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LEGISLATIVE ACTION

Senate . House

. . . . .

The Committee on Health Policy (Bean) recommended the following:

Senate Amendment (with directory and title amendments)

Delete lines 101 - 741

and insert:

(14) A provider of prescribed drugs shall be reimbursed in an amount not to exceed the lesser of the actual acquisition cost based on the Centers for Medicare and Medicaid Services National Average Drug Acquisition Cost pricing files plus a professional dispensing fee, the wholesale acquisition cost plus a professional dispensing fee, the state maximum allowable cost plus a professional dispensing fee, or the usual and customary

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charge billed by the provider ~~the least of the amount billed by the provider, the provider's usual and customary charge, or the Medicaid maximum allowable fee established by the agency, plus a dispensing fee. The Medicaid maximum allowable fee for ingredient cost must be based on the lowest of: the average wholesale price (AWP) minus 16.4 percent, the wholesaler acquisition cost (WAC) plus 1.5 percent, the federal upper limit (FUL), the state maximum allowable cost (SMAC), or the usual and customary (UAC) charge billed by the provider~~.

(a) Medicaid providers must dispense generic drugs if available at lower cost and the agency has not determined that the branded product is more cost-effective, unless the prescriber has requested and received approval to require the branded product.

(b) ~~The agency shall implement a variable dispensing fee for prescribed medicines while ensuring continued access for Medicaid recipients. The variable dispensing fee may be based upon, but not limited to, either or both the volume of prescriptions dispensed by a specific pharmacy provider, the volume of prescriptions dispensed to an individual recipient, and dispensing of preferred-drug-list products.~~

~~(c) The agency may increase the pharmacy dispensing fee authorized by statute and in the General Appropriations Act by $0.50 for the dispensing of a Medicaid preferred-drug-list product and reduce the pharmacy dispensing fee by $0.50 for the dispensing of a Medicaid product that is not included on the preferred drug list.~~

~~(d)~~ The agency may establish a supplemental pharmaceutical dispensing fee to be paid to providers returning unused unit-

dose packaged medications to stock and crediting the Medicaid program for the ingredient cost of those medications if the ingredient costs to be credited exceed the value of the supplemental dispensing fee.

(c) ~~(c)~~ The agency may limit reimbursement for prescribed medicine in order to comply with any limitations or directions provided in the General Appropriations Act, which may include implementing a prospective or concurrent utilization review program.

Section 4. Subsections (9) and (11) of section 409.91195, Florida Statutes, are amended, and subsection (4) of that section is reenacted for the purpose of incorporating the amendment made by this act to section 409.912, Florida Statutes, in a reference thereto, to read:

409.91195 Medicaid Pharmaceutical and Therapeutics Committee.—There is created a Medicaid Pharmaceutical and Therapeutics Committee within the agency for the purpose of developing a Medicaid preferred drug list.

(4) Upon recommendation of the committee, the agency shall adopt a preferred drug list as described in s. 409.912(5). To the extent feasible, the committee shall review all drug classes included on the preferred drug list every 12 months, and may recommend additions to and deletions from the preferred drug list, such that the preferred drug list provides for medically appropriate drug therapies for Medicaid patients which achieve cost savings contained in the General Appropriations Act.

~~(9) Upon timely notice, the agency shall ensure that any therapeutic class of drugs which includes a drug that has been removed from distribution to the public by its manufacturer or~~

~~the United States Food and Drug Administration or has been required to carry a black box warning label by the United States Food and Drug Administration because of safety concerns is reviewed by the committee at the next regularly scheduled meeting. After such review, the committee must recommend whether to retain the therapeutic class of drugs or subcategories of drugs within a therapeutic class on the preferred drug list and whether to institute prior authorization requirements necessary to ensure patient safety.~~

(10) ~~(11)~~ Medicaid recipients may appeal agency preferred drug formulary decisions using the Medicaid fair hearing process administered by the Agency for Health Care Administration ~~Department of Children and Families~~.

