



August 20, 2020

Alfred M. Pollard
General Counsel
Federal Housing Finance Agency
8th Floor
400 7th Street, SW
Washington, DC 20219

RE: Enterprise Regulatory Capital Framework (RIN 2590-AA95)

Submitted by Electronic Delivery to <http://www.regulations.gov> and RegComments@fhfa.gov

Dear Mr. Pollard:

On behalf of the more than 140,000 members of the National Association of Home Builders (NAHB), I appreciate the opportunity to provide comments in response to the Federal Housing Finance Agency's (FHFA) Notice of Proposed Rulemaking (NPR) proposing a new regulatory capital framework for Fannie Mae and Freddie Mac ("the Enterprises"). Though the Enterprises remain in conservatorship, now is the time to establish a framework that will ensure the Enterprises have the requirements and structure in place to achieve a level of capital that will allow them to operate in a safe and sound manner and provide stability to the housing finance markets.

NAHB is a Washington DC-based trade association representing, among others, companies involved in the development and construction of for-sale single-family homes, including homes for first-time and low- and moderate-income homebuyers as well as the production and management of affordable multifamily rental housing. The ability of the home building industry to meet the demand for housing, including addressing affordable housing needs, and contribute significantly to the nation's economic growth is dependent on a sound and efficiently operating housing finance system.

Background

In July 2018, FHFA issued an NPR (2018 proposal) proposing a regulatory capital framework intended to start the conversation on how much capital Fannie Mae and Freddie Mac would need to be adequately capitalized if they were to remain relatively intact in a reformed housing finance system. NAHB expressed some concerns with the 2018 proposal, one of which was that the agency should not finalize a capital regime too quickly and the process should be iterative. We wrote that NAHB did not believe it was necessary to issue a final rule until there was a better sense of the future of the Enterprises. We are pleased FHFA has re-proposed the rule, taking into account responses to the 2018 NPR and giving stakeholders further opportunity to consider a proposed capital framework for the Enterprises in light of recent movement toward ending their conservatorships.

Proposed Rule

FHFA emphasizes that the purpose of the proposed rule is to establish a regulatory capital framework that ensures the both safety and soundness of each Enterprise and their ability to fulfill their statutory mission across the economic cycle. To those ends, the proposed rule calls for an increase in the quality and quantity of capital,

is based on a risk-based framework, and incorporates a countercyclical component to ensure capital is accumulated during times of economic prosperity to provide adequate support to the housing finance market in an economic downturn.

The NPR emphasizes that FHFA considered a number of factors to conclude that the 2018 proposal did not increase sufficiently the quantity of capital held by the Enterprises. Factors FHFA considered to establish the proposed increased capital requirements were the cumulative capital losses incurred by the Enterprises during the Great Recession and the level of single-family credit losses as of the end of 2007 compared to the capital levels that would have been required under 2018 proposal; a comparison to the regulatory capital requirements for financial institutions by Basel III and U.S. banking regulators; the effect of the Enterprises' monoline business model; limitations in the crisis-era data; potential overestimation of the reduction in risk with the elimination of high-risk loan products; and gaps in risk coverage, i.e. risks relating to uninsured or underinsured losses from floods, earthquakes, or other natural disasters that could pose reductions to property values in some localities.

Proposed Regulatory Capital Requirements

The NPR would require the Enterprises to maintain prescribed levels of risk-based capital and meet certain leverage capital ratios. If the calculated leverage capital is higher than the calculated risk-based capital, it would become the binding capital requirement. FHFA explains that it believes the circumstances under which a leverage ratio would be binding would be due to a robust economy and strong mortgage market conditions, i.e., single-family house prices are increasing, the unemployment rate is low, the credit performance of mortgage exposures is strong, and key mortgage market counterparties, such as mortgage insurers, are financially sound. Based on the Enterprises' data as of September 30, 2019, the required leverage capital would have been higher at \$243 billion than the risk-based capital that would have been \$234 billion.

