SECTION 1. SHORT TITLE.

This Act may be cited as the ''Comprehensive Care for Seniors Act of 2018''.

SEC. 2. DIRECTING THE SECRETARY OF HEALTH AND HUMAN SERVICES TO ISSUE A FINAL REGULATION BASED ON THE PROPOSED REGULATION RELATING TO THE PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE) UNDER THE MEDICARE AND MEDICAID PROGRAMS.

Not later than December 31, 2018, the Secretary of Health and Human Services shall issue a final regulation based on the provisions of the proposed regulation titled ''Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE)'' (81 Fed. Reg. 54666).

The SPEAKER pro tempore. Pursuant to the rule, the gentlewoman from Indiana (Mrs. WALORSKI) and the gentleman from Michigan (Mr. LEVIN) each will control 20 minutes.

The Chair recognizes the gentlewoman from Indiana.

GENERAL LEAVE

Mrs. WALORSKI. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and include extraneous material on H.R. 6561, currently under consideration.

The SPEAKER pro tempore. Is there objection to the request of the gentlewoman from Indiana?

There was no objection.

Mrs. WALORSKI. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise today in support of H.R. 6561, the Comprehensive Care for Seniors Act of 2018. This bipartisan legislation would require the Secretary of HHS to finalize updated regulations for the Programs of All-Inclusive Care for the Elderly, commonly known as PACE, while still giving the Secretary the flexibility to make updates and changes to the proposed regulation.

The PACE program is a proven model for delivering high-quality, comprehensive, community-based healthcare for seniors. It helps seniors whose health conditions would otherwise land them in a nursing home to remain in their homes for as long as possible by allowing them to see health professionals and social service providers at local PACE centers.

There are currently 123 PACE organizations in 31 States that serve over 45,000 Medicare and Medicaid beneficiaries, enabling them to live safely in the community through the fully integrated services and support provided. This allows beneficiaries to live longer, experience better health, and have fewer hospital visits. Seniors facing health challenges should have the option to receive high-quality healthcare while continuing to live at home, and programs like St. Joseph PACE in Mishawaka, in my district, allow them to do just that.

In 2016, CMS released a proposed rule to update the original guidelines from 2006. A bipartisan group of Members of Congress sent letters in November of 2017 and June of 2018 urging CMS to prioritize updating the existing regulatory framework, which is more than a decade old. The agency has, unfortunately, not taken any action.

This much-needed update would allow PACE programs to customize their interdisciplinary team around the needs of each enrollee, provide more services in the community, and give greater flexibility to partner with community providers.

Mr. Speaker, I reserve the balance of my time.

Mr. LEVIN. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, my colleague from Indiana has described very well the purpose of this legislation. There are, I think, at least five sponsors of this legislation, Democrats and Republicans, and it is another example of bipartisanship on a rather technical issue, technical in this sense.

There was always a need for regulation, and CMS proposed, now, 2 years ago, a regulation updating the requirements governing PACE. Unfortunately, under this present administration, CMS has not finalized these rules. What this bill essentially requires is that CMS finalize these regulations by December 31, 2018. Hopefully, that can occur before 2031.

We sometimes do too much on December 31 of a year. I have been here in session a few times on December 31, I think.

Mr. Speaker, I support this bill and recommend its passage, and I yield back the balance of my time.

Mrs. WALORSKI. Mr. Speaker, I yield myself the balance of my time.

Mr. Speaker, I want to thank my colleagues, Representatives JENKINS, BLUMENAUER, CHU, KIND, BILIRAKIS, DINGELL, and CHRIS SMITH, for their hard work getting this bill to this point and their previous work on this issue.

The PACE program is long overdue for an update. This bipartisan, commonsense legislation will ensure improvements are made quickly so more seniors can live in their communities longer.

Mr. Speaker, I urge my colleague to support this bill, and I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentlewoman from Indiana (Mrs. WALORSKI) that the House suspend the rules and pass the bill, H.R. 6561, as amended.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

The title of the bill was amended so as to read: ''A bill to direct the Secretary of Health and Human Services to issue a final regulation based on the proposed regulation relating to the Programs of All-Inclusive Care for the Elderly (PACE) under the Medicare and Medicaid programs.''.

