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August 2012 "The Patient Protection & Affordable Care Act"

THIS MONTH
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"Affordable Care Act"

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The Patient Protection & Affordable Care Act was passed in 2010. It has some definite portions that impact pharmacy, and it is the goal of this lesson to comment upon those issues.
This lesson provides 1.25 hours (0.125 CEUs) of credit, and is intended for pharmacists in all practice settings. **The program ID # for this lesson is 707-000-12-008-H01-P. Pharmacists completing this lesson by August 31, 2015 may receive full credit.**

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The objectives of this lesson are such that upon completion the participant will be able to:

1. Describe the Patient Protection and Affordable Care Act (ACA) of 2010.
2. Discuss the specific changes that will be rolled out each year.
3. Summarize the changes in the ACA that have a significant impact on pharmacy practice.

INTRODUCTION

Regardless of one's politics, the Patient Protection & Affordable Care Act was passed in 2010. It has some definite portions that impact pharmacy, and it is the goal of this lesson to comment upon those issues.

The overall rationale is to review the portions that affect us as pharmacy practitioners. Some sections were intended to have already begun. Some have started. Some may have been delayed. It is only our intent to report, and not to take sides regarding the ongoing debate. Some of it may have already been altered. Because there is so much discussion going on, there may yet be additional modification and change.

As time passes, and further implementation occurs, we will report on this also. We have done our best to report the situation as it existed at the time of distribution of this lesson.

BACKGROUND

On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act (HR 3590, Public Law 111-148).[1] This action ushered in a new approach to healthcare in the United States. One of the most significant changes is that all uninsured Americans will receive healthcare benefits by 2014. Since this change affects approximately 32 million uninsured people, it is expected to result in a dramatic increase in prescription volume and the need for additional pharmacy services. This lesson will focus on the key changes in healthcare that are part of the Affordable Care Act (ACA) and how these changes will affect pharmacy.

The Patient Protection and Affordable Care Act (ACA) although signed into law in 2010 has been challenged in the courts. A lawsuit was filed by the Attorney Generals from 13 states exactly 7 minutes after President Obama signed the act into law.[2] Earlier this year, the U.S. Supreme Court ruled. Further challenges may arise, but, again, it is the goal in this lesson to discuss pharmacy related issues. The description of the ACA and its impact on pharmacy discussed in this program is based on the current status of the Act. Changes may occur as a result of future legal entanglements.

AFFORDABLE CARE ACT (ACA)

There are three basic tenets to this law.[4] The first is insurance market reform. Insurance companies will no longer be able to exclude patients with preexisting conditions or denying or dropping coverage based on an individual's health. The second component of the ACA is the requirement that all Americans purchase coverage as long as it is affordable. Affordable coverage is defined as < 8% of a person's income. The third and final tenet is the availability of extensive subsidies to make healthcare insurance affordable to those who are unable to purchase insurance. In order to implement the many changes in healthcare reform outlined in the ACA, specific sections will be phased in over several years. The following summarizes the major changes and the timeframe for implementation.

Overview of the ACA by year[4]

2010

- Children with preexisting conditions will be able to receive insurance coverage.
- Existing policies may not be revoked when individuals become ill.
- Lifetime limits on coverage banned.
- Dependent children will be covered up to age 26.
- Preventive services will be fully covered without co-pays or deductibles.
- 10% tax on indoor tanning services.
- New physician-owned hospitals barred from participating in Medicare.
- Food and Drug Administration can approve generic versions of biologics.
- Expansion of primary-care residency programs.