The NPR proposes the following capital requirements for the Enterprises:

Risk-based capital:

Total Capital not less than 8.00 percent of risk-weighted assets

Supplementary risk-based capital components:

Adjusted total capital not less than 8.00 percent of risk-weighted assets

Tier 1 capital not less than 6.00 percent of risk-weighted assets

Common equity tier 1 (CET1) capital not less than 4.5 percent of risk-weighted assets

Leverage capital:

Core capital not less than 2.5 percent of adjusted total assets

Tier 1 capital not less than 2.5 percent of adjusted total assets

Risk-based capital

The NPR's risk-based capital requirements mirror the risk-based capital requirements of commercial banks under Basel III. These requirements would significantly increase the amount of capital currently held by the Enterprises and are significantly increased from the capital that would have been required under the 2018 proposal. Under the NPR, the Enterprises risk-based capital requirement as of September 30, 2019 would have been \$234 billion. Under the 2018 proposal, as of the same period, the risk-based capital requirement would have been \$137 billion.

A major reason for the NPR's increased risk-based capital requirement is that, like the Basel III capital requirements for banks, a capital buffer is required for the supplemental risk-based capital requirements. A capital buffer is additional, mandatory capital above the minimum requirements. The prescribed capital conservation buffer amount (PCCBA) would materially increase the risk-based capital that each Enterprise would have to maintain in order to avoid restrictions on capital distributions and discretionary bonuses.

Each Enterprise would have to maintain risk-based capital that exceeds each of the supplementary risk-based capital components by at least the amount of its PCCBA, which is comprised of three separate buffers: the stress capital buffer, the stability capital buffer, and the countercyclical capital buffer. Each buffer would have its own calculation with the total of all calculations added together to reach the total PCCBA. The stress capital buffer would be 0.75 percent of adjusted total assets. This buffer replaces the 2018 proposal's "going-concern" buffer. In the 2018 proposal, an Enterprise would have been subject to enforcement action if it drew down this going-concern buffer. Under the NPR, drawing down the stress capital buffer generally would trigger limits on capital distributions and discretionary bonus payments, but would not trigger enforcement actions by FHFA.

The stability capital buffer and the counter cyclical capital buffer calculations would vary based on market conditions.

Like the U.S. banking framework, each Enterprise would be required to determine its risk-weighted assets under two approaches—a standardized approach and an advanced approach—with the greater of the two risk-weighted assets calculations used to determine its risk-based capital requirements. Under both approaches, an Enterprise's risk-weighted assets would equal the sum of its credit risk-weighted assets, market risk-weighted assets, and operational risk-weighted assets. While the standardized approach would utilize FHFA-prescribed lookup grids and risk multipliers and formulas, the advanced approach would rely on each Enterprise's internal models.

Leverage Capital

The NPR's leverage capital is higher than the leverage capital options proposed in the 2018 proposal and like the risk-based capital requirement also includes a mandatory capital buffer. With proposed Core capital and Tier 1 capital not less than 2.5 percent of adjusted total capital and the prescribed leverage buffer amount (PLBA) of 1.5 percent to adjusted total assets, total leverage capital would be 4.0 percent. As with the PCCBA, to avoid limits on capital distributions and discretionary bonus payments, each Enterprise would be required to maintain Tier 1 capital in excess of the amount of the 1.5 percent PLBA. Under the proposal it is estimated as of September 30, 2019, the Enterprises would have been required to hold \$243 billion in leverage capital.

Currently, U.S. banks are subject to a balance sheet leverage ratio of Tier 1 capital to balance sheet assets at a minimum level of 5.0 percent.

Proposed strategy to mitigate pro-cyclicality

To insure the proposed rule does not encourage pro-cyclicality, i.e. requiring the Enterprises to hold less capital during a robust housing market and thereby enhancing an already strong market and more capital in times of a deteriorating housing market when this might impede their ability to adequately support the mortgage market, FHFA incorporates four components to the proposed rule it believes will allow the Enterprises to play an appropriate countercyclical role in the market:

An adjustment to each single-family mortgage loan's mark-to-market loan-to-value (MTMLTV) when national housing prices are 5.0 percent above or below the inflation-adjusted long-term trend. A countercyclical adjustment would adjust single family MTMLTVs upward when the House Price Index (HPI) is above trend by more than 5 percent and adjust MTMLTVs downward when the HPI is below trend by more than 5 percent.

The stress capital buffer and the leverage buffer to encourage each Enterprise to retain capital when the market is experiencing growth to utilize capital during a period of financial stress as losses are experienced.

A prudential floor on the credit risk capital requirement for mortgage exposures.

A requirement that each Enterprise maintain its own view of credit and other risks, including as to the relationship between housing prices and market fundamentals, by maintaining its own internal models for determining risk-based capital.