A motion to reconsider was laid on the table.

LOCAL COVERAGE DETERMINATION CLARIFICATION ACT OF 2018

Ms. JENKINS of Kansas. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 3635) to amend title XVIII of the Social Security Act in order to improve the process whereby medicare administrative contractors issue local coverage determinations under the Medicare program, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 3635

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Local Coverage Determination Clarification Act of 2018''.

SEC. 2. IMPROVEMENTS IN THE MEDICARE LOCAL COVERAGE DETERMINATION (LCD) PROCESS FOR SPECIFIED LCDS.

(a) DEVELOPMENT PROCESS FOR SPECIFIED LCDS.—Section 1862(l)(5)(D) of the Social Security Act (42 U.S.C. 1395y(l)(5)(D)) is amended to read as follows:

''(D) PROCESS FOR ISSUING SPECIFIED LOCAL COVERAGE DETERMINATIONS.—

''(i) IN GENERAL.—In the case of a specified local coverage determination (as defined in clause (iii)) within an area by a medicare administrative contractor, such medicare administrative contractor must take the following actions with respect to such determination before such determination may take effect:

''(I) Publish on the public Internet website of the intermediary or carrier a proposed version of the specified local coverage determination (in this subparagraph referred to as a 'draft determination'), a written rationale for the draft determination, and a description of all evidence relied upon and considered by the intermediary or carrier in the development of the draft determination.

''(II) Not later than 60 days after the date on which the intermediary or carrier publishes the draft determination in accordance with subclause (I), convene one or more open, public meetings to review the draft determination, receive comments with respect to the draft determination, and secure the advice of an expert panel (such as a carrier advisory committee described in chapter 13 of the Medicare Program Integrity Manual in effect on August 31, 2015) with respect to the draft determination. The intermediary or carrier shall make available means for the public to attend such meetings remotely, such as via teleconference.

''(III) With respect to each meeting convened pursuant to subclause (II), post on the public Internet website of the intermediary or carrier, not later than 14 days after such meeting is convened, a record of the minutes for such meeting, which may be a recording of the meeting.

''(IV) Provide a period for submission of written public comment on such draft determination that begins on the date on which all records required to be posted with respect to such draft determination under subclause (III) are so posted and that is not fewer than 30 days in duration.

''(ii) FINALIZING A SPECIFIED LOCAL COVERAGE DETERMINATION.—A fiscal intermediary or carrier that has entered into a contract with the Secretary under section 1874A shall, with respect to a specified local coverage determination, post on the public Internet website of the fiscal intermediary or carrier the following information before

the specified local coverage determination (in this subparagraph referred to as the 'final determination') takes effect—

''(I) a response to the relevant issues raised at meetings convened pursuant to clause (i)(II) with respect to the draft determination;

''(II) the rationale for the final determination;

''(III) in the case that the intermediary or carrier considered qualifying evidence (as defined in clause (v)) that was not described in the written notice provided pursuant to clause (i)(I), a description of such qualifying evidence; and

''(IV) an effective date for the final determination that is not less than 30 days after the date on which such determination is so posted.

''(iii) SPECIFIED LOCAL COVERAGE DETERMINATION DEFINED.—For purposes of this subparagraph, the term 'specified local coverage determination' means, with respect to the relevant geographic area—

''(I) a new local coverage determination;

''(II) a revised local coverage determination for such geographic area that restricts one or more existing terms of coverage for such area (such as by adding requirement to an existing local coverage determination that results in decreased coverage or by deleting previously covered ICD–9 or ICD–10 codes (for reasons other than routine coding changes));

''(III) a revised local coverage determination that makes a substantive revision to one or more existing local coverage determinations; or

''(IV) any other local coverage determination specified by the Secretary pursuant to regulations.

''(iv) QUALIFYING EVIDENCE DEFINED.—For purposes of this subparagraph, the term 'qualifying evidence' means publicly available evidence of general acceptance by the medical community, such as published original research in peer-reviewed medical journals, systematic reviews and meta-analyses, evidence-based consensus statements, and clinical guidelines.''.

