“This whole third party in between the doctor and the patient is not only jacking up...
“I always make sure that patients that are having struggles [financially] contact the manufacturer directly because usually they’ll offer some type of discount.”
—MEGAN WILLIAMS, MD, FAMILY AND OBESITY MEDICINE PHYSICIAN, SAN ANTONIO, TEXAS

When PBMs manage the pharmacy benefit portion of a health plan, the ADA working group points out, they are beholden to their clients, health insurers and employers, not patients.

Though the three insulin manufacturers—Sanofi of France, Novo Nordisk of Denmark, and Eli Lilly and Co.—all make similar insulin, whichever company is willing to give the largest rebate is the one that gets put on the formulary, Heilaman explains.

“The United States healthcare game is not an open, free, fair market. It’s captive by big corporations that call all the shots,” he says.

INCREMENTAL PATENT CHANGES
Another driver of higher cost, Waldman says, is that pharmaceutical companies have figured out ways to tweak drugs that are about to go off patent, enabling the manufacturer to extend the patent on the drugs or obtain new ones. This process prevents generic drug manufacturers from producing cheaper versions of the drugs.

“A drug company can take a known drug that is about to go off patent and simply combine it with another drug that never was on patent in the first place, and get a new patent,” Waldman says.

The pharmaceutical companies have come under fire for such practices but are not prevented from doing so.

WAYS TO GET AFFORDABLE INSULIN
Other than lobbying for legislative checks and greater transparency for PBMs and pharmaceutical companies, where does this leave physicians who just want to make sure their patients can get the insulin they need?

There are a variety of programs to which physicians can direct patients in need of financial help. Eli Lilly, Sanofi, and Novo Nordisk all offer patient assistance programs, but these are generally reserved for people whose income is less than $36,000 per year
and who do not have health insurance. Blink Health and Inside Rx are programs that may offer discounts of up to 40 percent on insulin compared to pharmacy prices.

According to the Juvenile Diabetes Research Foundation, several nonprofit patient and insulin assistance programs are available to help with the costs of Type 1 diabetes medication. They include:

**Partnership for Prescription Assistance**, which is sponsored by pharmaceutical companies, doctors, patient advocacy organizations, and civic groups. It helps low-income, uninsured patients get free or low-cost brand-name medications.

**NeedyMeds** maintains a free, extensive database of patient assistance programs, state assistance, medication discount programs, and free or low-cost medical care. The site also includes information on programs geared to help consumers through the application process.

**RxAssist** is an online database of pharmaceutical company programs that provide free or affordable medicines and co-pay assistance.

**RxHope** is an online resource patients can search for an assistance program according to the type of medication. It also helps with the application process.

**RxOutreach** is a nonprofit mail-order pharmacy for uninsured or underinsured people.

**The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)** publishes a resource called “Financial Help for Diabetes Care,” containing information about resources that may help with medical expenses of a person with diabetes. You can view this publication online or order copies from the National Diabetes Information Clearinghouse at 1-800-860-8747.

**OLDER FORMULATIONS OF INSULIN**
The JDRF also recommends that physicians with low-income, uninsured patients in immediate need of insulin seek out an older formulation of insulin that may be sold over the counter at Walmart or Sam’s Club. This insulin is typically sold under the name ReliOn.

However, it does work differently than newer insulins, so physicians will need to be sure they help patients dose it correctly.

**ORAL MEDICATIONS AND LIFESTYLE CHANGES FOR TYPE 2 DIABETES**
For patients with Type 2 diabetes who are taking insulin, lifestyle changes might be a way to reduce the amount of insulin they’re taking, or eliminate the need for it altogether, according to Megan Williams, MD, who is board certified in family and obesity medicine and owner of Elemental Weight Loss and Wellness Clinic in San Antonio, Texas.

“Physician to physician, don’t forget that there are lifestyle interventions that can be very powerful,” Williams says. “A major cost-reduction technique would be to try to move more, eat less, lower sugar and carb intake, and lose weight.”

Also, for Type 2 diabetes patients, she always looks for an oral insulin alternative that might be more affordable. “I’m a firm believer in evidence-based medicines over jumping straight to the most expensive thing, when the patient may not even be able to afford it,” she says.

Williams emphasizes the importance of physicians discussing cost with their patients before making any diabetes treatment plan, since it won’t do any good if the patient can’t afford it.

“I always make sure that patients that are having struggles [financially] contact the manufacturer directly because usually they’ll offer some type of discount,” she says.