Proposed treatment of Credit Risk Transfers

FHFA has proposed a credit risk capital requirement subject to a 10 percent floor on senior tranches of credit risk transfers (CRT) held by an Enterprise, an adjustment to the CRT capital treatment to reflect that CRT is not equivalent in loss-absorbing capacity to equity financing, and operational criteria for CRT structures that together the agency believes would mitigate the structuring, recourse, and other risks associated with these securitizations.

Proposed treatment of Mortgage Risk-weights

Risk-based capital for single-family mortgage loans would be subject to a 15 percent risk weight floor. The 15 percent risk weight floor is intended to mitigate the risk that the 2018 proposal overestimated the impact to credit losses that would be incurred in an economic downturn with national housing price declines of similar magnitude by the elimination of certain loan products such as "Alt-A," negative amortization, interest-only, and low- or no-documentation loans, as well as loans with a debt-to-income ratio at origination greater than 50 percent, cash out refinances with total LTV greater than 85 percent, and investor loans with LTV greater than or equal to 90 percent.

In the proposal, each single-family mortgage loan is assigned an individual adjusted risk weight. This is determined by a base risk-weight as established by a number of factors, including a loan's performance status, such as whether it is a new origination or a delinquent loan, or a reperforming loan, and the LTV and credit score. It is then adjusted for other risk factors such as loan type, property type, debt-to-income ratio and any credit enhancements such as mortgage insurance. The proposal removes the single-family risk multipliers in the 2018 proposal that would have allocated much more capital to small balance mortgages and single-family mortgages with only one borrower.

Risk-based capital for multifamily mortgage loans also would be subject to a 15 percent risk-weight floor. In addition, FHFA changed the multifamily risk multipliers by enhancing the risk multiplier for loan size to make it

more granular and less prone to large jumps in credit risk capital from moving from one bracket to the next; and removing the risk multiplier for multifamily loans with a government subsidy.

Proposed treatment of crossholdings of Enterprise MBS

Each Enterprise would be required to hold capital against any holdings of MBS guaranteed by the other Enterprise to cover counterparty risk in the absence of a full faith and guarantee from the U.S. Treasury. Consistent with the U.S. banking framework, the proposed rule would assign a 20 percent risk weight to these MBS holdings. Under the 2018 proposal, an Enterprise would have had a credit risk capital requirement of zero percent for holding an MBS guaranteed by the other Enterprise.

NAHB Comments

There is no doubt the Enterprises play an enormous and critical role in the housing finance market. Remarkably, there is no groundswell of market participants calling for them to be eliminated as was the case immediately following the meltdown of the mortgage market and the bailout of the Enterprises in 2008. The current groundswell is for reform of the Enterprises and certainty of their safety and soundness and ability to support the mortgage market throughout inevitable market and economic cycles.

The NPR conveys FHFA's view that in the absence of legislation to provide an explicit federal government guaranty on MBS issued by the Enterprises, the Enterprises must have significant capital to assure the market they can protect investors, taxpayers and consumers in a severe market downturn. Toward that goal, FHFA has addressed what it believes were significant flaws in the 2018 proposal and has taken several opportunities to require additional capital calculations, increase capital levels on Enterprise assets and reduce the value of credit risk mitigation tools. These measures include risk-weight floors on CRT transactions and mortgage exposures, a requirement for risk-weight capital to be calculated under dual methodologies with the highest level binding, a requirement for the higher of risk-weight capital and leverage capital to be the binding overall capital level, the addition of buffers to risk-weight and leverage capital calculations to result in even higher required levels of capital and a reduction in the ability of credit enhancements to contribute meaningful risk-based capital mitigation. Taken together, these actions seemingly demonstrate FHFA believes high levels of capital on-hand is a better method for keeping the Enterprises safe and sound and able to support the mortgage market than reducing their credit risk.

NAHB supports FHFA's efforts to ensure the safety and soundness of the Enterprises. However, NAHB is concerned the proposed approach to setting the Enterprises' regulatory capital may result in unintended consequences. While significant increases in capital may ease market concerns about safety and soundness and reduce the possibility that taxpayers will be required to bail out the Enterprises again, the proposed capital requirements will undoubtedly impact the cost and availability of housing credit. NAHB urges FHFA to consider equally the safety and soundness of the Enterprises as well as their public mission to provide affordable and accessible credit to the housing market. NAHB believes an appropriate balance between the two goals is critical. Without the proper balance, NAHB is concerned that increased cost and decreased access to credit will disproportionately impact minority and first-time homebuyers.