Section 5. Paragraphs (a) and (c) of subsection (5) of section 409.912, Florida Statutes, are amended to read:

409.912 Cost-effective purchasing of health care.—The agency shall purchase goods and services for Medicaid recipients in the most cost-effective manner consistent with the delivery of quality medical care. To ensure that medical services are effectively utilized, the agency may, in any case, require a confirmation or second physician’s opinion of the correct diagnosis for purposes of authorizing future services under the Medicaid program. This section does not restrict access to emergency services or poststabilization care services as defined in 42 C.F.R. s. 438.114. Such confirmation or second opinion shall be rendered in a manner approved by the agency. The agency shall maximize the use of prepaid per capita and prepaid aggregate fixed-sum basis services when appropriate and other alternative service delivery and reimbursement methodologies,

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including competitive bidding pursuant to s. 287.057, designed to facilitate the cost-effective purchase of a case-managed continuum of care. The agency shall also require providers to minimize the exposure of recipients to the need for acute inpatient, custodial, and other institutional care and the inappropriate or unnecessary use of high-cost services. The agency shall contract with a vendor to monitor and evaluate the clinical practice patterns of providers in order to identify trends that are outside the normal practice patterns of a provider’s professional peers or the national guidelines of a provider’s professional association. The vendor must be able to provide information and counseling to a provider whose practice patterns are outside the norms, in consultation with the agency, to improve patient care and reduce inappropriate utilization. The agency may mandate prior authorization, drug therapy management, or disease management participation for certain populations of Medicaid beneficiaries, certain drug classes, or particular drugs to prevent fraud, abuse, overuse, and possible dangerous drug interactions. The Pharmaceutical and Therapeutics Committee shall make recommendations to the agency on drugs for which prior authorization is required. The agency shall inform the Pharmaceutical and Therapeutics Committee of its decisions regarding drugs subject to prior authorization. The agency is authorized to limit the entities it contracts with or enrolls as Medicaid providers by developing a provider network through provider credentialing. The agency may competitively bid single-source-provider contracts if procurement of goods or services results in demonstrated cost savings to the state without limiting access to care. The agency may limit its network based

on the assessment of beneficiary access to care, provider availability, provider quality standards, time and distance standards for access to care, the cultural competence of the provider network, demographic characteristics of Medicaid beneficiaries, practice and provider-to-beneficiary standards, appointment wait times, beneficiary use of services, provider turnover, provider profiling, provider licensure history, previous program integrity investigations and findings, peer review, provider Medicaid policy and billing compliance records, clinical and medical record audits, and other factors. Providers are not entitled to enrollment in the Medicaid provider network. The agency shall determine instances in which allowing Medicaid beneficiaries to purchase durable medical equipment and other goods is less expensive to the Medicaid program than long-term rental of the equipment or goods. The agency may establish rules to facilitate purchases in lieu of long-term rentals in order to protect against fraud and abuse in the Medicaid program as defined in s. 409.913. The agency may seek federal waivers necessary to administer these policies.

(5)(a) The agency shall implement a Medicaid prescribed-drug spending-control program that includes the following components:

1. A Medicaid preferred drug list, which shall be a listing of cost-effective therapeutic options recommended by the Medicaid Pharmacy and Therapeutics Committee established pursuant to s. 409.91195 and adopted by the agency for each therapeutic class on the preferred drug list. At the discretion of the committee, and when feasible, the preferred drug list should include at least two products in a therapeutic class. The

agency may post the preferred drug list and updates to the list on an Internet website without following the rulemaking procedures of chapter 120. Antiretroviral agents are excluded from the preferred drug list. The agency shall also limit the amount of a prescribed drug dispensed to no more than a 34-day supply unless the drug products' smallest marketed package is greater than a 34-day supply, or the drug is determined by the agency to be a maintenance drug in which case a 100-day maximum supply may be authorized. The agency may seek any federal waivers necessary to implement these cost-control programs and to continue participation in the federal Medicaid rebate program, or alternatively to negotiate state-only manufacturer rebates. The agency may adopt rules to administer this subparagraph. The agency shall continue to provide unlimited contraceptive drugs and items. The agency must establish procedures to ensure that:

a. There is a response to a request for prior authorization ~~consultation~~ by telephone or other telecommunication device within 24 hours after receipt of a request for prior authorization ~~consultation~~; and

b. A 72-hour supply of the drug prescribed is provided in an emergency or when the agency does not provide a response within 24 hours as required by sub-subparagraph a.