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2011	• Annual wellness visits covered by Medicare at no charge. • Preventative care (vaccines, cancer screening) available at nominal fee. • Over the counter (OTC) drugs no longer covered by flexible spending or health savings accounts. • 50% discount on brand name drugs from pharmaceutical companies purchased through Medicare Part D. • Subsidies for patients in the “donut hole” for generic drugs.
2012	• Incentives for providers to join accountable care organizations (ACOs). • Tracking of readmission rates at hospitals.
2013	• Income tax increase for individuals >$200,000 income or household >$250,000. • New 2.9% tax on medical devices. • Limit of $2500 per year on pre-tax Flexible Spending Accounts.
2014	• Annual limits on coverage will end. • Penalties for individuals not purchasing health insurance will begin ($95 in 2014, $695 in 2016). • Medicaid eligibility will increase to include individuals living ≤133% of poverty level for everyone < 65 yrs. • Limits will be instituted preventing insurance companies from charging higher rates based on tobacco use, family size, age or geography. • Tax credits for individuals who do not qualify for Medicaid but are < 400% of poverty level.
2015	• Independent payment advisory board will be established to evaluate ways to lower Medicare costs and improve care.
2018	• 40% tax on insurance companies and health plans for any family health plan that costs >$27,500. Those individuals in high-risk professions or the elderly will have higher thresholds.

ACA CHANGES THAT IMPACT PHARMACY

There are several provisions within the ACA that will have a profound effect on pharmacists and the practice of pharmacy.[4]

LONG TERM CARE (LTC) DISPENSING CHANGES (SECTION 3310)

The ACA requires Medicare Part D plans to reduce wasteful dispensing practices in long term care facilities.[4] Health plans will be required to implement short-cycle dispensing: dispensing doses of prescription and non-prescription medications on a weekly, daily or automatic basis for all Medicare Part D recipients. This will eliminate the 30 day fills for Part D enrollees residing in long term care facilities. CMS (Centers for Medicare & Medicaid Services) projects $2.3 billion in savings over five years and nearly $6 billion over the next ten years from this program. The final rules have been released with some major changes from the original proposed terms. The first major change is that the final rule will now take effect on January 1, 2013, rather than January 1, 2012, as was previously proposed. This will give LTC pharmacies and skilled nursing facilities more time to transition to short-cycle dispensing. Pharmacy providers will be able to compare dispensing methodologies so that the most effective and efficient systems can be implemented. There will also be more time for facilities to work directly with their pharmacists to ensure that staff is trained with the new workflows and processes. The second major change is that LTC pharmacies will have to dispense solid, oral doses of brand name medications to patients in 14 day or less supplies. This change will lessen the burden of implementing short cycle dispensing compared with the 7 day requirement proposed in the original rule. Certain medications will be excluded from the 14 day or less packaging (antibiotics and drugs that must be dispensed in their original container).

For those pharmacies who make the decision to use the more stringent 7 day dispensing cycle, CMS will not require them to report the percent of unused drugs.[5] CMS implemented this “incentive” to move pharmacies to a 7 day dispensing

cycle. Pharmacies that choose the 14 day dispensing cycle will need to calculate and report the amount of unused drug to CMS. This calculation is based on amount of drug dispensed compared to amount of drug consumed.

THE MEDICARE PART D DONUT HOLE (SECTION 1101)

Through the ACA, the Medicare Part D "donut hole" will be closed over the next decade (2010 to 2020).[6] Federal funds will be used in conjunction with pharmaceutical manufacturer's discounts on brand drugs. In 2010, elderly patients in the donut hole received a one-time rebate of $250. Starting in 2011, patients received a 50% discount on negotiated prices for brand-name drugs covered under Part D. These discounts increase to 75% on brand name and generic name drugs by 2020. Therefore, elderly patients who are not able to purchase their medication as ordered should be able to afford them with these changes. This program is designed to improve adherence to medications. In order to protect pharmacies dispensing medications at this discount, the law also requires they be paid within 14 days of dispensing the brand name products in these Medicare cases. The Secretary of Health and Human Services must establish a prompt payment system (14 days after electronic submission; 30 days for written submission) for pharmacies that provide a discount at the point of sale.

MEDICATION THERAPY MANAGEMENT (SECTION 3503)

Medication therapy management (MTM) is not a new concept. MTM was established in the Medicare Modernization Act of 2003.[4] It required that by 2005, all Medicare Part D plans offer an MTM program to specific beneficiaries. The initial MTM focused on elderly patients with multiple chronic illnesses or those taking specific targeted drugs. The pharmacist worked together with the patient and the physician to ensure appropriate medication therapy. Since that time, providers have expanded MTM services to prevent medication-related complications and reduce healthcare costs.

The ACA has established an expanded patient care role for pharmacists in the new health system models including accountable care organizations, patient centered medical homes, and transition of care teams.[4] The components of MTM as set forth in section 3505 of the ACA are listed below.