(b) LCD RECONSIDERATION PROCESS.—Section 1869(f) of the Social Security Act (42 U.S.C. 1395ff(f)) is amended—

(1) in paragraph (2)(A), by inserting ''(including the reconsiderations described in paragraphs (8) and (9))'' after ''local coverage determination'';

(2) in paragraph (5), by inserting ''(except for a reconsideration described in paragraphs (8) and (9))'' after ''the coverage determination'';

(3) by redesignating paragraph (8) as paragraph (13); and

(4) by inserting after paragraph (7) the following new paragraphs:

''(8) CARRIER OR FISCAL INTERMEDIARY RECONSIDERATION PROCESS FOR SPECIFIED LOCAL COVERAGE DETERMINATIONS.—Upon the filing of a request by an interested party (as defined in paragraph (11)(B))with respect to a specified local coverage determination by a fiscal intermediary or carrier that has entered into a contract with the Secretary under section 1874A, the intermediary or carrier shall reconsider such determination in accordance with the following process:

''(A) Not later than 30 days after such a request is filed with the fiscal intermediary or carrier by the interested party with respect to such determination, the intermediary or carrier shall—

''(i) determine whether the request is an applicable request; and

''(ii) in the case that the request is not an applicable request, inform the interested party of the reasons why such request is not an applicable request.

''(B) In the case that the intermediary or carrier determines under subparagraph (A) that the request described in such subparagraph is an applicable request, the intermediary or carrier shall, not later than 90 days after the date on which the request was filed with the intermediary or carrier, take the actions described in subparagraphs (C), (D), and (E) with respect to the determination.

''(C) The action described in this subparagraph is the action of specifying whether any of the following statements is applicable to the determination:

''(i) The determination did not reasonably consider qualifying evidence relevant to such determination.

''(ii) The determination used language that exceeded the scope of the intended purpose of the determination.

''(iii) The determination was incorrect in its determination of whether such item or service is reasonable and necessary for the diagnosis or treatment of illness or injury under section 1862(a)(1)(A).

''(iv) The determination failed to describe, with respect to such an item or service, the clinical conditions to be used for purposes of determining whether such item or service is reasonable and necessary for the diagnosis or treatment of illness or injury under section 1862(a)(1)(A).

''(v) The determination does not apply with respect to items or services to which it was intended to apply.

''(vi) The determination is erroneous for another reason that the intermediary or carrier identifies.

''(D) The action described in this subparagraph, with respect to the determination, is the action of taking, based on the specification under subparagraph (C) of whether any of the statements in such subparagraph applied to such determination, one or more of the following actions:

''(i) Making no change in the determination.

''(ii) Rescinding all or a part of the determination.

''(iii) Modifying the determination to restrict the coverage provided under this title for an item or service that is subject to the determination.

''(iv) Modifying the determination to expand the coverage provided under this title for an item or service that is subject to the determination.

''(E) The action described in this subparagraph is the action of making publicly available a written description of the action taken under subparagraph (D) with respect to the determination, including the evidence considered by the medicare administrative contractor.

''(9) AGENCY REVIEW OF RECONSIDERATION DECISION.—The Secretary shall establish a process to review a medicare administrative contractor's technical compliance with the requirements, including ensuring that the medicare administrative contractor independently reviewed the evidence involved, of the reconsideration under paragraph (8).

''(10) RULE OF CONSTRUCTION.—Nothing in paragraph (8) may be construed as affecting the right of an aggrieved party to file a complaint under paragraph (2)(A) and receive a determination in accordance with the provisions of such paragraph. An aggrieved prty is not required to file a request under paragraph (8) or (9) prior to filing a complaint under paragraph (2).

''(11) DEFINITIONS APPLICABLE TO PARAGRAPHS (8) AND (9).—For purposes of paragraphs (8) and (9):

''(A) The term 'applicable request' means a request that is submitted in fiscal year 2019 or a subsequent fiscal year, that is solely with respect to a specified local coverage determination, and that includes a description of the rationale for such request and any information or evidence supporting such request. For purposes of the preceding sentence, the Secretary may not require, as a condition of treating a request with respect to such a determination as an applicable request, that the request contain qualifying evidence that was not considered in the development of such determination.