2. A provider of prescribed drugs is reimbursed in an amount not to exceed the lesser of the actual acquisition cost based on the Centers for Medicare and Medicaid Services National Average Drug Acquisition Cost pricing files plus a professional dispensing fee, the wholesale acquisition cost plus a professional dispensing fee, the state maximum allowable cost


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plus a professional dispensing fee, or the usual and customary charge billed by the provider ~~Reimbursement to pharmacies for Medicaid prescribed drugs shall be set at the lowest of: the average wholesale price (AWP) minus 16.4 percent, the wholesaler acquisition cost (WAC) plus 1.5 percent, the federal upper limit (FUL), the state maximum allowable cost (SMAC), or the usual and customary (UAC) charge billed by the provider~~.

3. The agency shall develop and implement a process for managing the drug therapies of Medicaid recipients who are using significant numbers of prescribed drugs each month. The management process may include, but is not limited to, comprehensive, physician-directed medical-record reviews, claims analyses, and case evaluations to determine the medical necessity and appropriateness of a patient's treatment plan and drug therapies. The agency may contract with a private organization to provide drug-program-management services. The Medicaid drug benefit management program shall include initiatives to manage drug therapies for HIV/AIDS patients, patients using 20 or more unique prescriptions in a 180-day period, and the top 1,000 patients in annual spending. The agency shall enroll any Medicaid recipient in the drug benefit management program if he or she meets the specifications of this provision and is not enrolled in a Medicaid health maintenance organization.

4. The agency may limit the size of its pharmacy network based on need, competitive bidding, price negotiations, credentialing, or similar criteria. The agency shall give special consideration to rural areas in determining the size and location of pharmacies included in the Medicaid pharmacy

network. A pharmacy credentialing process may include criteria such as a pharmacy's full-service status, location, size, patient educational programs, patient consultation, disease management services, and other characteristics. The agency may impose a moratorium on Medicaid pharmacy enrollment if it is determined that it has a sufficient number of Medicaid-participating providers. The agency must allow dispensing practitioners to participate as a part of the Medicaid pharmacy network regardless of the practitioner's proximity to any other entity that is dispensing prescription drugs under the Medicaid program. A dispensing practitioner must meet all credentialing requirements applicable to his or her practice, as determined by the agency.

5. The agency shall develop and implement a program that requires Medicaid practitioners who issue written prescriptions for medicinal drugs to use a counterfeit-proof prescription pad for Medicaid prescriptions. The agency shall require the use of standardized counterfeit-proof prescription pads by prescribers who issue written prescriptions for Medicaid recipients. The agency may implement the program in targeted geographic areas or statewide.

6. The agency may enter into arrangements that require manufacturers of generic drugs prescribed to Medicaid recipients to provide rebates of at least 15.1 percent of the average manufacturer price for the manufacturer's generic products. These arrangements shall require that if a generic-drug manufacturer pays federal rebates for Medicaid-reimbursed drugs at a level below 15.1 percent, the manufacturer must provide a supplemental rebate to the state in an amount necessary to

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achieve a 15.1-percent rebate level.

7. The agency may establish a preferred drug list as described in this subsection, and, pursuant to the establishment of such preferred drug list, negotiate supplemental rebates from manufacturers that are in addition to those required by Title XIX of the Social Security Act and at no less than 14 percent of the average manufacturer price as defined in 42 U.S.C. s. 1936 on the last day of a quarter unless the federal or supplemental rebate, or both, equals or exceeds 29 percent. There is no upper limit on the supplemental rebates the agency may negotiate. The agency may determine that specific products, brand-name or generic, are competitive at lower rebate percentages. Agreement to pay the minimum supplemental rebate percentage guarantees a manufacturer that the Medicaid Pharmaceutical and Therapeutics Committee will consider a product for inclusion on the preferred drug list. However, a pharmaceutical manufacturer is not guaranteed placement on the preferred drug list by simply paying the minimum supplemental rebate. Agency decisions will be made on the clinical efficacy of a drug and recommendations of the Medicaid Pharmaceutical and Therapeutics Committee, as well as the price of competing products minus federal and state rebates. The agency may contract with an outside agency or contractor to conduct negotiations for supplemental rebates. For the purposes of this section, the term "supplemental rebates" means cash rebates. Value-added programs as a substitution for supplemental rebates are prohibited. The agency may seek any federal waivers to implement this initiative.