Components of MTM outlined in the Affordable Care Act[4]

1. Develop a treatment plan based on the therapeutic goals established by the prescriber and patient.
2. Select, modify, initiate or administer medications.
3. Monitor, order or perform laboratory tests.
4. Evaluate patient's response to therapy.
5. Conduct an initial Comprehensive Medication Review (CMR) to identify and prevent adverse outcomes.
6. Conduct quarterly targeted medication reviews on a schedule developed with the prescriber.
7. Conduct education and training of the patient to improve appropriate medication use.
8. Work with patient to identify opportunities to improve adherence to therapy.

It is important for the community pharmacist to understand the new health system models and how they might integrate their pharmacy business into these models.

Accountable Care Organizations (ACO)

An ACO combines hospitals, physician practice groups and other healthcare providers to establish an organization that provides coordinated care to Medicare patients.[7] The goal of an ACO is to provide the appropriate care in a coordinated manner to reduce duplication of services and prevent errors. The Medicare Shared Savings Program provides incentives for ACOs that meet standards for quality performance and reduce cost while putting patients first.

CMS established the Pioneer ACO Model program designed to support organizations that have experience operating as an ACO. The goal of that program is to test the impact of this different payment plan to determine if improved care and cost savings can be achieved.[7] This program was developed as a CMS Innovation Center initiative. Below are the 32 organizations that were part of the Pioneer ACO Model.

Pioneer ACOs[7]

1. Allina Health (formerly Allina Hospitals & Clinics)-servicing Minnesota & Western Wisconsin.
2. Atrius Health- servicing Eastern & Central Massachusetts.
3. Banner Health Network- servicing Phoenix Metropolitan Area (Maricopa and Pinal Counties).
4. Beacon, LLC (formerly Eastern Maine Healthcare System) - servicing Central, Eastern, & Northern Maine.
5. Bellin Thedacare Healthcare Partners- servicing Northeast Wisconsin.
6. Beth Israel Deaconess Physician Organization- servicing Eastern Massachusetts.
7. Brown & Toland Physicians-servicing San Francisco Bay Area.
8. Dartmouth-Hitchcock ACO-servicing New Hampshire & Eastern Vermont.
9. Fairview Health System-servicing Minneapolis Metropolitan Area.
10. Franciscan Alliance-servicing Indianapolis & Central Indiana.
11. Genesys PHO-servicing Southeastern Michigan.
12. Healthcare Partners Medical Group (alternative name: Healthcare Partners of California)-servicing Los Angeles & Orange Counties.
13. Healthcare Partners of Nevada-servicing Clark & Nye Counties, NV.
14. Heritage California ACO-servicing Southern, Central, & Coastal California.
15. JSA Medical Group, a division of HealthCare Partners-servicing Orlando, Tampa Bay, & surrounding South Florida.
16. Michigan Pioneer ACO-servicing Southeastern Michigan.
17. Monarch Healthcare-servicing Orange County, CA.
18. Montefiore ACO (formerly Bronx Accountable Healthcare Network (BAHN))-servicing New York City (the Bronx) and lower Westchester County.
19. Mount Auburn Cambridge Independent Practice Association (MACIPA)-servicing Eastern Massachusetts.
20. OSF HealthCare System-servicing Central Illinois.
21. Park Nicollet Health Services-servicing Minneapolis Metropolitan Area.
22. Partners Healthcare-servicing Eastern Massachusetts.
23. Physician Health Partners-servicing Denver Metropolitan Area.
24. Plus! (formerly North Texas ACO)-servicing Tarrant, Johnson & Parker counties in North Texas.
25. Presbyterian Healthcare Services (formerly Presbyterian Healthcare Services Central New Mexico Pioneer Accountable Care Organization)-servicing Central New Mexico.
26. Primecare Medical Network-servicing Southern California (San Bernardino & Riverside Counties).
27. Renaissance Health Network (formerly Renaissance Medical Management Company)-servicing Southeastern Pennsylvania.
28. Seton Health Alliance-servicing Central Texas.
29. Sharp Healthcare System-servicing San Diego County.
30. Steward Health Care System-servicing Eastern Massachusetts.
31. Trinity Pioneer ACO, LC-servicing Northwest Central Iowa.
32. University of Michigan-servicing Southeastern Michigan.