''(B) The term 'interested party' means, with respect to a specified local coverage determination within an area by a fiscal intermediary or carrier that has entered into a contract with the Secretary under section 1874A, a beneficiary or stakeholder (including a medical professional society or physician).

''(C) The term 'qualifying evidence' has the meaning given such term by clause (iv) of section 1862(l)(5)(D).

''(D) The term 'specified local coverage determination' has the meaning given such term by clause (iii) of such section.

''(12) REPORT.—Not later than December 31 of each year (beginning with 2019), the Secretary shall submit to Congress a report containing the following:

''(A) The number of requests filed with fiscal intermediaries and carriers under paragraph (8), and the number of appeals filed with the Secretary under paragraph (9), during the 1-year period ending on such date.

''(B) With respect to such requests filed with such intermediaries and carriers under paragraph (8) during such period, the number of times that intermediaries and carriers took, with respect to the actions described in subparagraphs (C) through (E) of such paragraph, each such action.

''(C) With respect to such appeals filed with the Secretary under paragraph (9) during such period, the number of times that the Secretary took, with respect to the actions described in subparagraph (D) of paragraph (8), each such action.

''(D) Recommendations on ways to improve—

''(i) the efficacy and the efficiency of the process described in paragraph (8); and

''(ii) communication with individuals entitled to benefits under part A or enrolled under part B, providers of services, and suppliers regarding such process.''.

SEC. 3. PROMULGATION OF REGULATIONS; APPLICATION DATE.

The Secretary of Health and Human Services shall promulgate regulations to carry out paragraph (5)(D) of section 1862(l) of the Social Security Act (42 U.S.C. 1395y(l)), as amended by subsection (a), and paragraphs (8) and (9) of section 1869(f) of such Act (42 U.S.C. 1395ff(f)), as inserted by subsection (b), in such a manner as to ensure that the processes described in such paragraphs are fully implemented by January 1, 2020.

The SPEAKER pro tempore. Pursuant to the rule, the gentlewoman from Kansas (Ms. JENKINS) and the gentleman from Michigan (Mr. LEVIN) each will control 20 minutes.

The Chair recognizes the gentlewoman from Kansas.

GENERAL LEAVE

Ms. JENKINS of Kansas. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and include extraneous material on H.R. 3635, currently under consideration.

The SPEAKER pro tempore. Is there objection to the request of the gentlewoman from Kansas?

There was no objection.

Ms. JENKINS of Kansas. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, today, I rise in support of H.R. 3635, the Local Coverage Determination Clarification Act. I introduced this legislation along with Congressman KIND, which will help ensure the Medicare coverage decisions are made by qualified health experts through a transparent process that is based on sound medical evidence.

Medicare administrative contractors, or MACs, play a critical role in ensuring that Medicare beneficiaries have access to needed care. However, the less-than-transparent process used by MACs to make coverage decisions can limit or deny patients' access to necessary care.

Specifically, the science that guides some of these decisions can be flawed, mischaracterized, or misapplied. The deliberations and decisions of the MACs, which should be based on medical science, are often conducted behind closed doors, with little opportunity for interested stakeholders to raise issues or offer alternatives. These decisions affect millions of Medicare beneficiaries and impact crucial access to innovative technologies and services.

The establishment of a clear process informed by health experts will make the local coverage determination, or LCD, process and the decisions developed by that process more sound, more transparent, and ensure accountability among MACs. These requirements are necessary to ensure that our Nation's seniors receive quality healthcare treatment.

Specifically, H.R. 3635 would improve the LCD process by requiring that carrier advisory committee meetings of the MAC are open, public, and on the record, with minutes taken and posted to the MAC's website for public inspection. The gravity of limiting or precluding coverage for both beneficiaries and practitioners heightens the need for transparency, especially when such meetings are currently closed off.

MACs would be required to include, at the outset of the coverage determination process, a description of the evidence a MAC considered when drafting a local coverage determination as well as the rationale it relies on to deny coverage.