8.a. ~~The agency shall expand home delivery of pharmacy products. The agency may amend the state plan and issue a~~

~~procurement, as necessary, in order to implement this program. The procurements must include agreements with a pharmacy or pharmacies located in the state to provide mail order delivery services at no cost to the recipients who elect to receive home delivery of pharmacy products. The procurement must focus on serving recipients with chronic diseases for which pharmacy expenditures represent a significant portion of Medicaid pharmacy expenditures or which impact a significant portion of the Medicaid population. The agency may seek and implement any federal waivers necessary to implement this subparagraph.~~

~~9. The agency shall limit to one dose per month any drug prescribed to treat erectile dysfunction.~~

~~10.a.~~ The agency may implement a Medicaid behavioral drug management system. The agency may contract with a vendor that has experience in operating behavioral drug management systems to implement this program. The agency may seek federal waivers to implement this program.

b. The agency, in conjunction with the Department of Children and Families, may implement the Medicaid behavioral drug management system that is designed to improve the quality of care and behavioral health prescribing practices based on best practice guidelines, improve patient adherence to medication plans, reduce clinical risk, and lower prescribed drug costs and the rate of inappropriate spending on Medicaid behavioral drugs. The program may include the following elements:

(I) Provide for the development and adoption of best practice guidelines for behavioral health-related drugs such as antipsychotics, antidepressants, and medications for treating

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bipolar disorders and other behavioral conditions; translate them into practice; review behavioral health prescribers and compare their prescribing patterns to a number of indicators that are based on national standards; and determine deviations from best practice guidelines.

(II) Implement processes for providing feedback to and educating prescribers using best practice educational materials and peer-to-peer consultation.

(III) Assess Medicaid beneficiaries who are outliers in their use of behavioral health drugs with regard to the numbers and types of drugs taken, drug dosages, combination drug therapies, and other indicators of improper use of behavioral health drugs.

(IV) Alert prescribers to patients who fail to refill prescriptions in a timely fashion, are prescribed multiple same-class behavioral health drugs, and may have other potential medication problems.

(V) Track spending trends for behavioral health drugs and deviation from best practice guidelines.

(VI) Use educational and technological approaches to promote best practices, educate consumers, and train prescribers in the use of practice guidelines.

(VII) Disseminate electronic and published materials.

(VIII) Hold statewide and regional conferences.

(IX) Implement a disease management program with a model quality-based medication component for severely mentally ill individuals and emotionally disturbed children who are high users of care.

9.~~11.~~ The agency shall implement a Medicaid prescription

drug management system.

a. The agency may contract with a vendor that has experience in operating prescription drug management systems in order to implement this system. Any management system that is implemented in accordance with this subparagraph must rely on cooperation between physicians and pharmacists to determine appropriate practice patterns and clinical guidelines to improve the prescribing, dispensing, and use of drugs in the Medicaid program. The agency may seek federal waivers to implement this program.

b. The drug management system must be designed to improve the quality of care and prescribing practices based on best practice guidelines, improve patient adherence to medication plans, reduce clinical risk, and lower prescribed drug costs and the rate of inappropriate spending on Medicaid prescription drugs. The program must:

(I) Provide for the adoption of best practice guidelines for the prescribing and use of drugs in the Medicaid program, including translating best practice guidelines into practice; reviewing prescriber patterns and comparing them to indicators that are based on national standards and practice patterns of clinical peers in their community, statewide, and nationally; and determine deviations from best practice guidelines.

(II) Implement processes for providing feedback to and educating prescribers using best practice educational materials and peer-to-peer consultation.

(III) Assess Medicaid recipients who are outliers in their use of a single or multiple prescription drugs with regard to the numbers and types of drugs taken, drug dosages, combination

drug therapies, and other indicators of improper use of prescription drugs.

(IV) Alert prescribers to recipients who fail to refill prescriptions in a timely fashion, are prescribed multiple drugs that may be redundant or contraindicated, or may have other potential medication problems.