NAHB is a strong proponent of a comprehensive legislative solution to housing finance system reform that provides explicit federal support, among other changes. Congressional action is the only true way to provide

certainty to the housing market and NAHB is disappointed that Congress has not yet taken action. NAHB agrees that the Enterprises should hold adequate capital. However, implementing the proposed complex regulatory capital framework may not be the appropriate solution.

Proposed capital requirements are high.

NAHB believes the proposed framework calls for unnecessarily high levels of capital. The FHFA has based some of the calculations in the proposal on the capital requirements of U.S. banks with inadequate concession to the fact that the Enterprises are not banks. Though they are large, and in fact, large enough to be considered systemically important financial institutions, there are mitigating factors that warrant acknowledgement and different capital considerations related to risk. The Enterprises have only mortgage-related assets and corresponding risks. They lay off liquidity risk, prepayment risk and interest rate risk through their MBS issuance and CRT issuance significantly reduces their credit risk. Meanwhile, all of these mortgage-related risks may remain on a bank's balance sheet and require them to hold corresponding capital. In addition, banks have many other products that require risk management and must have significant capital on hand for unexpected depositor withdrawals. The capital levels imposed on banks are appropriately designed for institutions that hold risk while the Enterprises are institutions whose business model calls for them to disperse risk.

NAHB also is concerned that the Enterprises will view the required capital levels as the base capital level and strive to hold a self-imposed capital cushion above each required capital calculation. This would, in essence, make the capital levels even higher than those mandated by FHFA and further negatively impact mortgage pricing.

Proposed leverage ratio should not encourage the Enterprises to hold credit risk.

The Enterprises must hold the higher of risk-based capital or leverage capital. A leverage ratio is independent of risk and is intended to act as a backstop to risk-based capital requirements. However, at 4 percent, FHFA has set the leverage ratio at a level that NAHB believes may often exceed the risk-based capital ratio and be binding. NAHB is concerned that this possibility as well as the uncertainty of which ratio will be higher in any given quarter may encourage the Enterprises to hold riskier assets and simply manage to the leverage ratio. This would reduce the Enterprise's incentive to issue CRTs and take other risk mitigation actions which currently reduce the credit risk they hold.

Proposed strategy to mitigate pro-cyclicality has merit, but needs further consideration.

A primary criticism of the 2018 proposal was that it promoted a pro-cyclical role for the Enterprises. Risk-based capital requirements are inherently pro-cyclical. They support holding less capital and increasing extensions of credit during good economic times and discourage extensions of credit during economic downturns as capital requirements increase. This is the opposite of how the housing market needs the Enterprises to operate, especially during a downturn. The Enterprises must have sufficient capital to operate efficiently through all economic cycles, but importantly they must have appropriate capital to play a countercyclical role in the mortgage market when necessary.

Notably, government support of the Enterprises has been essential to their ability to play a countercyclical role in the housing market, as needed.

NAHB appreciates FHFA's efforts in the NPR's framework to mitigate this pro-cyclicality. However, we encourage FHFA to consider the following concerns prior to finalizing a capital rule for the Enterprises.

Countercyclical adjustment using the House Price Index

The framework continues to rely on a MTMLTV to determine the risk weight of single-family mortgage loans. Using a MTMLTV approach to assigning risk-weights to both single family and multifamily mortgage assets exacerbates a pro-cyclical approach to the Enterprises' capital requirements. The proposed method to mitigate pro-cyclicality is a countercyclical adjustment that would adjust single-family MTMLTVs upward when the House Price Index (HPI) is above trend by more than 5 percent and adjusts MTMLTVs downward when the HPI is below trend by more than 5 percent. While NAHB believes this will have a mitigating impact on the pro-cyclicality for the single-family housing market, we are concerned that there is no solution proposed for the multifamily market.

FHFA explained that it does not produce multifamily data comparable to that used for the single-family countercyclical adjustment. FHFA is unclear whether there is sufficient data from which to develop a reliable long-term trend in multifamily property values. FHFA acknowledged the pro-cyclicality that would be introduced by its multifamily credit risk capital framework and could see considerable merit to a countercyclical or similar adjustment.