Patient-Centered Medical Home (PCMH)

A Patient-Centered Medical Home (PCMH) is a team-based approach to care led by a personal physician who provides ongoing coordinated care to maximize health outcomes.[8] The PCMH practice is responsible for providing for all of a patient's health care needs and coordinating care with other healthcare professionals. The PCMH includes preventive services, along with treatment of acute and chronic illness. It is a model of practice in which a team of health professionals, coordinated by a personal physician, works collaboratively to provide quality care coordination and communication to prevent adverse outcomes.

Transition of Care Teams

Transition of care is the movement patients make between healthcare providers and settings as their condition changes.[9] For example, an individual patient may be cared for in the outpatient setting by their primary physician. If an acute event requires them to be hospitalized, the care is transferred to a hospital physician. When the patient is transferred to home or a skilled facility, their care is transferred to the family or staff at the nursing home. The success of transitional care depends upon a complete treatment plan, developed by the healthcare team at both the transferring facility and the receiving facility. A successful transition of care not only includes medication reconciliation but also provides patient education and coordination of services between the healthcare professionals involved in each transition.

One example of pharmacist involvement in transition of care is at Thomas Jefferson Medical Center in Pennsylvania.[10] Pharmacists are involved in transitioning patients with heart failure to home. In this program, the hospital pharmacist calls the patient at home on days 2, 7, 14, 21 and 30 to ensure adherence, and they address any potential medication-related problem.

Another example of a successful transition of care team that involves community pharmacists is in Lady Lake, Florida. Greystone Healthcare Management partnered with one of the retail chains to improve care for patients being discharged from their 145 bed rehabilitation center.[11] Community pharmacists delivered medications to patients in the rehabilitation center and performed discharge counseling. The pharmacist contacted the patient within 72 hours of returning home. During this telephone call, the pharmacist provided additional adherence counseling and answered any patient questions. Based on the success of this pilot, Greystone is planning to expand the program to other facilities in their network.

MTM GRANTS

In addition to the roles and responsibilities described above, the Act establishes a grant program to determine new and improved ways to deliver medication therapy management. [4] The goal of the grant program is to reduce the $200 billion dollars spent on inappropriate drug use or non-adherence to therapy. Community pharmacies will be eligible for these MTM grants. Community pharmacies may consider partnering with local hospital pharmacies or physician groups to submit grants to support a team approach to reducing non-adherence as patients move from the hospital to the community setting.

DURABLE MEDICAL EQUIPMENT ACCREDITATION EXEMPTION (SECTION 3109)

Pharmacies will be exempt from the accreditation requirements to provide durable medical equipment (DME) to Medicare patients.[4] CMS currently requires that all providers of DME complete an accreditation process that is expensive and time consuming. Pharmacies can be exempt from the requirement if their total Medicare DME billings are ≤ 5% of total prescription sales and no fraud or abuse determinations have occurred in the past 5 years. The pharmacy must submit documentation to the Secretary of Human Services attesting to the accuracy of this information. If your pharmacy has already undergone accreditation, you will not be required to re-accredit if you meet the exemption requirements. For those pharmacies who wish to submit competitive bids for DME, accreditation requirements remain in place. Community pharmacies that are not currently involved in the DME business may consider expanding into this market since the requirement for accreditation has been changed.

MEDICAID PAYMENT FOR GENERIC DRUGS (SECTION 2503)

The Deficit Reduction Act of 2005 (DRA) included a change in pharmacy reimbursement for generic prescription drugs. This change would have resulted in pharmacies receiving reimbursement below their acquisition cost for generic Medicaid prescriptions. A court injunction suspended the implementation of this section of the DRA. The ACA will "fix" this problem by improving the definition of average manufacturer price (AMP) so that only retail pharmacy sales are included in the calculation.[4,6] The Centers for Medicare and Medicaid (CMS) will be required to set the Medicaid federal upper limit for reimbursement of generics at no less than 175% of average weighted AMP.