10.~~12.~~ The agency may contract for drug rebate administration, including, but not limited to, calculating rebate amounts, invoicing manufacturers, negotiating disputes with manufacturers, and maintaining a database of rebate collections.

11.~~13.~~ The agency may specify the preferred daily dosing form or strength for the purpose of promoting best practices with regard to the prescribing of certain drugs as specified in the General Appropriations Act and ensuring cost-effective prescribing practices.

12.~~14.~~ The agency may require prior authorization for Medicaid-covered prescribed drugs. The agency may prior-authorize the use of a product:

a. For an indication not approved in labeling;

b. To comply with certain clinical guidelines; or

c. If the product has the potential for overuse, misuse, or abuse.

The agency may require the prescribing professional to provide information about the rationale and supporting medical evidence for the use of a drug. The agency shall post prior authorization, step-edit criteria and protocol, and updates to the list of drugs that are subject to prior authorization on the

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agency's Internet website within 21 days after the prior authorization and step-edit criteria and protocol and updates are approved by the agency. For purposes of this subparagraph, the term "step-edit" means an automatic electronic review of certain medications subject to prior authorization.

13.~~15.~~ The agency, in conjunction with the Pharmaceutical and Therapeutics Committee, may require age-related prior authorizations for certain prescribed drugs. The agency may preauthorize the use of a drug for a recipient who may not meet the age requirement or may exceed the length of therapy for use of this product as recommended by the manufacturer and approved by the Food and Drug Administration. Prior authorization may require the prescribing professional to provide information about the rationale and supporting medical evidence for the use of a drug.

14.~~16.~~ The agency shall implement a step-therapy prior authorization approval process for medications excluded from the preferred drug list. Medications listed on the preferred drug list must be used within the previous 12 months before the alternative medications that are not listed. The step-therapy prior authorization may require the prescriber to use the medications of a similar drug class or for a similar medical indication unless contraindicated in the Food and Drug Administration labeling. The trial period between the specified steps may vary according to the medical indication. The step-therapy approval process shall be developed in accordance with the committee as stated in s. 409.91195(7) and (8). A drug product may be approved without meeting the step-therapy prior authorization criteria if the prescribing physician provides the

agency with additional written medical or clinical documentation that the product is medically necessary because:

a. There is not a drug on the preferred drug list to treat the disease or medical condition which is an acceptable clinical alternative;

b. The alternatives have been ineffective in the treatment of the beneficiary's disease; or

c. Based on historic evidence and known characteristics of the patient and the drug, the drug is likely to be ineffective, or the number of doses have been ineffective.

The agency shall work with the physician to determine the best alternative for the patient. The agency may adopt rules waiving the requirements for written clinical documentation for specific drugs in limited clinical situations.

15.~~17.~~ The agency shall implement a return and reuse program for drugs dispensed by pharmacies to institutional recipients, which includes payment of a $5 restocking fee for the implementation and operation of the program. The return and reuse program shall be implemented electronically and in a manner that promotes efficiency. The program must permit a pharmacy to exclude drugs from the program if it is not practical or cost-effective for the drug to be included and must provide for the return to inventory of drugs that cannot be credited or returned in a cost-effective manner. The agency shall determine if the program has reduced the amount of Medicaid prescription drugs which are destroyed on an annual basis and if there are additional ways to ensure more prescription drugs are not destroyed which could safely be

reused.

~~(c) The agency shall submit quarterly reports to the Governor, the President of the Senate, and the Speaker of the House of Representatives which must include, but need not be limited to, the progress made in implementing this subsection and its effect on Medicaid prescribed-drug expenditures.~~

Section 6. Section 409.91213, Florida Statutes, is repealed.