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**Eli Lilly to sell cheaper insulin**

In the wake of massive negative media attention to the plight of people who are unable to afford their lifesaving insulin, drug maker Eli Lilly has announced that they will begin to sell a cheaper insulin.

The new version will be an “authorized generic” of Humalog 100, according to the New York Times, and will sell for $137.35 per vial, which is a 50 percent discount from the list price.

The new drug, though identical to Humalog, will be called Insulin Lispro. Eli Lilly will continue to sell Humalog 100 at its regular price to insurers and employers.

Affordable insulin advocates hope this move pushes other drug companies to follow suit.
IT services at your practice: In-house or outsourced?

by RAY PELOSI | Contributing author

Small medical practices must perform many IT functions—among others, EHR system management, cybersecurity, imaging, billing, and controlling and keeping tabs on infrastructure operations—to achieve the clinical and financial outcomes necessary for their success. While most such offices don’t have in-house IT staff, some do, whether they train existing personnel to perform these functions or hire dedicated staff who already have these skills.

This article looks at both approaches, examining the pros and cons of each, and when, or if, it can make sense to combine the two.

Before a practice decides who will handle its IT, it must know what IT functions are essential to clinical and financial success. EHRs are a given, but so is a practice management system whose patient data can be integrated with the health records and that creates a workflow that expedites patient appointments.

To accomplish this, the EHR must have an API (Application Programming Interface) that has easy back-and-forth communication with the management system, and both components must be HIPAA-compliant. In addition, while it isn’t mandatory, it’s certainly desirable to have a patient portal that lets patients access their appointment schedules and records online.

COSTS AND RISKS

The major trade-off with hiring IT staff versus outsourcing the function is that a practice has greater operational control with staff, but assumes higher costs and risks. says Graham Caparulo, principal consultant with Diligex, a New York City-based provider of IT services to small and medium-sized medical practices.

“On the risk side, if you have your own staff and a data breach, there’s no one to point the finger at except yourself,” Caparulo says. (Under the HIPAA Omnibus Rule, if the contractor has signed a HIPAA Business Associate agreement with the practice to comply with HIPAA privacy, security and breach notification requirements, it is liable for any HIPAA infractions it commits.)

Contracting out IT lets a practice focus on its core business of providing healthcare. Moreover, the practice may get a broad base of contract employees with a wide variety of technical competencies, and it’s not left exposed if the in-house IT staff gets sick, goes on vacation, or leaves the practice.

“The average tenure of an IT person is about two or three years,” says Caparulo, “so do you want to go through this every couple of years or shift that over to somebody else?”

Before hiring outside contractors, the practice needs to conduct a thorough internal inventory to determine what the staff members and doctors already know about the existing IT system, identify their IT product and service needs, and then develop a Request for Proposals based on those precise needs.

“For instance, do you need to select a system?” says Ken Hertz, FACMPE, a principal with MGMA Health Care Consulting Group, in Englewood, Colo. “Is it hardware you need? Is it networking? Is it EHR selec-
EXPLAIN THE DANGERS
"'Checking boxes' without thought ultimately defeats the purpose of what cybersecurity programs are about," says Brian Yeaman, MD, a solo primary care physician in Oklahoma and health IT expert. "It’s really so much more significant in terms of protecting our patients’ privacy and protecting our practice because data breaches and their penalties are serious and severe.

Practices must convince employees that training is more than a mandatory exercise that takes up their time; it’s integral to protecting patients, the practice, and their jobs.

SELECT A SECURITY OFFICER
Success starts at the top. Therefore, it’s crucial that practice leadership and security officials be devoted to protecting the organization from cyber threats, says Borten.

First, practices of all sizes should recognize that they are required to have a privacy official and a security official. "I’ve seen some backsliding on compliance with this point," Borten says.

She advises appointing practice privacy and security officers (who can be the same or separate individuals, according to HIPAA regulations) who welcome the role. Physician owners shouldn’t “automatically appoint the practice manager, for example;" Borten says. "You really want somebody who cares, who’s interested in privacy and security, and who will go out and actually seek information to understand his or her responsibilities."

KEEP TRAINING SHORT AND STIMULATING
The frequency and content of security training are not spelled out explicitly in federal regulations, says Borten. She recommends that all employees, including physicians, receive comprehensive training upon hire and annually thereafter, with short refreshers on specific topics at least monthly. One way to carve out the time is to include some cyber training on the agenda of existing staff meetings, she says.

To keep employees engaged, conduct the training using a variety of formats and tools. For example, Pabrai suggests, hold a brief roundtable discussion about ransomware. Or develop a handout focused on a particular area, such as how to report a potential electronic data breach. "Identify your core topics and circle through them in different ways," he says. "Keep trainings short, fast-paced, and relevant to current events."