Additionally, under current rules, local coverage determinations are essentially unreviewable once they become final. This legislation would create a process for stakeholders to request additional review of a MAC's local coverage decision from the Centers for Medicare and Medicaid Services.

It would also require the Secretary to submit a report to Congress regarding the number of requests filed with fiscal intermediaries and carriers and the number of appeals filed with the Secretary, as well as the actions in response. Additionally, the report would recommend ways to improve the usefulness and efficiency of the process as well as the communication with Medicare beneficiaries and providers.

While I am pleased that the legislation we have here today takes steps to improve the process and bring transparency to protect access for Medicare patients, we must continue to work to ensure that MACs independently evaluate the evidence of other MACs' coverage decisions. Local coverage determinations should be thoroughly evaluated by experts in each local jurisdiction.

Currently, loopholes in the process allow contractors to adopt another MAC's coverage determination without the necessary scientific rigor and meaningful engagement with stakeholders that is vital in forming the most appropriate policy. Due to regional, geographic, and population-based deficiencies, these carbon-copied LCDs may not reflect the specific geographic region they are intended to serve. Local coverage determinations should be just that—local.

Put simply, what works best for one location does not always work best for another location. Applying local coverage determinations across jurisdictions has the practical effect of establishing national coverage policies without having followed the more rigorous national coverage determination process. As such, I look forward to working with my colleagues on this issue, moving forward.

Medicare beneficiaries deserve transparency and accountability for these decisions that directly impact their access to care. These reforms are necessary to ensure that local coverage determinations do not impede a physician's medical judgment and deny patients access to medically necessary care. By changing the LCD process, Congress can ensure that medical and scientific evidence is not used selectively to deny appropriate coverage to seniors.

I want to thank Mr. KIND, who joined me in introducing this legislation.

I want to ask my colleagues for their bipartisan support of this bill as we work to improve access and care for every American.

Mr. Speaker, I reserve the balance of my time.

Mr. LEVIN. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, my colleague has well described the purpose of this legislation. As she indicated, the bill establishes a timeline through which MACs must publish proposed LCDs online. She described what they are so the public can be sure what MACs and LCDs are.

It would further require public meetings to review draft determinations and ensure expert input is being sought on all proposals.

The bill also provides that stakeholders and beneficiaries, as she mentioned, may request reconsideration of LCDs and that MACs must respond to these requests.

These are small but useful improvements to the local coverage determination process. It will help improve transparency and ensure that appropriate coverage determinations are made for Medicare beneficiaries.

Mr. Speaker, I am pleased to indicate support for this bill, and I yield back the balance of my time.

Ms. JENKINS of Kansas. Mr. Speaker, I yield myself the balance of my time.

Mr. Speaker, in closing, I am proud to stand here today in support of this commonsense legislation that creates transparency and accountability to the local coverage determinations process and will help ensure that Medicare patients receive the medical care they need.

Mr. Speaker, I hope everyone will join me in voting for this legislation on the House floor today as we work to improve access and care for every American, and I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentlewoman from Kansas (Ms. JENKINS) that the House suspend the rules and pass the bill, H.R. 3635, as amended.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

□ 1530

STATE INSURANCE REGULATION PRESERVATION ACT

Mr. ROTHFUS. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 5059) to amend the Home Owners' Loan Act with respect to the registration and supervision of insurance savings and loan holding companies, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 5059

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''State Insurance Regulation Preservation Act''.

SEC. 2. SUPERVISION OF INSURANCE SAVINGS AND LOAN HOLDING COMPANIES.

(a) DEFINITIONS.—Section 10(a)(1) of the Home Owners' Loan Act (12 U.S.C. 1467a(a)(1)) is amended by inserting at the end the following:

''(K) DOMICILE.—The term 'domicile' means the State in which an insurance underwriting company or the holding company for such company is incorporated, chartered, or organized.

''(L) BUSINESS OF INSURANCE.—The term 'business of insurance' means any activity that is regulated in accordance with the relevant State insurance laws and regulations, including the writing of insurance and the reinsuring of risks.

''(M) INSURANCE SAVINGS AND LOAN HOLDING COMPANY.—The term 'insurance savings and loan holding company' means—