It is essential that the Enterprises are sufficiently capitalized to play a countercyclical role in providing liquidity to the secondary multifamily market during times of economic distress when other sources of capital (i.e. life insurance companies, banks, commercial mortgage-backed securities) retreat from the market. This regulation, as proposed, could seriously impair the Enterprises' ability to do so. For these reasons, NAHB recommends that FHFA continue working to develop a multifamily countercyclical adjustment prior to implementing the multifamily regulatory framework.

Accessing the stress capital buffer and the leverage buffer during economic downturns

The stress capital buffer and the leverage buffer would be put in place to provide extra assurance the Enterprises have capital to draw down during times of economic crisis. FHFA has proposed that allowing the levels of this capital to fall below the mandatory level if used to support the market during an economic downturn would not trigger enforcement action, but generally would only trigger limits on capital distributions and discretionary bonus payments. By prescribing less severe sanctions for drawing down this buffer during a period of financial stress, FHFA believes the Enterprises will use the buffer capital to support the housing market during economic stress. However, NAHB is concerned these limitations would discourage the Enterprises from drawing down on these buffers and possibly cause them to restrict credit rather than fall below the prescribed limits. FHFA should eliminate any penalties for using the buffers as they are intended.

Credit Risk Transfers should be incented not disincented.

In 2013, FHFA directed the Enterprises to reduce risk to taxpayers by increasing the use of private capital to manage credit risk. The resulting credit risk transfer (CRT) program was extremely well-received by the market and quickly became a core business practice for the Enterprises, allowing them to transfer significant amounts of credit risk to private investors. As of March 30, 2020, Fannie Mae has transferred a portion of credit risk via CRTs on \$2.19 trillion of the unpaid principal balance of purchased mortgages and Freddie Mac has transferred partial

risk on \$1.6 trillion of the unpaid principal balance of purchased mortgages. CRTs have been touted as one of the significant reforms of the Enterprises implemented by the regulator as comprehensive housing finance system reform legislation has stalled.

NAHB agrees with the broad consensus among industry stakeholders that the incentive for Fannie Mae and Freddie Mac to engage in CRTs would be severely diminished by the proposed rule and credit risk held by the Enterprises would significantly increase. The Enterprises would have to hold significant capital against retained CRT tranches and would not necessarily be afforded a sufficient reduction in risk-based capital to make CRT issuance advantageous. Additionally, fees paid to investors for taking on the credit risk through CRTs reduce each Enterprises' profits so without a corresponding benefit to the Enterprises, they are further disincented to issue CRTs.

In recent documents discussing the strategic direction of the Enterprises¹, FHFA has indicated it will evaluate business activities including the CRT program to ensure they reduce risk and transfer risk from the Enterprises in a responsible way, however, FHFA has been clear in noting the significance of the program and has not contemplated actions that reverse or disrupt the program to the degree the NPR, as proposed, would cause.

NAHB acknowledges that at the time FHFA issued the above referenced documents, the performance of the Enterprises' CRTs had not been tested in declining economic conditions. However, the recent turmoil in the economy caused by the coronavirus pandemic tested the effectiveness of the CRTs and there is general agreement that they performed as hoped with the primary disruption being a lack of new issuance for one to two months.

Furthermore, FHFA should not discount the important market benefits of CRTs, which include encouraging private capital to support the housing market and a reduced risk to taxpayers for the Enterprises' potential credit losses. The value of CRTs should not be discounted, nor should their use be disincented or discouraged. If FHFA has concerns with the effectiveness of CRTs, these concerns should be addressed directly with the Enterprises.

Proposed risk-weight floor on single-family mortgage exposures is unnecessary.

FHFA takes great pains to explain that it has calibrated base risk weights and risk multipliers for single-family mortgage exposures in order to ensure credit risk capital sufficient to absorb the lifetime unexpected losses incurred on single-family mortgage exposures experiencing a shock to house prices similar to that observed during the 2008 financial crisis. In light of these detailed calibrations, NAHB questions why FHFA has proposed a 15 percent risk-weight floor on all single-family mortgage exposures. This especially appears to be unnecessary due to the requirement that the leverage ratio becomes binding when risk-based capital calculations are below 4 percent.