REDUCE INTERNAL RISKS
Especially in small practices, the trustworthiness of employees can be easily taken for granted. However, a 2018 survey from Accenture found that 18 percent of healthcare employees said they would be willing to sell confidential data to unauthorized individuals. Furthermore, about a quarter of those surveyed said they knew someone in their organization who had sold their login credentials or similar information.

Yeaman recommends, for example, shutting down USB ports on all equipment to prevent individuals from downloading data onto a thumb drive or other device. Network activity monitors should also be set to track any aberrant patterns that could signal inappropriate activity, he adds.

Reporting procedures should be included in training, she says. Both the HIPAA privacy and security rules require that covered entities have a written process for discovering and reporting even suspected misuse or breach of patient information.

4 TIPS FOR SUCCESSFUL CYBERSECURITY TRAINING

"There’s so many services that external vendors offer that you need to be very clear about what it is that you want to get."

TRAINING AND SUPER USERS
At some point, however, it makes sense for a small practice to hire some in-house IT staff, for what Caparulo calls “level one or front-end triage issues,” such as if a front-desk staff er can’t log in to the EHR, access e-mail, or print out a medical record. In those instances, it’s better to have a technically adept practice employee on hand to solve the problem. "They’ll likely get things resolved quicker than if they go through an outsourced provider," says Caparulo.

Alternatively, a practice might train its own employees—even if they have little or no IT experience—instead of hiring new personnel. While this certainly costs much less than hiring a full-time IT staffer, the questions become: is it worth the time to
train a tech neophyte on the practice’s staff, and will the growth in size and complexity of an IT structure make it too difficult for that staffer to manage in the future? It might be easier to choose this path if the practice’s IT vendor makes training and system support part of the technology purchase cost.

On the other hand, Hertz posits that many workers today are comfortable with sophisticated digital technology. These staffers can use their familiarity to learn the workings of the EHR and perform certain IT functions in a practice, potentially removing the need for a full-time IT staff person. These “super-users” can be and “are highly trained in software, and in understanding and problem-solving with the EHR or practice management software. A vendor can furnish that training.”

However, “they’re not going to solve your network problems and things like that,” Hertz cautions. Even so, he notes, super-users who develop more experience handling software can sometimes help with networking and hardware problems. One caveat, though: super-users have other jobs in the practice that they could neglect if called upon to spend hours diagnosing and fixing an IT problem.

Thus the more complex services, such as interoperability and telemedicine, ought to be left to contract experts, Hertz says. “You want somebody who knows all about HIPAA issues, cybersecurity issues, encoding messages and so forth, so that’s where you’re going to use outsourced vendors.” Specifically, Hertz recommends that a practice should have “one really good external, outsourced IT support” vendor it can rely upon for guidance in these areas.

WHEN TO SUBCONTRACT
For some small practices—like that of Karen Smith, MD, a family physician in rural Raeford, N.C.—hiring new or training existing in-house staff isn’t an option. First, the cost is prohibitive—about $30,000 per year, according to practice administrator Michael Hendricks. That would be an operations budget-buster for Smith, who also has a practice manager, registered medical assistant, part-time nurse practitioner, and billing coordinator on staff.

Second, it’s more practical to use a sub-contractor from nearby Fort Bragg to provide IT support, just as he does in his full-time position on the base. (This sub-contractor’s predecessor, another Ft. Bragg IT specialist, originally set up Smith’s IT systems and made the practice completely paperless.) “Even if we had an IT specialist to come in and train us it’s out of our purview because we would literally have to study that technology and know what the upgrades are,” explains Smith, adding that it’s “far more cost-effective” to leave that up to her sub-contractor, who does this every day for the U.S. Army.

Moreover, each service the practice installs, like the patient portal Smith is about to install for opioid addiction treatment, or the telepsychiatry functionality her practice has had for some time (to offset the dearth of pediatric psychiatrists in the state), always comes with training costs. Here, too, it’s much better having an IT-savvy sub like Moore learn this, “because we just don’t have the knowledge base for it,” Smith admits.

It’s also highly important that the contractor have an industry-specific knowledge base. “Subcontract with someone who stays up to date with technology and who understands healthcare,” Smith urges. “You really need an IT person who understands the nuances of medicine”—e.g., the kind of person who knows that since CMS (the Centers for Medicare & Medicaid) might change its rules next year, you’ll need to be prepared to upgrade data security so that you can qualify for CMS’s Merit-based Incentive Payment System.