Section 7. Paragraph (d) of subsection (1) of section 409.913, Florida Statutes, is amended to read:

409.913 Oversight of the integrity of the Medicaid program.—The agency shall operate a program to oversee the activities of Florida Medicaid recipients, and providers and their representatives, to ensure that fraudulent and abusive behavior and neglect of recipients occur to the minimum extent possible, and to recover overpayments and impose sanctions as appropriate. Each January 15, the agency and the Medicaid Fraud Control Unit of the Department of Legal Affairs shall submit a report to the Legislature documenting the effectiveness of the state’s efforts to control Medicaid fraud and abuse and to recover Medicaid overpayments during the previous fiscal year. The report must describe the number of cases opened and investigated each year; the sources of the cases opened; the disposition of the cases closed each year; the amount of overpayments alleged in preliminary and final audit letters; the number and amount of fines or penalties imposed; any reductions in overpayment amounts negotiated in settlement agreements or by other means; the amount of final agency determinations of overpayments; the amount deducted from federal claiming as a

result of overpayments; the amount of overpayments recovered each year; the amount of cost of investigation recovered each year; the average length of time to collect from the time the case was opened until the overpayment is paid in full; the amount determined as uncollectible and the portion of the uncollectible amount subsequently reclaimed from the Federal Government; the number of providers, by type, that are terminated from participation in the Medicaid program as a result of fraud and abuse; and all costs associated with discovering and prosecuting cases of Medicaid overpayments and making recoveries in such cases. The report must also document actions taken to prevent overpayments and the number of providers prevented from enrolling in or reenrolling in the Medicaid program as a result of documented Medicaid fraud and abuse and must include policy recommendations necessary to prevent or recover overpayments and changes necessary to prevent and detect Medicaid fraud. All policy recommendations in the report must include a detailed fiscal analysis, including, but not limited to, implementation costs, estimated savings to the Medicaid program, and the return on investment. The agency must submit the policy recommendations and fiscal analyses in the report to the appropriate estimating conference, pursuant to s. 216.137, by February 15 of each year. The agency and the Medicaid Fraud Control Unit of the Department of Legal Affairs each must include detailed unit-specific performance standards, benchmarks, and metrics in the report, including projected cost savings to the state Medicaid program during the following fiscal year.

(1) For the purposes of this section, the term:

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(d) "Medical necessity" or "medically necessary" means any goods or services necessary to palliate the effects of a terminal condition, or to prevent, diagnose, correct, cure, alleviate, or preclude deterioration of a condition that threatens life, causes pain or suffering, or results in illness or infirmity, which goods or services are provided in accordance with generally accepted standards of medical practice. For purposes of determining Medicaid reimbursement, the agency is the final arbiter of medical necessity. Determinations of medical necessity must be made by a licensed physician employed by or under contract with the agency, except for behavior analysis services, which may be determined by a licensed physician or a doctoral-level board-certified behavior analyst. Determinations ~~and~~ must be based upon information available at the time the goods or services are requested ~~provided~~.

====== D I R E C T O R Y C L A U S E A M E N D M E N T ======
And the directory clause is amended as follows:

Delete lines 71 - 72

and insert:

Section 3. Subsection (14) of section 409.908, Florida Statutes, is amended to read:

================ T I T L E A M E N D M E N T ================
And the title is amended as follows:

Delete lines 8 - 38

and insert:

amending s. 409.908, F.S.; revising the method for determining prescribed drug provider reimbursements;

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deleting a requirement for the agency to implement certain fees for prescribed medicines; deleting authorization for the agency to increase certain dispensing fees by certain amounts; reenacting and amending s. 409.91195, F.S., relating to the Medicaid Pharmaceutical and Therapeutics Committee; deleting a requirement for the agency to ensure that the committee reviews certain drugs under certain circumstances; designating the agency, rather than the Department of Children and Families, as the administrator for certain hearings; amending s. 409.912, F.S.; requiring the agency to establish certain procedures related to prior authorization requests rather than prior consultation requests; revising the method for determining prescribed drug provider reimbursements; deleting a requirement for the agency to expand home delivery of pharmacy products; deleting a dosage limitation on certain drugs; deleting a requirement for the agency to submit certain quarterly reports to the Governor and the Legislature; repealing s. 409.91213, F.S., relating to quarterly progress reports and annual reports; amending s. 409.913, F.S.; revising the definitions of the terms “medical necessity” and “medically necessary” to provide an exception for behavior analysis services determinations; requiring that determinations be based on information available at the time goods or services are requested, rather than at the time such goods or services are provided;

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repealing s. 765.53, F.S., relating to the