340B PRICING (SECTION 2501)

The 340B pricing structure was instituted in 1992 as part of the Veterans Health Care Act.[12] It required drug manufacturers to provide outpatient drugs at a reduced price to certain covered entities as defined in the Act. These included Federally Qualified Health Centers (FQHC), HIV/Ryan White clinics, hemophilia treatment centers, disproportionate share hospitals and certain types of clinics. The 340B pricing as defined in the Act was a highest price a "covered entity" would pay for an outpatient drug. Most 340B prices are 50% of the average wholesale price.

The ACA expands the number of "covered entities" eligible for 340B pricing.[4] In addition, covered entities can now contract with multiple pharmacies to provide pharmacy services extending 340B pricing to some community pharmacies. Therefore, a FQHC can contract with multiple community pharmacies to extend access to 340B pricing to their clients who choose to have their prescriptions filled with these partner pharmacies. This change in the law allows community pharmacies

to seek out new partnerships that expand their current prescription volume and provide needed clinical pharmacy services to an underserved population.

PHARMACY BENEFIT MANAGEMENT TRANSPARENCY (SECTION 6005)

Under this section, PBMs will be required to disclose financial information. This disclosure will be to the Secretary of Health and Human Services and will remain confidential.

SMALL BUSINESS REFORMS (SECTION 1003)

One component of the ACA penalizes businesses that do not provide health insurance and whose employees must purchase health plans through the new health insurance exchanges.[4] The penalty may be $2,000 for each employee who is subsidized to obtain coverage via these exchanges. This applies only to employers with more than 50 employees. If an employer has fewer than 25 employees, there will be tax credits to provide health insurance to employees. This portion of the ACA applies to any small business, including community pharmacies.

IMPROVING ACCESS TO BIOSIMILARS (SECTION 7001)

Through the ACA, the Food and Drug Administration (FDA) has an accelerated approval pathway for biological products that are biosimilar to an FDA-licensed biological product.[13] A biological product may be considered biosimilar if data show that the product is highly similar to an approved biological product and for which there are no clinically meaningful differences between the biosimilar and the approved biological product in terms of the safety, purity, and potency. There continues to be a significant push-back from pharmaceutical manufacturers regarding the validity of the biosimilar approval process. Although this rule was scheduled to be phased in during 2010, draft guidance to pharmaceutical firms detailing how these agents should be developed was released in February, 2012. It is not anticipated that biosimilars will be available on the market in the near future.

LIMIT OF $2,500 PER YEAR ON PRE-TAX HEALTHCARE FLEXIBLE SPENDING ACCOUNTS

In 2013, there will be a limit of $2,500 per year on pre-taxable flexible spending accounts (FSA).[4] FSAs are available through employers to allow employees to set aside pre-tax dollars for medical expenses. This provides a significant payroll savings for the employee. This limit on FSA will apply to all accounts regardless of the number of dependents an individual has on their plan. In addition to the $2,500 annual limit, over the counter medications will no longer be covered in the FSA unless the employee receives a prescription for the product. This is intended to deter the unnecessary “end-of-the-year” spend down of the FSA on over the counter products. Community pharmacists should take the opportunity to discuss these changes with patients. The pharmacist can educate them about cost savings with generic prescription medications and store-brand over the counter products. In cases of regular use of over the counter medications, the pharmacist can work with the patient to obtain a prescription for the product.

CONCLUSION

There are significant changes in the Affordable Care Act that will impact pharmacists and the practice of pharmacy. There are several opportunities for community and hospital pharmacists to expand their clinical role with their patients. This includes the provision of annual comprehensive drug reviews, vaccination programs, partnering with transition of care teams and medication therapy management. There will also be an impact on how the business of pharmacy will be conducted, including changes in 340B pricing, payment for patients in the “donut hole” and dispensing changes in long term care pharmacy. Now is the time for pharmacists to take advantage of these clinical and operational changes to expand roles in patient care. Pharmacists must continue to monitor changes in the ACA, particularly any announcements from the Supreme Court regarding the legality of the law.

CASE STUDY

Susan Moran is a pharmacist who owns an independent community pharmacy in the southeastern United States. Her pharmacy is in a town of approximately 101,000 people. The pharmacy is located within 0.5 mile of the Community Hospital. She has been looking for ways to expand her prescription business and she has been reading about the Affordable Care Act. She has decided that this is the time for her to implement some new approaches in the community.