RESPONSE TIME AND COST
A practice must know when a vendor can be available onsite to solve problems and how much downtime to expect, so the contract should address vendor response time. “They may say, ‘Yeah, we said we’d be onsite, but didn’t you read the part of the contract where we said we’d probably be there within three days?’” Hertz says.

You also should understand how the pricing works for your IT services. With more labor-intensive functions, such as a help desk, “you’re often going to see that those may run up a bill depending upon the number, length, and complexity of calls,” Hertz says. Some specific services, such as help with moving into an office, designing cabling, arranging for wi-fi, or teaching remote access to your doctors can be costly, too. But vendors may charge a reduced monthly fee for certain standard services, such as security, anti-virus security, back-up, monitoring alerts, and hardware support.
am a proponent of direct primary care (DPC). OK ... maybe I’m a fan-boy. It has changed my life so dramatically that it is hard to explain it without sounding like I’m giving a sales pitch. My practice, the quality of my care, and my life have all improved since making the change six years ago. But with such enthusiasm comes a danger: being blinded to the negatives, the risks, and the potential problems of the model, both in the present and future.

A letter to the editor of Medical Economics recently caught my eye. The author was a primary care doctor who had read my articles on DPC. While interested in the practice model, he pointed out the potential negatives: "...there is a dark side to the conversion that nobody in the DPC camp ever seems to talk about. While the new practice model might be great for the select group of patients who agree to stay on and pay their monthly fees, what about everyone else? Dr. Lamberts wrote that he averages 8 to 11 patients per day. I wonder how many he was seeing before he made the switch."

In my practice, I was routinely seeing 25 to 30 patients per day. Had I jumped on the DPC bandwagon, that would have meant about 20 patients per day would have been displaced and forced to find a new family doctor.

He goes on to spell out the obvious concern based on this real observation: "I just can’t help but wonder where the thousands of patients who get displaced are supposed to go for care once their family doctors can no longer see them. Urgent care picks up a lot of the slack for acute care needs (I still see 25 to 30 patients per day) but they don’t handle chronic conditions. Especially as the population ages, there is an ever-growing need for better primary care access. It seems to me that a growing DPC movement will make the access situation even worse.”

This is a very valid point that those at the head of the DPC movement need to address and answer up front. Yes, I did consider this when I left my old practice, and it was the largest source of hesitation I had in making the leap.

Beyond this, there are other, even larger concerns that could swallow up the DPC movement and shunt it from being a potential salvation for our system to being a flash in the pan. This article will explain the problems that direct care may cause and point toward a potential solution. I do realize that my foresight in this arena is limited, so I may be missing the real problems we will face in the future. But the best chance for this practice model, which has made my life and my care so much better, is to succeed in the long run.

PROBLEM 1: DPC ABANDONS PATIENTS
This is what the letter to the editor was saying: I and my DPC colleagues were abandoning patients, leaving care to be picked up by those who hadn’t made the switch. While I don’t think the number of office visits makes the case strongly, I do think this is a valid concern.

In truth, the lower number of office visits is a good thing. The reason I see less patients per day is not just because I have lower overall census, but because I don’t limit care to office visits. While I see between 8-12 patients per day, I actually give care to 20-50 patients each day via text messaging and phone calls. I found that only about 25 percent of my visits in my old practice required an office visit. I don’t have to worry about lost income in my new practice, so I can handle most problems without an office visit.

I think that the average primary care doctor’s schedule of 25-35 patients per day is a major indictment of
our system. It’s not possible to see that many patients (especially with the huge time burden of insurance compliance and unfriendly medical record systems) and still give high-quality care. This is what drove me to burn out: the knowledge that there was no way I could give the care my patients deserved when seeing so many people each day.

A more serious number, however, is the fact that I reduced my entire patient census from 2000-3000 to 800. How can this work if all doctors adopt it? What will happen to all of the patients if DPC becomes widely adopted?

I think the answer will not be as simple as many DPC proponents say. It will likely cause a crisis of access, which I hope will be met by an increased workforce of primary care doctors who no longer see the profession as a booby prize. Primary care has become the domain of the idealist—those willing to give up significant income to do good for people. DPC raises the possibility that primary care won’t be relegated to the realm of self-sacrifice and social good, but turned back into the most fulfilling and important job in the entire system.

Will that happen? Time will tell.

**PROBLEM 2: DPC IS UNREGULATED**

The other, more subtle risk of DPC comes from the blatantly independent nature of most doctors who adopt the practice model.