¹*FHFA Strategic Plan: Fiscal Years 2018-2022, January 2018; 2020 Scorecard for Fannie Mae, Freddie Mac and Common Securitization Solutions, October 2019; The 2019 Strategic Plan for the Conservatorships of Fannie Mae and Freddie Mac, October 2019.*

Proposed risk multipliers for multifamily housing are improved from 2018 proposal.

NAHB commends FHFA for removing the risk multiplier for subsidized multifamily housing. This action is appropriate considering the current affordable housing crisis, as well as the Enterprises' statutory obligations under the Housing Goals and Duty-to-Serve programs. Properties should not be stigmatized simply because they are government subsidized.

Proposed credit risk levels for cross holdings of Enterprise MBS should be revised.

Since FHFA's directive in 2012 requiring the Enterprises to develop a single agency security, NAHB has supported the initiative. NAHB believed the development of a single agency security, now called the Uniform Mortgage-Backed Security (UMBS), was an innovative strategy to eliminate pricing disparities between Fannie Mae MBS and Freddie Mac Participation Certificates (PCs) and increase the overall liquidity in the TBA MBS market. Today, each Enterprise currently issues and guarantees "Supers," which are single class securitizations backed by UMBS or other Supers that have been issued by either Enterprise or by a combination of both Enterprises. With FHFA's proposal to assign a 20 percent risk weight to UMBS guaranteed by one Enterprise and held by the other, NAHB believes each Enterprise will be forced to charge a fee for issuing Supers or cause each to use only UMBS it has issued and guaranteed to create Supers. NAHB believes both responses will cause an increase in the cost of mortgage loans. If an Enterprise will use only its own UMBS to create Supers, eventually different volumes and investor perception of Fannie Mae-guaranteed UMBS versus Freddie Mac-guaranteed UMBS will cause pricing to diverge and eliminate the fungibility of the Fannie Mae and Freddie Mac issued securities that is critical to the success of the UMBS market. Any perception of differences between the UMBS issued by Fannie Mae versus Freddie Mac will undermine the UMBS market and harm a significant, well-received reform that took years to develop and implement at FHFA's direction.

Under the 2018 proposal, an MBS guaranteed by an Enterprise would have had a credit risk capital requirement of zero percent. NAHB asks the FHFA to revise the proposal and eliminate the credit risk weight for these MBS as the 2018 proposal did.

FHFA should ensure that the rule will not hinder the Enterprises' affordable housing obligations and initiatives.

NAHB has strongly and consistently advocated that the Enterprises demonstrate leadership in affordable housing by providing liquidity and supporting housing for families at different income levels in various geographic markets and in various market segments. To achieve these goals, the secondary market must be structured to ensure that the appropriate range of products is available to provide the capital needed to develop new and to preserve existing rental housing, as well as to refinance and acquire properties. An adequate flow of capital will ensure that demand for rental housing is met and that affordable options are available for a range of households and communities.

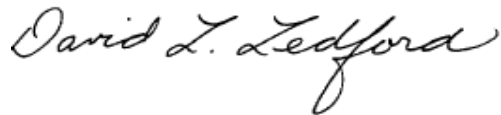
FHFA should analyze the proposed rule's impact on the Enterprises' ability to provide the necessary capital, liquidity and innovation to meet the financing demands for affordable and workforce housing, particularly as regards their current statutory obligations. Absent statutory changes, the Enterprises will still be subject to Affordable Housing Goals and the Duty- to-Serve Underserved Markets (i.e. Manufactured Housing, Affordable Housing Preservation and Rural Housing) after being released from conservatorship. It is critical that the Enterprises can continue their important affordable housing initiatives under the final rule.

Conclusion

NAHB appreciates the opportunity to submit our recommendations to FHFA on this important rulemaking. The FHFA has proven to be a strong and conscientious regulator and conservator of the Enterprises. Establishing the appropriate capital framework for the Enterprises is a critical step in setting the guidelines for the expectations for the Enterprises to operate post-conservatorship. NAHB encourages FHFA to be prepared to continue its oversight role and ensure the Enterprises fulfill their mission to support the housing market.

Thank you for considering our recommendations. Please contact Becky Froass, Director, Financial Institutions and Capital Markets, at rfroass@nahb.org or 202-266-8259 with any questions.

Sincerely,

A handwritten signature in cursive script that reads "David L. Ledford".

David L. Ledford
Executive Vice President
Housing Finance and Regulatory Affairs