List 3 ideas that Susan may wish to consider to expand her business based on the ACA changes.

- Consider implementing a transition of care program with the community hospital. Since her pharmacy is in close proximity to the hospital, she could discuss the possibility of partnering with the hospital to manage specific groups of patients that are being discharged and negotiate a fee for this service. It is important to identify at risk populations in the community. Hospitals are currently tracking readmission rates for heart failure, pneumonia and acute myocardial infarction. CMS will institute payment reductions for high readmission rates for these conditions in 2013. Susan may be able to work together with the hospital to try to reduce re-admission rates for these patients by dispensing the medication to the patient and conducting adherence counseling.
- Investigate the possibility of working together with local physician practices to provide a comprehensive medication review annually for their patients. This review could be used to make recommendations in therapy and identify those patients who may be non-adherent to treatment. Susan could negotiate a fee for conducting each review. She would work with the physicians to identify at-risk patients who may need targeted quarterly reviews.
- Implement an immunization practice at the pharmacy. Susan should complete training in vaccine administration and offer routine vaccinations to patients. She may be able to work with the local physician offices and hospital to offer specific vaccines to high risk patients.

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1. Does the program meet the learning objectives?
   - Describe the Patient Protection & Affordable Care Act (ACA) of 2010. YES NO
   - Discuss the specific changes that will be rolled out each year. YES NO
   - Summarize the changes in the ACA that have a significant impact on pharmacy. YES NO

2. Was the program independent & non-commercial YES NO

	Poor			Average		Excellent
3. Relevance of topic	1	2	3	4	5	6	7

4. What did you like most about this lesson?_____

5. What did you like least about this lesson?_____

Please Select the Most Correct Answer(s)

1. The number of uninsured individuals in the U.S. is approximately 32 million.
   A. True
   B. False
2. 340B pricing is:
   A. The highest price that a "covered entity" will pay
   B. Is generally 50% of the average wholesale price
   C. Expanded as part of the ACA
   D. All of these
3. The 3 tenants of the ACA are: insurance market reform, coverage of dependent children thru age 26, & elimination of the "donut hole."
   A. True B. False
4. The following sections of the ACA will be rolled out in 2014:
   A. Penalties to individuals who do not purchase health insurance
   B. Annual limits on coverage will end
   C. New 2.9% tax on medical devices
   D. A & B only
5. All of the following were implemented in 2010, except:
   A. Annual Wellness Visits for Medicare patients at no charge
   B. Tax on indoor tanning
   C. Dependent children covered up to age 26
   D. Children with preexisting conditions receive healthcare coverage
6. In 2010, patients in the Medicare "donut hole" received a one-time rebate of:
   A. $350
   B. $450
   C. $250
   D. None of these
7. Medication Therapy Management has been expanded in the ACA to include:
   A. Conduct Annual Comprehensive Medication Reviews
   B. Monitor, order or perform laboratory tests
   C. Select, modify or administer medications
   D. All of these
8. The new Medicaid Federal Upper Limit is:
   A. Based on retail sales only
   B. No less than 175% of actual manufacturer price
   C. Is no less than 125% AMP
   D. A & B
9. The Patient Protection & Affordable Care Act was signed into law in 2011.
   A. True
   B. False
10. Examples of programs that pharmacists may implement as a result of the ACA include:
    A. Transition of care programs
    B. No copay for Medicare patients
    C. Vaccine programs
    D. A & C

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Since May 1, 2012, we have been electronically transmitting your CE credits to ***CPE MONITOR.***

So, if you have not signed up with ***CPE MONITOR***, do it now.

We must have your ***CPE MONITOR*** ID# & your birthdate (day & month only).

Always, continue to send quiz answers to us like in the past.

YOUR CE CREDIT IS STILL BASED ON YOUR SENDING IN THE QUIZ ANSWERS TO US.

In December, 2012, you’ll receive a hard copy, paper, Credit Statement from us for 2012.

Beginning in 2013, you’ll download your Credit Statements from the ***CPE MONITOR*** site.