This seems like apostasy within a “movement” in medicine that is defined by its libertarian leanings. I am, by definition, anti-insurance company and anti-government in my practice. I accept no payment from either, which is part of what makes the model so great. But while I am dedicated to giving excellent evidence-based care to my patients, what keeps other doctors from wearing the “noble” DPC mantle and not being so dedicated?

I have seen much discussion about approaches to care within DPC practices that are far from mainstream. DPC groups (such as the DPC alliance, of which I am a founding member) are regularly approached by naturopaths for membership. Within our membership are doctors who engage in medical practices I do not endorse, and I’m sure that some of my approaches to care wouldn’t be endorsed by all of my colleagues.

There is nothing keeping a medical provider, regardless of training or practice, from claiming to be DPC. Left to chance, this could dilute the current goodwill enjoyed by the direct care community. It seems to me that the only real solution to the lack of regulation is a set of criteria and certification by a medical body/society.

Can the DPC movement police itself? Can a group of vigilantes who are largely defined by what they aren’t become a cohesive and influential mover in our system? These are real questions that the DPC leadership must address, and ones that will be met with much resistance from some of the current members (and leaders) of the DPC movement.

I certainly hope that DPC is here to stay. But we in the early stages of this movement must look ahead to our biggest challenges. We can’t deny there are negatives, because doing so will play into the hands of those with a vested interest in seeing this movement fail.

I think that DPC is the best model we have at this time. I believe I give better care than most other doctors, and not because I am smarter or more talented. I think it’s because the model encourages me to give good care, not bad (as is the case with regular fee-for-service medicine). We in leadership need to assure that this good care will be available to everyone in the future.

**“I certainly hope that DPC is here to stay. But we in the early stages of this movement... can’t deny there are negatives, because doing so will play into the hands of those with a vested interest in seeing the movement fail.”**

Rob Lamberts, MD, is a board-certified internist and pediatrician who runs Dr. Rob Lamberts, LLC, a direct primary care practice in Augusta, Ga. He also recently gave a TED talk on the DPC model. Have questions about DPC? Email medec@ubm.com.
### Who are your role models?

<table>
<thead>
<tr>
<th>Name</th>
<th>Role Models</th>
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<tbody>
<tr>
<td>Maria Young Chandler, MD, MBA</td>
<td>“My father, who is a child psychiatrist and the most patient person I know.”</td>
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<tr>
<td>George G. Ellis, Jr., MD</td>
<td>“My family doctor growing up.”</td>
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<tr>
<td>Antonio Gamboa, MD, MBA</td>
<td>“Steve Jobs, Elon Musk, Warren Buffet, and [University of Texas-El Paso President] Diana Natalicio.”</td>
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<tr>
<td>Melissa E. Lucarelli MD, FAAFP</td>
<td>“Mrs. Kobida (my 8th grade math teacher), Marie Curie, and my mom.”</td>
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<tr>
<td>Joseph E. Scherger, MD</td>
<td>“[Neurologist] David Perlmutter, MD.”</td>
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<tr>
<td>Salvatore Volpe, MD</td>
<td>“My parents.”</td>
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The board members that contribute expertise and analysis to help shape content of *Medical Economics.*
“Millennials are busy and cash-strapped, so they go where care is cheap, effective, and easy.”  

AARON GEORGE, DO, FAMILY PHYSICIAN

“The amount the U.S. could save on chronic conditions by using health apps, according to IQVIA.”  

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“I refuse to accept that the patient-physician relationship is on life support.”  

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$7 billion
Eliminate claim denials

There are numerous reasons for claims denials but most of them come down to some form of documentation error, according to Karen Meador, MD, MBA, Senior Physician Executive and Managing Director at the BDO Center for Healthcare Excellence in New York, NY.

One of the common problems contributing to poor documentation, Meador says, is a byproduct of EHRs. In a bid to save time, certain functions, such as copy and paste features and generic templates, can lead to a lack of specificity as physicians copy notes into claims.

She says physicians must take care to make sure that each note is “specific and unique to that patient” even when using templates.

In addition, the check-one-box function of many templates isn’t always enough to make the case for medical necessity; more complex notes are often required. “I can often review medical records and see that based on the vital signs, certain labs and the overall exam, this patient needed to be admitted, but the physician wrote a very brief plan, often following a template,” Meador says.

Having a coding expert or a coding team on board can provide feedback to ensure that the code was appropriate for what was documented, she says. Such feedback might help physicians code appropriately to a higher level.

She recommends physicians hire an outside group to come in regularly for a preventative claims audit.”

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